College of Pharmacists of British Columbia

**Board Meeting**
**April 21st, 2017**
**Held at the College of Pharmacists of British Columbia**
**200-1765 West 8th Avenue, Vancouver, BC**

**MINUTES**

**Members Present:**
Anar Dossa, Chair, District 6
Mona Kwong, Vice-Chair, District 1
Ming Chang, District 2
Tara Oxford, District 3
Christopher Szeman, District 4
Frank Lucarelli, District 5
Arden Barry, District 7
Sorell Wellon, District 8
Norman Embree, Public *(via webex and teleconference)*
Kris Gustavson, Public
Jeremy Walden, Public
George Walton, Public

**Staff:**
Bob Nakagawa, Registrar
David Pavan, Deputy Registrar
Mary O'Callaghan, Chief Operating Officer
Ashifa Keshavji, Director of Practice Reviews and Quality Assurance
Doreen Leong, Director of Registration, Licensure and PharmaNet
Christine Paramonczyk, Director of Policy and Legislation
Gillian Vrooman, Director of Communications and Engagement
Lori Tanaka, Board & Legislation Coordinator
Jon Chen, Communications Project Officer
Kitty Chiu, Executive Operations Manager

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1. **WELCOME & CALL TO ORDER**
   Chair Dossa called the meeting to order at 11:15am on April 21st, 2017.

## 2. CONSENT AGENDA

### a) Items for further discussion

No items were removed from the Consent Agenda and placed onto the regular Agenda for further discussion.

### b) Approval of Consent Items (Appendix 1)

It was moved and seconded that the Board:

Approve the Consent Agenda as circulated.

**CARRIED**

## 3. CONFIRMATION OF AGENDA (Appendix 2)

The agenda was amended by adding a new item titled 4.1 Registrar's Evaluation.

It was moved and seconded that the Board:

Approve the April 21, 2017 Draft Board Meeting Agenda as amended.

**CARRIED**

## 4. LEGISLATION REVIEW COMMITTEE

Jeremy Walden, Board member and Chair of the Legislation Review Committee, presented

### a) HPA Bylaws – Filing (Application Committee) (Appendix 3)

It was moved and seconded that the Board:

Approve the following resolution to amend the Health Professions Act Bylaws to establish the Application Committee:

RESOLVED THAT, in accordance with the authority established in section 19(1) of the *Health Professions Act*, and subject to filing with the Minister as required by section 19(3) of the *Health Professions Act*, the board amend the bylaws of the College of Pharmacists of British Columbia, as set out in the schedule attached to this resolution.

**CARRIED**

It was moved and seconded that the Board:

Approve the Terms of Reference of the Application Committee, as circulated.

**CARRIED**

### b) Compounding – Implementation Plan (Appendix 4)

Jeremy Walden introduced presenter Dana Lyons, pharmacy technician and subject matter expert.

It was moved and seconded that the Board:

Approve the four-year implementation plan to adopt the *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations* and the *Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations,* with the following recommended phases:

- Phase 1 (gap analysis and site plan, personnel conduct): November 2017
- Phase 2 (personnel training, policies and procedures): May 2019
- Phase 3 (beyond-use dates, verification of facilities): May 2020
- Phase 4 (facility infrastructure): May 2021

**CARRIED**

It was moved and seconded that the Board:

Direct the Registrar to draft bylaws to adopt the *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations* and the *Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations,* to be effective for May 2021, which will officially establish minimum requirements to be applied in compounding sterile preparations.

**CARRIED**

**c) Fees and Forms**

**i. HPA – Filing (Fees) (Appendix 5)**

It was moved and seconded that the Board:

RESOLVED THAT, in accordance with the authority established in section 19(1) of the *Health Professions Act*, and subject to filing with the Minister as required by section 19(3) of the *Health Professions Act*, the board amend the bylaws of the College of Pharmacists of British Columbia, as set out in the schedule attached to this resolution.

**CARRIED**

**ii. PODSA – Public Posting (Fees and Forms) (Appendix 6)**

It was moved and seconded that the Board:

Approve the proposed draft Pharmacy Operations and Drug Scheduling Act Bylaws Schedule A – Fee Schedule and related forms for public posting, as circulated.

**CARRIED**

**d) PODSA Bylaws – Public Posting (Telepharmacy) (Appendix 7)**

It was moved and seconded that the Board:

Approve the following resolution to publicly post the draft telepharmacy bylaws:

RESOLVED THAT, in accordance with the authority established in section 21(8) of the *Pharmacy Operations and Drug Scheduling Act*, the board approve the proposed draft bylaws of the College of Pharmacists of British Columbia regarding telepharmacies, and related schedules and forms for public posting, as circulated.

**CARRIED**

*Note: approval of the above motion imposes additional changes to PODSA Schedule A and Form 2 that were previously approved in item 4.c.ii. for public posting.*

### 4.1 REGISTRAR'S EVALUATION

It was moved and seconded that the Board:

Approve up to $50,000.00 to hire an external consultant to start the Registrar evaluation process.

**CARRIED**

### 5. SCOPE OF PODSA MODERNIZATION – PHASE 1

Doreen Leong, Director of Registration, Licensure & PharmaNet, presented **(Appendix 8)**.

### 6. GOVERNANCE COMMITTEE

#### a) Update

Norman Embree, Board member and Chair of the Governance Committee, provided the following brief update:

- The Governance Committee met by teleconference on March 22 and discussed the following:
  - Existing committee structure and vacancies including the process followed this year for recruitment of new registrant and public members, and the desire to move towards Board members chairing all committees in an effort to streamline communication back up to the Board level. Recommendations for committee membership were circulated in the briefing package and approved with the Consent Agenda.
  - The committee also discussed Board self-evaluation, and agreed that beginning in 2018, a Board self-evaluation would be conducted on an annual basis with results being provided at each June Board meeting. It was agreed that Phase 2 of the EY review will serve as the self-evaluation for 2017.
- Update on EY – Phase 2 Review:
  - All of the information has now been collected from Board members, and individual stakeholders. Data is being analyzed to formulate key themes and findings, and a draft of the results is expected by the end of April or first week of May 2017.

#### b) Committee Terms of Reference (Appendix 9)

Norman Embree, Board member and Chair of the Governance Committee, provided a brief update of the ongoing priorities of the Governance Committee.

It was moved and seconded that the Board:

Approve the following amendment:

**Term of Appointment**

- Appointments are determined by the Board and will not exceed ~~2~~3 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.

To the following committees` terms of reference:

| | |
|---|---|
| Audit and Finance | Jurisprudence Examination |
| Community Pharmacy Advisory | Legislation Review |

| | |
|---|---|
| Discipline | Practice Review |
| Ethics Advisory | Quality Assurance |
| Governance | Registration |
| Hospital Pharmacy Advisory | Residential Care Advisory |
| Inquiry | |

**CARRIED**

It was moved and seconded that the Board:

Approve the following amendments to the Drug Administration Committee`s terms of reference:

**Mandate**
To review, develop and recommend the standards, limits and conditions under which a registrant may administer a drug or substance to patients and to maintain patient safety and public protection with respect to authorized pharmacist`s administration of injections or administration of drugs by the intranasal route to patients.

**Term of Appointment**

- Appointments are determined by the Board and will not exceed ~~2~~3 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.

**CARRIED**

**7. ITEMS BROUGHT FORWARD FROM CONSENT AGENDA**
No items were brought forward from the consent agenda for further discussion.

**ADJOURNMENT**
Chair Dossa adjourned the meeting at 2:23pm.

College of Pharmacists of British Columbia

# BOARD MEETING
# April 21, 2017

## 2. Consent Agenda
## b) Approval of Consent Items

## DECISION REQUIRED

### Recommended Board Motion:

*Approve the Consent Agenda as circulated, or amended.*

i. Chair's Report

ii. Registrar's Update
   a. Activity Report
   b. Action Items & Business Arising

iii. February 17, 2017 Draft Board Meeting Minutes **[DECISION]**

iv. Committee Updates (Links to Minutes)

v. Committee Annual Reports to the Board

vi. Privacy Policy **[DECISION]**

vii. Audit & Finance Committee – Financial Report (January)

viii. Governance Committee
   a. Committee Member Appointments **[DECISION]**
   b. Committee Terms of Reference **[DECISION]**

ix. Practice Review Program Update

x. Marijuana for Medical Purposes

College of Pharmacists of British Columbia

# BOARD MEETING
# April 21, 2017

## 2.b.i. Chair's Report

## INFORMATION ONLY

Since the February Board meeting, I have been involved in the following activities:

- Audit and Finance Committee meeting,
- Governance Committee meeting,
- Legislative Review Committee meetings,
- Registrar, Deputy Registrar, and Vice-Chair weekly meetings, and
- UBC Faculty of Pharmaceutical Sciences Strategic Planning Session Summit.

College of Pharmacists of British Columbia

# BOARD MEETING
# April 21, 2017

## 2.b.ii. Registrar's Update
## a) Activity Report

## INFORMATION ONLY

Since the February Board meeting, I have been involved in the following activities:

- Held Leadership meetings, weekly meetings or teleconferences with the Chair and Vice Chair
- Had several discussions re: marijuana for medical purposes
- Prepared Registrar's message for Readlinks
- Had telepharmacy bylaws meetings with MoH and Health Canada
- Had numerous discussions and meetings implementing various aspects of the Excellence Canada program, including a gap analysis and structure for the program (Appendix 1 and Appendix 2)
- As Chair of the Conference of Pharmacy Registrars of Canada, participated in NAPRA executive, Governance, and CPRC meetings including a meeting with Health Canada on opioids, and a session with CPRC focused on marijuana
- Had stakeholder meetings with hospital pharmacy managers, UBC and a patient group re: pharmacy services
- Signed a Declaration of Commitment to Advancing Cultural Humility and Cultural Safety within Health Services in B.C. along with other Health Registrars
- Presented to the PHRM241 class: Pharmacists in Practice
- Participated in the UBC strategic planning process

| Appendix | |
|---|---|
| 1 | Feedback letter from Catherine Neville, Excellence Canada |
| 2 | Action Plan Timeline |

**From:** Catherine Neville <catherine@excellence.ca>
**Date:** March 13, 2017 at 4:01:43 PM PDT
**To:** Bob Nakagawa <Bob.Nakagawa@bcpharmacists.org>
**Cc:** Mary O'Callaghan <Mary.OCallaghan@bcpharmacists.org>, "david.pavan@bcpharmacists.org"
**Subject: High level feedback**

Good evening Bob,

I want to share with you how impressed I was with your staff during our recent self-assessment. It was quite an undertaking to have half of your staff participate for a half-day and they did you proud! (Please note the survey for all staff is scheduled for next week after March break – this way we will have the input of all staff as we proceed).

It is impressive that the Executive decided to pursue EIW Going for Silver, when many would simply begin with EIW Bronze (with its focus on policies and procedures). The staff members were candid in their remarks and in fact were pretty tough on the organization (in a very positive way – they clearly see your potential!). Even with pretty tough scoring, you scored very well for this stage of the journey (69% of the score you require to be successful). Given that and the enthusiasm of the staff, you are well positioned to pursue your journey of excellence.

It was also impressive to witness the behavior of the Executive during this self-assessment. You welcomed everyone to participate fully and openly. All three of you actively participated in the self-assessment (which does not always happen). You worked just as hard on your assigned Driver of Leadership as the rest of the staff (it is a wonder Mary's hand did not seize up completely). And interestingly, many of your identified strengths and opportunities as well as your scores on leadership were very close indeed to that of the staff team assigned to Leadership. This is unusual and very encouraging.

We accomplished a great deal together in a little more than a day, resulting in an actionable plan to address identified priorities to move forward. More than ever, I have no doubt you will be successful!

Kind regards,

Catherine

Catherine Neville | Vice President, Integrated Quality-based Programs
Excellence Canada
Mobile: 647.973.2244 | catherine@excellence.ca |
154 University Avenue, Suite 402, Toronto, Ontario M5H 3Y9

**Purpose: To address first priorities identified during the March 6, 2017 EIW Going For Silver Self-Assessment.**

| Driver / Criteria # | Identified Gaps | Key Activities / Milestones | Activity Owner / Others on Team | Projected Start Date / Actual Start Date | Projected Completion Date / Actual Completion Date | Comments |
|---|---|---|---|---|---|---|
| **LEADERSHIP** **Governance** a) Governance Framework (Board Role) | | Governance Consultant attending with Board regarding mandate | Bob/Sr. Mgmt | Apr 20, 2017 | | |
| | | Share resultant Board mandate | Bob/Sr. Mgmt | Apr 30, 2017 | | |
| **LEADERSHIP** **Governance** b) Leadership Effectiveness | | In progress – high level goals from the strategic plan | Bob/Sr. Mgmt | Jun 2017 | | |
| **LEADERSHIP** **Leadership** e) Continual Improvement | | Provide samples | Catherine | Apr 2017 | | |
| | | Council review and prepare draft admin policy | David/Project Team | Jun 2017 | | |
| **LEADERSHIP** **Leadership** i) Leadership Development Program | | Research available programs | Kitty/Project Team | May 2017 | | |
| | | Recommend approach to Sr. Mgmt | Kitty | Jun 2017 | | |
| | | Sr. Mgmt approval and implement | Sr. Mgmt/Kitty | Sep 2017 | | |
| **LEADERSHIP** **Leadership** k) Innovation, Successes and Lessons Learned | | Review innovation and knowledge sharing (and celebration) approaches | Kitty/Project Team | Sep 2017 | | |

| Driver / Criteria # | Identified Gaps | Key Activities / Milestones | Activity Owner / Others on Team | Projected Start Date / Actual Start Date | Projected Completion Date / Actual Completion Date | Comments |
|---|---|---|---|---|---|---|
| **PLANNING** b) Excellence, Innovation and Wellness Assessment | | Complete and review assessment | Mary/Council | Mid-Mar 2017 | | |
| | | Discuss next steps | Mary/Council | Mid-Mar 2017 | | |
| **PLANNING** e) Enterprise Risk Management Plan | | Provide additional samples | Catherine | End-Mar 2017 | | |
| | | Review approaches (PESTLE) | Mary/Sr. Mgmt | Jun\ 2017 | | |
| | | Take to Audit & Finance Committee | Mary/Sr. Mgmt | Oct 2017 | | |
| | | Advise Board and staff | Mary/Sr. Mgmt | Nov 2017 | | |
| **PLANNING** f) Innovation Plan | | Review sample plans | Patricia/Project Team | Dec 2017 | | |
| | | Establish a plan | Patricia/Project Team | Q1 2018 | | |
| **PLANNING** g) Knowledge Management System (including lesson learned) | | *(Refer to Leadership k)* | | | | |
| **PLANNING** h) IT Plan | | Continue to refine IT Plan | Mary/Project Team | In progress | | |
| | | Obtain user input | Mary/Project Team | | | |
| | | Establish priorities based on strategic plan/consultations | Mary/Project Team | | | |
| | | Finalize Plan | Mary | | | |
| | | Communicate Plan | Mary | Q1 2018 | | |

| Driver / Criteria # | Identified Gaps | Key Activities / Milestones | Activity Owner / Others on Team | Projected Start Date / Actual Start Date | Projected Completion Date / Actual Completion Date | Comments |
|---|---|---|---|---|---|---|
| **CUSTOMERS** **Customers** a) Customer Segmentation | | Define and segment customers (e.g. end user and distribution network) and recommend findings to Sr. Mgmt | Jon C/Project Team | Sep 2017 | | |
| | | Finalize and share with staff | Jon C/Project Team | Oct 2017 | | |
| **CUSTOMERS** **Customers** d) Customer Experience Plan | | Review requirements of customer segments | Jon C/Project Team | Nov 2017 | | |
| | | Prepare customer strategy for Sr. Mgmt and CPLT review | Jon C/Project Team | Dec 2017 | | |
| | | Finalize and share with staff | Jon C/Project Team | Q1 2018 | | |
| **CUSTOMERS** **Customers** f) Service Standards | | Review service standards in all areas | Jon C/Project Team | Q1 2018 | | |
| | | Compare with customer requirements | Jon C/Project Team | Q1 2018 | | |
| | | Adjust as required and communicate | Jon C/Project Team | Q1 2018 | | |
| **CUSTOMERS** **Customers** h) Baseline Feedback Measures | | Catherine provide sample satisfaction surveys (external/internal) | Jon C/Project Team | Apr 2017 | | |
| | | Review surveying samples in addition to existing internal surveys from HR | Jon C/Project Team | Jun 2017 | | |
| | | Implement satisfaction survey(s) | Jon C/Project Team | Dec 2017 | | |
| **CUSTOMERS** **Partners** j) Key Partners | | Identify key partners | Jon Chen (Comm) | Aug 2017 | | |

| Driver / Criteria # | Identified Gaps | Key Activities / Milestones | Activity Owner / Others on Team | Projected Start Date / Actual Start Date | Projected Completion Date / Actual Completion Date | Comments |
|---|---|---|---|---|---|---|
| **PEOPLE** a) Healthy Workplace Policy | | Provide HWP samples | Catherine | Apr 2017 | | |
| | | Draft HWP admin policy | Cass/Project Team | Apr 2017 | | |
| | | Review with Council | Cassandra | Apr 2017 | | |
| | | Recommend to CPLT | Kitty | Apr 2017 | | |
| **PEOPLE** f) Wellness Plan | | Provide plan samples | Catherine | Apr 2017 | | |
| | | Draft HR (including wellness) plan | Cass/Project Team | Jun 2017 | | |
| | | Review with Council | Cassandra | Sep 2017 | | |
| | | Recommend to CPLT | Kitty | Oct 2017 | | |
| **PEOPLE** g) Workplace Plan | | Draft Workforce Plan | Kitty/Project Team | Jul 2017 | | |
| | | Review with Mary | Kitty | Aug 2017 | | |
| | | Review with Council | Kitty | Sep 2017 | | |
| | | Recommend to Sr. Mgmt | Mary/Kitty | Oct 2017 | | |
| **PEOPLE** k) HR Indicators | | Provide sample indicators | Catherine | Apr 2017 | | |
| | | Identify indicators and related metrics | Cass/Project Team | Aug 2017 | | |
| | | Review with Kitty | Cassandra | Sep 2017 | | |
| | | Determine what PayWorks can supply | Cassandra/Kitty | Aug 2017 | | |
| | | Make recommendations to Sr. Mgmt | Cassandra/Kitty | Oct 2017 | | |
| **PEOPLE** m) Wellness Assessment | | Provide wellness assessments samples (HRA) | Catherine | Apr 2017 | | |
| | | Make recommendations to Mary | Cass/Project Team | Nov 2017 | | |
| | | Share results with Council | Cassandra | Nov 2017 | | |
| | | Recommend to Sr. Management | Cassandra/Kitty | Dec 2017 | | |

| Driver / Criteria # | Identified Gaps | Key Activities / Milestones | Activity Owner / Others on Team | Projected Start Date<br>Actual Start Date | Projected Completion Date<br>Actual Completion Date | Comments |
|---|---|---|---|---|---|---|
| **PROCESS**<br>**Process Improvement**<br>a) Process and Owners | | Identify key processes | Luis/Project Team | Mar 2017 | | |
| **PROCESS**<br>**Process Improvement**<br>b) Process Training | | Provide course/approach for process improvement (include decision matrix) | Catherine | Mar 2017 | | |
| | | Review and approve | Mary | Mar 2017 | | |
| | | Conduct training | Catherine | May 15, 2017 | | |
| **PROCESS**<br>**Process Improvement**<br>c) Process Documentation | | Review how key processes and procedures are documented across CPBC and present to Council | Luis/Project Team | Mar 2017 | | |
| | | List undocumented and prioritize based on strategic plan | Luis/Mary/Project Team | May 2017 | | |
| | | Council make recommendations to Exec | Mary | Jun 2017 | | |
| **PROCESS**<br>**Process Improvement**<br>d) Stakeholder Involvement | | See Process b) to ensure key internal stakeholders are included | | Jun 2017 | | |
| **PROCESS**<br>**Improvement**<br>e) Processes Impact | | Assess impact on staff | Luis/Project Team | ? | | |
| | | Make related recommendations to Council | Luis | ? | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **PROCESS**<br>**Change Management**<br>j) Change Management | | Provide change management training with process improvement course | Catherine | May 15, 2017 | | |
| | | CN provide 'Process Kaizen' | Catherine | May 15, 2017 | | |
| | | Build in to process improvement system | Luis/Project Team | ? | | |
| **PROCESS**<br>**Procurement**<br>o) Supplier Performance | | Identify baseline supplier measures and collect them for IT service provider | Mary/Project Team | Aug 2017 | | |

College of Pharmacists of British Columbia

# BOARD MEETING
# April 21, 2017

## 2.b.ii. Registrar's Update
## b) Action Items & Business Arising

## INFORMATION ONLY

| MOTIONS/ACTION ITEMS | RELEVANT BOARD MEETING | STATUS UDPATE |
|---|---|---|
| Motion: Direct the Registrar to take the following actions as outlined in the MMT Action Plan:<br>• Develop, plan and implement new undercover investigations,<br>• Conduct priority inspection of identified MMT dispensing pharmacies,<br>• Continue to build and maintain collaborative relationships with key stakeholders, and<br>• Provide recommendations to the Board to strengthen legislation and licensure requirements. | Jun 2015 | IN PROGRESS |
| Motion: Direct staff to investigate options around site inspection fees and report back to the Board by the June 2017 Board meeting. | Sep 2016 | IN PROGRESS |
| Motion: Pursue officially changing the name of the College of Pharmacists of British Columbia to the College of Pharmacy of British Columbia. | Sep 2016 | IN PROGRESS |
| Motion: Direct the Registrar to pursue a bylaw amendment that would change the term of office for elected Board members from two years to three years, and from a maximum of 3 consecutive terms to a maximum of 2 consecutive terms. | Nov 2016 | IN PROGRESS |
| Motion: Direct the Registrar to amend the Certified Pharmacist Prescriber Draft Framework by narrowing the scope of pharmacist prescribing to be within collaborative practice settings. | NOV 2016 | IN PROGRESS |
| Motion: Direct the Registrar to develop a proposal for pharmacist prescribing within collaborative practice settings – based on the amendment Draft Framework and results of the stakeholder engagement – to be brought to the Board for approval to submit to the Minister of Health for consideration. | NOV 2016 | IN PROGRESS |

College of Pharmacists of British Columbia

# BOARD MEETING
# April 21, 2017

## 2.b.iii. February 17, 2017 Draft Board Meeting Minutes

## DECISION REQUIRED

### Recommended Board Motion:

*Approve the Draft February 17, 2017 Board Meeting Minutes as circulated.*

| Appendix | |
|---|---|
| 1 | Draft February 17, 2017 Board Meeting Minutes (appendices available on Board site) |

College of Pharmacists of British Columbia

**Board Meeting**
**February 17th, 2017**
**Held at the College of Pharmacists of British Columbia**
**200-1765 West 8th Avenue, Vancouver, BC**

**MINUTES**

**Members Present:**
Anar Dossa, Chair, District 6
Mona Kwong, Vice-Chair, District 1
Ming Chang, District 2
Tara Oxford, District 3
Christopher Szeman, District 4
Frank Lucarelli, District 5
Arden Barry, District 7
Sorell Wellon, District 8
Norman Embree, Public
Kris Gustavson, Public
Jeremy Walden, Public
George Walton, Public

**Staff:**
Bob Nakagawa, Registrar
David Pavan, Deputy Registrar
Mary O'Callaghan, Chief Operating Officer
Ashifa Keshavji, Director of Practice Reviews and Quality Assurance
Doreen Leong, Director of Registration, Licensure and PharmaNet
Christine Paramonczyk, Director of Policy and Legislation
Gillian Vrooman, Director of Communications and Engagement
Kitty Chiu, Executive Operations Manager
Lori Tanaka, Board & Legislation Coordinator
Jon Chen, Communications Project Officer

**Invited Guests:**
Michael Coughtrie, Dean, Faculty of Pharmaceutical Sciences, UBC



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1. **WELCOME & CALL TO ORDER**
   Chair Dossa called the meeting to order at 9:00am on February 17th, 2017.

## 2. CONSENT AGENDA

### a) Items for further discussion

No items were removed from the Consent Agenda and placed onto the regular Agenda for further discussion.

### b) Approval of Consent Items (Appendix 1)

It was moved and seconded that the Board:

*Approve the Consent Agenda as circulated.*

**CARRIED**

## 3. CONFIRMATION OF AGENDA (Appendix 2)

It was moved and seconded that the Board:

*Approve the February 17, 2017 Draft Board Meeting Agenda as circulated.*

**CARRIED**

## 4. STRATEGIC PLAN

Mary O'Callaghan, Chief Operating Officer, presented **(Appendix 3)**.

It was moved and seconded that the Board:

*Approve the 2017/18 – 2019/20 Strategic Plan as circulated.*

**CARRIED**

## 5. AUDIT AND FINANCE COMMITTEE

George Walton, Board member and Chair of the Audit and Finance Committee, presented **(Appendix 4)**.

It was moved and seconded that the Board:

*Approve the 2017/18 budget Plan C, with revenue totaling $8,244,070 and expenditures totaling $9,594,567, and the accompanying list of fees, as attached in the appendix to this motion.*

**CARRIED**

## 6. GOVERNANCE COMMITTEE UPDATE

Norman Embree, Board member and Chair of the Governance Committee, provided a brief update of the ongoing priorities of the Governance Committee as distributed in the briefing package **(Appendix 5)**, and added that the yearly Registrar Evaluation process has been initiated.

## 7. NAPRA GOVERNANCE

Blake Reynolds, Director on the NAPRA Board representing the College of Pharmacists of BC, provided a presentation on the proposed changes to NAPRA governance **(Appendix 6)**.

## 8. EXCELLENCE CANADA

Catherine Neville, Vice President of Quality & Integrated Programs with Excellence Canada, presented **(Appendix 7)**.

## 9. LEGISLATION REVIEW COMMITTEE

### a) Pharmacy Security Bylaws – Filing

Jeremy Walden, Board member and Chair of the Legislation Review Committee, presented **(Appendix 8)**.

It was moved and seconded that the Board:

*Approve the following resolution to amend the Pharmacy Operations and Drug Scheduling Act Bylaws to create minimum security measures for community pharmacies:*

*RESOLVED THAT, in accordance with the authority established in section 21(1) of the Pharmacy Operations and Drug Scheduling Act, and subject to filing with the Minister as required by section 21(4) of the Pharmacy Operations and Drug Scheduling Act, the board amend the bylaws of the College of Pharmacists of British Columbia, as set out in the schedule attached to this resolution*

**CARRIED***

*Frank Lucarelli and Christopher Szeman requested that their negative votes be recorded.

It was moved and seconded that the Board:

*Approve amendments to Professional Practice Policy #74: Community Pharmacy Security as circulated, to come into force at the same time as the bylaws.*

**CARRIED**

It was moved and seconded that the Board:

*Repeal the Community Pharmacy Security Resource Guide, effective at the same time as the bylaws come into force.*

**CARRIED**

### b) Legislation and Policy Review

Jeremy Walden, Board member and Chair of the Legislation Review Committee, presented an update on the prioritization of projects currently tasked to the College's Policy and Legislation team **(Appendix 9)**.

## 10. ITEMS BROUGHT FORWARD FROM CONSENT AGENDA

No items were brought forward from the consent agenda for further discussion.

**ADJOURNMENT**

Chair Dossa adjourned the meeting at 1:53pm.

College of Pharmacists of British Columbia

# BOARD MEETING
# April 21, 2017

## 2.b.iv. Committee Updates (Minutes)

## INFORMATION ONLY

Committees who have met and approved previous meeting minutes have submitted them to the Board for information purposes.

The following committees do not have a submission:

- Audit and Finance Committee Meeting,
- Drug Administration Committee,
- Jurisprudence Examination Committee,
- Quality Assurance Committee Meeting, and
- Registration Committee.

For confidentiality purposes, the Inquiry Committee has provided a summary of their meetings, but will not be submitting minutes.

| **Appendix – available on the Board Portal under 'Committee Minutes'** | |
|---|---|
| 1 | Discipline Committee Update |
| 2 | Inquiry Committee Update |
| 3 | Governance Committee Minutes |
| 4 | Legislation Review Committee Meeting Minutes |
| 5 | Practice Review Committee Meeting Minutes |

College of Pharmacists of British Columbia

# BOARD MEETING
# April 21, 2017

## 2.b.v. Committee Annual Reports to the Board

## INFORMATION ONLY

Annual reports of committee activities are submitted.

| Appendix | |
|---|---|
| 1 | Annual Reports for all College committees |

College of Pharmacists of British Columbia

# Annual Report to the Board for Audit & Finance Committee

**Reporting Period:** Mar 1, 2016 – Feb 28, 2017

**Membership:**

| | |
|---|---|
| George Walton | Blake Reynolds (Mona Kwong - effective January 13, 2017) |
| Norman Embree | Anar Dossa |
| Bob Nakagawa | Mary O'Callaghan |

**Chair:** George Walton
**Vice Chair:** Norman Embree (Mona Kwong – effective January 13, 2017)

**Staff Resource:** Bob Nakagawa, Mary O'Callaghan

**Mandate:** To provide recommendations to the Board relating to the annual audit and financial management of the College.

**Responsibilities:**

***Annual Audit Planning and preparation***

- Review with the auditors the scope of the upcoming year's audit, including any areas where the auditors have identified a risk of potential error in the financial condition and/or results of operations.
- Review with College management control weaknesses detected in the prior year's audit, and determine whether practical steps have been taken to overcome them.

***Audit results***

- Review the auditors' draft report on the financial statements.
- Review auditors' evaluation of internal controls and processes, including internal controls over financial reporting and any material weaknesses or risks of fraud. Assess the steps management has taken to minimize significant risk of exposure. Consider effectiveness of control systems including information technology.
- Enquire into the condition of the records and the adequacy of resources committed to accounting and control.
- Enquire about changes in finance/auditing/control standards that have occurred during the year and whether there is any impact on the College financial systems.
- Meet with the auditors (without College management) to ascertain whether there are concerns that should be brought to the committee's attention.

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- Coordinate with College management: the presentation of the audit findings by the auditors to the Board for Board approval; incorporate the Board approved audit report into the College Annual Report; have the auditors' present the results to the College registrants at the AGM.

***Auditors' appointment***

- Meet with senior management to ensure that management has no concerns about the conduct of the most recent audit.
- Recommend to the Board the auditors to be appointed for the following year, and in consultation with College management determine the appropriate compensation.
- Approve the selected auditors' engagement letter, receive the independence letter, review and approve any related materials.

***Financial oversight***

- Review the quarterly financial statements at the committee meetings during the year.
- Annually, review the proposed fiscal budget with College management.
- Annually review the College multi-year (2-5 year) financial plan.
- At least annually, review the College investment policy and ensure that the existing policy is being followed.
- Enquire about changes in professional standards or regulatory requirements.
- Ensure financial planning adequately addresses risks and long term planning e.g. insurance, litigation, joint venture, other contingency funds, capital investments.
- Make recommendations to the Board with regard to the above and any other aspects of the financial management of the College as required.

**Relevant Statistical information:**

- Number of meetings: 5

**Accomplishments:**

- Reviewed annual audit and auditor's recommendations with the auditors.
- Recommended renewal of the current contract with Grant Thornton for the 2016/17 audits and recommended a competitive bid for future years.
- Recommended a new Reserve Policy.
- Performed an expenditure review; recommended discontinuation of some programs and recommended a fee increase for late 2016.
- Reviewed and recommended approval of the 2017/18 annual budget, including a fee increase for late 2107.

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**Goals for Next Fiscal Year:**

- Review the annual audit.
- Recommend approval of an audit firm after the competitive bid process.
- Monitor the current year financial reports and multi-year estimates.
- Review annual budget.
- Review financial reports.

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**Annual Report to the Board for Community Pharmacy Advisory Committee**

**Reporting Period:** Mar 1, 2016 – Feb 28, 2017

**Membership:**
Ming Chang
Cassandra Elstak-Blackwell
Parveen Mangat
Tara Oxford
Aaron Sihota
Elijah Ssemaluulu
Tiffany Tam
Cindy Zhang

**Chair:** Fady Moussa
**Vice Chair:** Mohinder Jaswal

**Staff Resource:** Ashifa Keshavji

**Mandate:** To provide recommendations to the Board on matters relating to community pharmacy practice.

**Responsibilities:**

- Review issues related to the practice of pharmacy that have been directed to the committee by the Board, Board committee or College staff.
- Assist in the development of policies, procedures, guidelines and legislation pertaining to pharmacy practice issues and standards.
- Assist in the development of information materials for circulation to practicing registrants.
- Recommend appropriate action to the Board regarding pharmacy practice issues.
- Work collaboratively with other College practice advisory committees to ensure a cohesive approach to common practice issues.

**Relevant Statistical information:**

- Number of meetings: 0

**Accomplishments:**

- Attended meetings and/or provided feedback by email on the bylaws and standards of practice relevant to the following projects
    - Medical Assistance in Dying (MAID)
    - Un-scheduling of Naloxone
    - Palliative care kits
    - Standards for Product preparation and final check
    - Standards for Patient identification
    - Compounding; sterile hazardous and sterile non-hazardous

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**Goals for Next Fiscal Year:**

- Continue to work with committee Chairs/Vice Chairs to identify agenda items relevant to current community pharmacy issues
    - For review/discussion and recommendation to the Board as needed
- Continue to review professional practice policies and other standards of practice
- Continue to support the Practice Review Committee on the maintenance of the Practice Review Program

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# Annual Report to the Board for Drug Administration Committee

**Reporting Period:** March 1, 2016 – February 28, 2017

**Membership:**
Omar Alasaly
Elizabeth Brodkin
Jagpaul Deol
Aileen Mira
Mitch Moneo
Chris Salgado
Cameron Zaremba

**Chair:** Cameron Zaremba
**Vice Chair:** Omar Alasaly

**Staff Resource:** Doreen Leong

**Mandate:** To develop, review and recommend the standards, limits and conditions under which a registrant may administer a drug or substance to patients and to maintain patient safety and public protection with respect to authorized pharmacist's administration of injections to patients.

**Responsibilities:**
- Must review, develop and recommend to the Board standards, limits and conditions respecting the performance by full pharmacists of restricted activities under section 4(1) (c.1) of the Pharmacists Regulation for the purposes of preventing diseases, disorders and conditions.
- May review the role of full pharmacists in regard to the performance of restricted activities under section 4(1) (c.1) of the Pharmacists Regulation.
- May make recommendations to the Board, for submission to the Ministry of Health Services, respecting the standards, limits and conditions for practice and any other requirements it considers necessary or appropriate to support the performance by full pharmacists of restricted activities under section 4(1) (c.1) of the Pharmacists Regulation for the purposes of treating diseases, disorders and conditions.
- May consult, as it considers necessary or appropriate, with registrants or other individuals who have expertise relevant to drug administration by injection or on any other matter considered by the committee.

**Relevant Statistical information:**
- Number of meetings: 0

**Accomplishments:**
- No meetings

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**Goals for the Next Fiscal Year:**

- Review and recommend changes to the *HPA bylaws* related to drug administration, including removing the restrictions on drug administration authority in the Standards, Limits and Conditions for Drug Administration by Injection and Intranasal Route.

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# Annual Report to the Board for Discipline Committee

**Reporting Period**: March 1, 2016 – February 28, 2017

**Membership**:

| | |
|---|---|
| Jerrold Casanova | Chris Kooner |
| Wayne Chen | Howard Kushner |
| Suzanne Coughtry | Derek Lee |
| Jody Croft | Leza Muir |
| Bal Dhillon | Annette Robinson |
| Anneke Driessen | Jeremy Walden |
| James Ellsworth | Carol Williams |
| Patricia Gerber | Mabel Yan (resigned IN October) |
| Nerys Hughes | Amparo Yen |

**Chair:** Jerrold Casanova
**Vice Chair:** Patricia Gerber

**Staff Resource:** David Pavan

**Mandate**: Hear and make a determination of a matter referred to the committee regarding a pharmacist's or pharmacy technician's conduct, competency and/or ability to practice, pursuant to legislation.

**Responsibilities:**

- Conduct hearings of a matter;
- Determine disposition of the matter;
- Inform respondents, complainants and the public about action taken;
- Inform respondents and complainants about the discipline process as applicable.

**Relevant Statistical information:**

- Number of hearing days/teleconferences: 2
- Number of discipline files heard in court: 0
- Number of pending files: 1 registrant

**Current Discipline Cases:**

- **Isodoro Andres "Rudy" Sanchez / Marigold Compounding and Natural Pharmacy and Marigold Natural Pharmacy Ltd.**

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The Inquiry Committee directed the Registrar of the College to issue a citation against registrant Isodoro Andres “Rudy” Sanchez. Mr. Sanchez had been the owner, manager and director a pharmacy where numerous practice infractions and deficiencies had been identified during an investigation:

- Manufacturing and selling prescription, over-the-counter and natural health products on site at Marigold Pharmacy without valid licences from Health Canada;
- Non-compliance with prescribed standards for pharmacy practice and pharmacy management;
- Making therapeutic and product recommendations to patients outside the scope of pharmacy practice;
- Handling and preparing placenta for encapsulation without regulatory clearance required for ensuring safety of said biologic materials;
- Failure to comply with compounding standards.

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# Annual Report to the Board for Ethics Advisory Committee

**Reporting Period:** March 1, 2016 – February 28, 2017

**Membership:**

| | |
|---|---|
| Cristina Alarcon | Tara Lecavalier |
| Shivinder Badyal | Vanessa Lee |
| Alison Dempsey | Robyn Miyata |
| Bashir Jiwani | Jing-Yi Ng |

**Chair:** Dr. Bashir Jiwani
**Vice-Chair:** Robyn Miyata

**Staff Resource:** David Pavan

**Mandate:** To provide recommendations to the Board and the registrar on matters relating to the code of ethics, conflict of interest standards and any related policies or guidelines.

**Responsibilities:**

- Provide advice and guidance regarding ethical questions and dilemmas that have been directed to the committee from the Board, Board committees or College staff;
- Review and recommend updates to the code of ethics and conflict of interest standards as necessary;
- Consult on education program proposals relating to ethics issues.

**Relevant Statistical Information:**

- Number of meetings: 1

**Accomplishments:**

- Provided interim guidance for registrants regarding medical assistance in dying.
- Updated the code of ethics in consideration of medical assistance in dying.

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# Annual Report to the Board: Governance Committee

**Reporting Period:** March 1, 2016 – Feb 28, 2017

**Membership:** Anar Dossa
Norman Embree
Mona Kwong
George Walton

**Chair:** Norman Embree

**Vice-Chair:** Anar Dossa

**Staff Resource:** David Pavan

**Mandate:** To provide recommendations to the Board on matters relating to Board Governance.

**Responsibilities:**

- Review Board policies and manuals and recommend revisions to these documents.
- Review and make recommendations regarding Board member orientation and ongoing development.
- Review and make recommendations on policies and practices related to the recruitment, election and/or appointment of Board and committee members.
- Provide advice and guidance on Board evaluations, including Board meeting evaluations.
- Assess and make recommendations regarding the governance-related needs of the Board.

**Relevant Statistical information:**

- Number of meetings: 4

**Accomplishments:**

- The following recommendations were approved at the April 2016 Board meeting:
  1. Dissolve the following committees:
     - Communications and Engagement Advisory Committee,
     - Interdisciplinary Relationships Advisory Committee, and
     - Technology Advisory Committee.
  2. Re-structure the following committees as Ad Hoc:
     - Community Pharmacy Advisory Committee,
     - Ethics Advisory Committee,
     - Hospital Pharmacy Advisory Committee, and
     - Residential Care Advisory Committee.

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3. Require all committees to provide a report to the Board at least annually, and all committees except ad-hoc committees must update the Board at every Board meeting.

4. Extend all committee member terms until April 2017 to allow the Governance Committee to establish a recruitment and appointment process.

- Obtained approval at the June 2016 Board meeting to search for an external consultant to conduct an external review of the organization

- Obtained approval at the August 2016 Board teleconference meeting to enter into a contract with Ernst & Young for the purpose of conducting an Organizational Review of the College as follows:
    - Phase 1 –
        - Online survey of all College staff, and
        - In-person interviews with approximately 25 staff.

      Consolidated high-level report of findings, themes, and recommendations presented to the Board prior to the November 2016 Board meeting.

- Obtained approval at the November 2016 Board meeting to enter into a second contract with Ernst and Young to conduct Phase 2 of the organizational review as follows:
    - Phase 2 –
        - Online survey of all Board members,
        - Telephone interviews with external stakeholders.

      Findings to be consolidated and presented in the spring of 2017.

- Recommended that the Board approve pursuing revisions to existing College bylaws that would change the term of office for elected Board members from two years to three years, and a maximum of 3 consecutive terms to a maximum of 2 consecutive terms. This recommendation was approved by the Board at the November 2016 Board meeting.

**Goals for Next Fiscal Year:**

- To recruit and appoint public and registrant volunteer committee members using a transparent process for selection which includes requiring submitting applications and resumes.
- Review of all committee terms of reference for consistency and relevancy.

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# Annual Report to the Board for Hospital Pharmacy Advisory Committee

**Reporting Period:** Mar 1, 2016 – Feb 28, 2017

**Membership:**
Elissa Aeng
Lily Cheng
Karen Dahri
Jennifer Dunkin
Aleisha Enemark
Ashley Fairfield
Anca Jelescu Bodos
Karen Lapointe
Aita Munroe
Fruzsina Pataky

**Chair:** Keith McDonald
**Vice Chair:** Anita Lo

**Staff Resource:** Ashifa Keshavji
Jonathan Lau

**Mandate:** To provide recommendations to the Board on matters relating to hospital pharmacy practice issues.

**Responsibilities:**

- To review issues related to the practice of hospital pharmacy that have been directed to the committee by the Board, Board committees or College staff.
- To assist in the development of policies, guidelines and legislation pertaining to hospital pharmacy issues and standards.
- Recommend appropriate action to the Board regarding hospital pharmacy issues.
- Work collaboratively with other College practice advisory committees to ensure a cohesive approach to common practice issues.

**Relevant Statistical information:**

- Number of meetings: 0

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**Accomplishments:**

- Attended meetings and/or provided feedback by email on the bylaws and standards of practice relevant to the following projects
    - Practice Review Program Phase 2: Hospital Practice
        - Process and policies
        - Review forms
        - Standards for
            - Product preparation and final check
            - Patient identification
    - Medical Assistance in Dying (MAID)
    - Un-scheduling of Naloxone
    - Palliative care kits
    - Compounding; sterile hazardous and sterile non-hazardous

**Goals for Next Fiscal Year:**

- Continue to work with committee Chairs/Vice Chairs to identify agenda items relevant to current hospital pharmacy issues
    - For review/discussion and recommendation to the Board as needed
- Continue to review professional practice policies and other standards of practice
- Continue to support the Practice Review Committee on the maintenance of the Practice Review Program

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# Annual Report to the Board for Inquiry Committee

**Reporting Period:** March 1, 2016 – February 28, 2017

**Membership:**

| | |
|---|---|
| Carla Ambrosini | George Kamensek |
| Dorothy Barkley | Patricia Kean |
| Cindy Bondaroff (retired in September) | Fatima Ladha |
| Karen Callaway | Jim Mercer |
| Sally Chai | Jing-Yi Ng |
| Ming Chang | Alison Rhodes |
| Michael Dunbar | Alana Ridgeley |
| Norman Embree | Susan Troesch |
| Sukhvir Gidda | Ann Wicks |
| John Hope | Cynthia Widder |

**Chair:** John Hope
**Vice-Chair:** Dorothy Barkley

**Staff Resource:** David Pavan

**Mandate:** Investigate complaints and concerns regarding a pharmacist's conduct, competency and/or ability to practice and decide on an appropriate course of action pursuant to legislation.

**Responsibilities:**

- Investigate complaints on its own motion or raised by a complainant within legislated timelines;
- Investigate registrants that fail to authorize a criminal records review check as well as registrants presenting a risk of physical or sexual abuse to children as determined by the Registrar of the Criminal Records Review Act;
- Determine disposition of items (1) and (2);
- Inform registrants, complainants and the Health Professions Review Board about the inquiry process and complaint outcomes, as necessary; and
- Report to the Board as applicable.

**Relevant Statistical Information:**

- Number of in-person meetings: 11
- Number of teleconferences: 44

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**Accomplishments:**

**Fiscal 2016/17 (March 1, 2016 – February 28, 2017)**

| **Total** | **Complaint Types (may be more than one type per complaint)** | **Disposition Status:** |
|---|---|---|
| Total # of official complaints: 105 | Medication-related: 28 | Total files reviewed by IC: 209 |
| Total # of registrants: 191 | Privacy/Confidentiality: 12 | Total new files reviewed: 103 |
| Total # of calls/tips/intelligence: 758 | Professional Conduct/ Competency: 67 | Total reconsiderations: 61* |
| Total # of PODSA s.17 investigations: 35 | Fitness to practice: 8 | Total PODSA S.18 files: 45 |
| Total # of complaints via HPRB: 4 | Business-related: 5 | |
| Total # of files referred to DC: 2 | Unlawful activity: 1 | |
| | Sexual misconduct: 0 | |

* *Some files may have been reconsidered more than once.*

**Notable Cases:**

**PharmaCare de-enrollment**

- **Jin Tong Li**

  The Inquiry Committee reached an agreement with Mr. Jin Tong (Tom) Li to suspend his registration as a pharmacist for 540 consecutive days.

  Mr. Li acknowledged that between January 1, 2014 and December 22, 2014, he submitted fraudulent claims to PharmaCare over the PharmaNet system on over 2400 occasions. On all occasions, he had billed a high dollar value medication on PharmaNet, then reversed the medication to manipulate PharmaCare deductibles and to effectively allow patients to receive financial benefits from PharmaCare to which they were not entitled.

  Mr. Li also acknowledged that between January 1, 2013 and December 31, 2014, he had been the dispensing pharmacist and/or pharmacy manager responsible for

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multiple practice deficiencies including dispensing quantities in large excess of what had been authorized, dispensing from invalid prescriptions, dispensing from incomplete prescriptions, dispensing prescriptions under the incorrect prescriber's name, dispensing incorrect medications, processing blood glucose test strips on PharmaNet in large excess of what could be accounted for by wholesaler invoices, and not keeping complete patient records and prescription documentation.

**Undercover**

- **Nikhil Buhecha**

  The Inquiry Committee received and agreed to a consent order proposal from Mr. Nikhil Kantilal Buhecha prior to the commencement of a hearing into allegations against him, set to proceed before the Discipline Committee on July 18, 2016. The Inquiry Committee reviewed the proposal, the allegations against Mr. Buhecha set out in the Citation and decided to accept the terms which are now orders pursuant to section 37.1(3)(a) of the *Health Professions Act*.

  Among other orders, the Inquiry Committee reached an agreement to suspend Mr. Buhecha's registration for a period of 3 years and was ordered to pay a fine of $50,000 and $100,000 in costs.

**Narcotic management**

- **King Cheong (Steven) Lum**

  The Inquiry Committee reached an agreement with Mr. King Cheong (Steven) Lum to suspend his registration as a pharmacist for 365 consecutive days.

  In or about April 2016, while pharmacy manager, director, and owner of a pharmacy, Mr. Lum discovered discrepancies between the on-hand quantities and computer quantities of 47 individual molecules of narcotic and controlled drugs and 21 individual molecules of benzodiazepines at the pharmacy. The most significant discrepancies were 165,998 tablets of Ratio-Oxycocet (oxycodone/acetaminophen 5mg/325mg), 1,030 tablets of Ratio-Lenoltec No. 3 (acetaminophen/caffeine/codeine 300mg/15mg/30mg), and 17,353 tablets of Mylan-Alprazolam 2mg. Mr. Lum had not noticed the discrepancies for many months until April 2016, and therefore the discrepancies had not been reported to Health Canada as required.

  After an investigation, it was substantiated that while Mr. Lum was pharmacy manager, director, and owner of a pharmacy, he failed to maintain a standard of practice of the

pharmacy profession and contravened the relevant provincial and federal legislation with respect to the following:

- Management of inventory of narcotics, controlled drugs and targeted substances under his control to prevent loss or theft, including failure to count and reconcile all narcotics, controlled drugs and targeted substances at least every three months as required by Professional Practice Policy #65;
- Failure to maintain records of purchases, sales and remaining inventory for narcotics and other controlled drugs;
- Failure to make timely reports of losses of narcotics and other controlled drugs to Health Canada; and
- Failure to adhere to s. 43 of the *Narcotic Control Regulations*, s. G.03.012 of the *Food and Drug Regulations*, and s. 7(1)(b) of the *Benzodiazepines and Other Targeted Substances Regulations*, in that he failed to take all reasonable steps that were necessary to protect narcotics, controlled drugs and targeted substances on the premises or under his control against loss or theft or to take steps necessary to ensure their security, including failure to count and reconcile narcotics, controlled drugs and targeted substances at least every three months.

The Inquiry Committee considered that Mr. Lum's serious lack of judgment constituted professional misconduct, therefore ordered him to successfully pass the College's Jurisprudence Exam, pay a $30,000 fine, among other orders.

**Methadone Maintenance Treatment – Results of 2016 Focused Inspections**

Methadone Maintenance Treatment is a complex area of pharmacy practice that is multi-faceted, cross professional, and cross-jurisdictional. In response to the numerous concerns and allegations received from members of the public, registrants, and other health care professionals regarding the dispensing of Methadone Maintenance Therapy (MMT) from pharmacies, the College Board approved a four-year MMT action plan to address the concerns raised and eliminate non-compliance with legislative requirements and practice standards.

One of the goals in the action plan was for the College to conduct focused inspections at BC pharmacies that provided MMT services. In 2016, the College selected 15 pharmacies for focused inspection based on the following criteria:

1. Amount and frequency of MMT dispensing within each district/region in 2015;
2. Past allegations/tips received; and
3. The need to ensure that pharmacies within each district/region of BC were inspected.

All pharmacists providing MMT services are expected to practice in compliance with Professional Practice Policy #66 (PPP-66), as well as relevant provisions in the

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*Pharmacy Operations and Drug Scheduling Act (PODSA)* and its Bylaws. College Inspectors used these provisions to guide their assessment of each pharmacy.

During each inspection, College Inspectors observed and evaluated methadone dispensing practices, including how staff at each pharmacy received, processed and released methadone prescriptions, as well as how they responded to methadone dosing issues. Inspectors also evaluated whether pharmacy operating hours were consistent with supervised dosing requirements of patients; whether the pharmacy had the required references; and whether the pharmacy premises met the standards for ensuring privacy, confidentiality and cleanliness.

After each inspection, the College Inspector sent a letter to the pharmacy manager outlining deficiencies noted during the inspection. The inspector then worked with each pharmacy manager to remediate deficiencies in a timely manner. The College's Inquiry Committee then reviewed the results of each inspection, and concluded every matter that was considered remediated. Matters where further investigation and/or remediation was needed were referred to the Inquiry Committee for investigation through a formal process.

The most common deficiencies identified by College Inspectors were:

- **Faxed MMT prescriptions did not have signatures on either the faxed copy or original prescription**. Methadone is vulnerable to theft and diversion. Stringent documentation is a necessary part of ensuring methadone security, and minimizing the potential public safety risk of diverted methadone.

- **The "sig field" on prescription labels did not include the start and end dates as indicated on the original prescriptions**. MMT requires stringent adherence to dosing regimens. Having clear start and end dates on a prescription label allows patients to plan their visits to prescribers, preventing confusion to ensure continuous, well-monitored care.

- **Changes to MMT prescriptions (split doses and date changes) were done as verbal orders.** PPP-66 requires all prescription alterations to be confirmed by the prescriber in writing. Narcotic prescriptions are vulnerable to forgery, and a written record of any changes minimizes this risk. PPP-66 also requires split dosing to be initiated by the prescriber on the original prescription. This cannot be done verbally.

- **Missed doses were verbally communicated to the prescriber, with no documentation of this communication kept on file with the original prescription.** PPP-66 requires that the notification document be retained and filed with the original prescription.

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- **Methadone was not being counted during regular narcotic counts and reconciliations**. Regular narcotic counts and reconciliation are a core responsibility of a pharmacy manager, and the safety and security of all controlled and narcotic drugs are the responsibility of all pharmacist registrants. These responsibilities are outlined in Professional Practice Policy #65.

- **Toxicity warning labels were adhered to bottles containing methadone.** Lethal respiratory depressive effects can occur in doses as low as 30mg in non-tolerant persons, the equivalent of 3ml (less than one teaspoon) of Methadose. Toxicity warning labels are essential to preventing accidental ingestion and harm.

- **Methadone was being measured with devices that did not meet required standards**. PPP-66 requires a measurement device with no more than a 0.1ml error rate. Methadose is a 10mg/ml methadone liquid. Because of this potency, small differences in volume may lead to under or over dosing. These measurement devices must be labelled with toxicity warnings, or they are to be used for methadone only. Because of the product's potency, even small amounts can have potentially clinical effects.

- **The pharmacy did not have the required references**, such as *CPSBC Methadone Maintenance Program: Clinical Practice Guideline or Opioid Agonist Maintenance Treatment*. Required references are listed on the College's website, and a complete set of references are required to ensure that all staff involved in MMT dispensing are well educated in methadone issues and regulations, and to provide easily accessible information should questions arise during daily practice.

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# Annual Report to the Board for Jurisprudence Examination Subcommittee

**Reporting Period:** March 1, 2016 – February 28, 2017

**Membership:**
Roberta Walker
Melanie Johnson
Tony Seet
Asal Taheri
Maria Ton
David Wang

**Chair:** Roberta Walker
**Vice Chair:** Melanie Johnson

**Staff Resource:** Doreen Leong, Denise Lin

**Mandate:** To ensure that the Jurisprudence Examination continues as a valid and reliable assessment instrument.

**Responsibilities:**
- Develop, update and maintain Jurisprudence Examination blueprint and content.
- Establish and validate assessment and assessment standards.
- Develop recommendations and policies for review and approval by the Registration Committee.
- Review correspondence and appeals pertaining to the examination questions and acceptable answers, and recommend outcomes for the Registration Committee's approval.

**Relevant Statistical information:**
- Number of meetings: 3

**Accomplishments:**
- All items were recoded using the new blueprint and new exam forms developed.
- Statistical data collated and provided to UBC Faculty of Pharmaceutical Sciences, CCAPP accredited pharmacy technician programs and CCAPP to inform their accreditation requirements.
- Items reviewed for any legislative changes.
- Review of results of past three Jurisprudence Exam sittings, item refined based on statistical analysis.

**Goals for Next Fiscal Year:**
- Conduct psychometric analysis of items.
- Conduct item review/item writing workshops.
- Explore the feasibility of administering the Jurisprudence Exam online.

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# Annual Report to the Board for Legislation Review Committee

**Reporting Period:** Mar 1, 2016 – Feb 28, 2017

**Membership:** Anar Dossa
Mona Kwong
Jeremy Walden
Sorell Wellon

**Chair:** Jeremy Walden

**Staff Resource:** Christine Paramonczyk

**Mandate:** To provide recommendations to the Board and the Registrar on matters relating to pharmacy legislation and policy review.

**Responsibilities:**

- Provide advice and guidance regarding proposed legislation/policy changes that have been directed to the committee from the Board, Board committees or College staff.
- Identify priorities for change within legislation review planning cycle.
- Determine if broader external stakeholder consultation is required.
- Chair of Committee presents priorities to the Board for approval.
- Approve final draft of proposed legislation/policy prior to presentation to Board.
- The Chair (supported by Policy and Legislation staff) presents proposed documents to Board for approval.
- Review public posting comments as necessary.

**Relevant Statistical information:**

- Number of meetings: 9

**Accomplishments:**

- Over the past year, the Legislation Review Committee recommended changes to policy, bylaws, fees, Standards of Practice and to the Drug Schedule Regulation.

| Legislation | Amendments |
|---|---|
| **Health Professions Act Bylaws** | **May 2016:**<br>• Bylaw amendments regarding medical assistance in dying (MAID).<br><br>**June 2016:**<br>• Structural Practical Training program fee changes. |

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| | |
|---|---|
| | **<u>July 2016:</u>**<br>• Amendments to MAID provisions to ensure alignment with new federal legislation.<br><br>**<u>August 2016:</u>**<br>• Amendments regarding PharmaNet patient profile review and pharmacist/patient consultation, in the Community Pharmacy Standards of Practice.<br>• Fee schedule changes.<br><br>**<u>October 2016:</u>**<br>• Approval to publicly post amendments to establish an Application Committee.<br>• Creating minimum standards for registrants regarding the preparation of prescription product, final product check, and patient identification. |
| **Pharmacy Operations and Drug Scheduling Act Bylaws** | **<u>April 2016:</u>**<br>• Approval to publicly post pharmacy security bylaws.<br><br>**<u>June 2016:</u>**<br>• Establishing a minimum standard regarding pharmacy workload.<br><br>**<u>August 2016:</u>**<br>• Approval of pharmacy security bylaws for a second public posting period.<br>• Fee schedule changes.<br><br>**<u>January 2017:</u>**<br>• Approval to file pharmacy security bylaws. |
| **Drug Schedule Regulation** | **<u>May 2016:</u>**<br>• Authorize and support the Nurse Practitioner prescribing standards of practice.<br><br>**<u>August 2016:</u>**<br>• Classifying naloxone as unscheduled to enhance accessibility in an effort to respond to BC's public health emergency.<br><br>**<u>October 2016:</u>**<br>• Re-classifying ibuprofen, esomeprazole, and fluticasone. |

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| | |
|---|---|
| **Professional Practice Policies (PPP) et al** | **<u>October 2016:</u>**<br>• Amending PPP-58 "Medication Management (Adapting a Prescription)" to include refills of a prescription.<br><br>**<u>October 2016:</u>**<br>• Approve a new PPP: PPP-75 "Patient Identification."<br><br>**<u>January 2017:</u>**<br>• Repeal the Community Pharmacy Security Resource Guide.<br>• Amend PPP -74 "Community Pharmacy Security." |

**Key Goals for Next Fiscal Year:**

- Drafting amendments regarding the telepharmacy provisions within the Pharmacy Operations and Drug Scheduling Act (PODSA) Bylaws and Professional Practice Policy.
- Develop and implement bylaws to operationalize the recent changes enacted by the provincial government regarding pharmacy ownership provisions under PODSA. These bylaws are to be in force by March 2018.
- Begin a comprehensive review and reform of legislative requirements under PODSA.
- Initiate work regarding the College's Methadone Action Plan. As part of that plan, existing policy and legislation on methadone will be reviewed. Amendments may be required. In addition, the existing PPP's on methadone will be transitioned to bylaws, as required.
- Potentially initiate scoping a comprehensive review and reform of legislative requirements under the Health Professions Act.

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# Annual Report to the Board for Practice Review Committee

**Reporting Period:** Mar 1, 2016 – Feb 28, 2017

**Membership:**
Patrick Chai
Kate Cockerill
Sean Gorman
Kris Gustavson
Joanne Konnert
Fady Moussa
Alison Rhodes
Helen Singh
Perry Tompkins (Resigned in May 2016)

**Chair:** Mike Ortynsky
**Vice Chair:** Aleisha (Thornhill) Enemark

**Staff Resource:** Ashifa Keshavji

**Mandate:** To monitor and enforce standards of practice to enhance the quality of pharmacy care for British Columbians.

**Responsibilities:**

- Develop and update the Practice Review Program (PRP) processes and policies for approval by the Board as required including but not limited to processes and policies that:
  - outline the Pharmacy Review component;
  - outline the Pharmacy Professionals' Review component;
  - outline follow-up and remediation.
- On a yearly basis review the statistics and outcomes and feedback of the PRP, determine recommendations for improvement and report to the Board as applicable.
- Liaise with the Hospital Pharmacy Advisory Committee, Community Pharmacy Advisory Committee and Residential Care Advisory Committee to make recommendations on current and outstanding issues pertaining to the PRP.
- Liaise with Health Authorities, owners and directors and other stakeholders to address current and outstanding issues pertaining to the PRP.

**Relevant Statistical information:**

- Number of meetings: 5

College of Pharmacists of British Columbia

**Accomplishments:**

Phase 1: Community Practice

- Launched PRP Application which consists of four modules:
  - Administrative Dashboard module which is used by staff for scheduling reviews, review form maintenance and pulling reports
  - Pharmacy Pre-Review module which is used by the Pharmacy Manager to complete a self-assessment of their pharmacy prior to the onsite practice reviews
  - Pharmacy Review and Pharmacy Professionals Review module which is used by the Compliance Officers to conduct the onsite practice reviews
  - Action Item Follow Up module which is used by registrants to submit their action items to the Compliance Officer for approval
- Enhancing Pharmacy Professionals Reviews for Pharmacy Technicians
  - Recommended new focus areas for approval by the Board (June 2017)
  - Developing review forms
- Outcomes of reviews
  - Revised escalation policy
  - Referral to the Inquiry Committee
- Updated Phase 1 Registrant Feedback Survey for the 2017-18 Fiscal Year

Phase 2: Hospital Practice

- Completed program development
  - Liaised with the Hospital Pharmacy Advisory Committee
  - Engaged with stakeholders through meetings and forums
  - Developed PRP policies for selection, deferral and exemption
- Received approval to launch at the Board's November 2016 meeting
- Preparations for launch
  - Executed communications plan
  - Finalized review tools (excel database)
- Sent first selection emails to hospital pharmacy managers on March 3rd, 2017
  - First onsite review scheduled for April 3rd, 2017
- Approved the Phase 2 Registrant Feedback Survey

**Goals for Next Fiscal Year:**

Phase 1: Community Practice

- Complete enhancement of Pharmacy Professionals Reviews for Pharmacy Technicians
- Develop and launch Release 2: Incorporate specialty services including residential care, compounding and methadone
- Develop Registrant Feedback Survey report for the 2016-17 Fiscal Year
  - To be presented to the Board at their June or September 2017 meeting

Phase 2: Hospital Practice

- Develop and launch Release 2: Incorporate specialty services including residential care and compounding

College of Pharmacists of British Columbia

# Annual Report to the Board for Quality Assurance Committee

**Reporting Period:** Mar 1, 2016 – Feb 28, 2017

**Membership:**
Hani Al-Tabbaa
Tess Cheng
Norm Embree
Frank Lucarelli
Rebecca Siah
Sukhvir Gidda
Dorothy Zahn

**Chair:** Gary Jung
**Vice Chair:** Bal Dhillon

**Staff Resource:** Ashifa Keshavji

**Mandate:** To ensure that registrants are competent to practice and to promote high practice standards amongst registrants.

**Responsibilities:**

- Monitor and enforce standards of practice to enhance the quality of practice and reduce incompetent, impaired or unethical practice amongst registrants.
- Establish and maintain a quality assurance program to promote high practice standards among registrants and continuous learning and professional development.
- Recommend standards of practice for continuing competency for the Board's approval.
- Develop practice guidelines and / or advisory statements when required.
- Establish and maintain a quality assurance program in accordance with current testing standards and assessment practices.
- Set, administer and maintain policies on all matters related to assessment competencies, standards, principles, selection or design and processes.
- Establish sub-committees and ad hoc working groups for Board appointment, to develop, administer and maintain assessments for the purposes of the quality assurance program.

**Relevant Statistical information:**

- Number of meetings: 4

College of Pharmacists of British Columbia

**Accomplishments:**

- Amended their deferral policy and application form to accept other statements as supporting documentation
- PDAP Portal
    - Mobile application
        - Named the application PDAP Mobile and developed a logo
        - Completed testing
    - Learning Record
        - Now requires supporting documentation to be submitted for all accredited learning
- Based on the results of the February 2016 educational needs assessment survey
    - Directed staff to work with UBC CPPD to develop and deliver seven CE programs
- Based on a request from the Practice Review Committee
    - Directed staff to work with UBC CPPD to develop tools for preparation and remediation for the Pharmacy Professionals Review focus areas
- Updated the CE audit procedure

**Goals for Next Fiscal Year:**

- Launch mobile application
- Monitor CE-Plus audit results

College of Pharmacists of British Columbia

# Annual Report to the Board for Residential Care Advisory Committee

**Reporting Period:** Mar 1, 2016 – Feb 28, 2017

**Membership:**
Ming Chang
Anna Kownacki
Joyce Quon
Alvin Singh

**Chair:** Douglas Danforth
**Vice Chair:** Maria Ton

**Staff Resource:** Ashifa Keshavji

**Mandate:** To provide recommendations to the Board on matters relating to residential care pharmacy practice issues.

**Responsibilities:**

- To review issues related to the practice of pharmacy for residential care facilities and homes that have been directed to the attention of the committee by the Board, Board committees or College staff.
- To assist in the development of policies, guidelines and legislation pertaining to residential care pharmacy practice and standards.
- Work collaboratively with other College practice advisory committees to ensure a cohesive approach to common practice issues.

**Relevant Statistical information:**

- Number of meetings: 0

**Accomplishments:**

- Attended meetings and/or provided feedback by email on the bylaws and standards of practice relevant to the following projects
    - Medical Assistance in Dying (MAID)
    - Un-scheduling of Naloxone
    - Palliative care kits
    - Standards for Product preparation and final check
    - Standards for Patient identification
    - Compounding; sterile hazardous and sterile non-hazardous

College of Pharmacists of British Columbia

**Goals for Next Fiscal Year:**

- Continue to work with committee Chairs/Vice Chairs to identify agenda items relevant to current residential care pharmacy issues
    - For review/discussion and recommendation to the Board as needed
- Continue to review professional practice policies and other standards of practice
- Continue to support the Practice Review Committee on the maintenance of the Practice Review Program

College of Pharmacists of British Columbia

# Annual Report to the Board for Registration Committee

**Reporting Period:** March 1, 2015 – Feb 29, 2016

**Membership:**
Laura Bickerton
Carolyn Cheung
Ashley Foreman
Yonette Harrod
Thuy Phuong Hoang
Raymond Jang
Derek Lee
Vanessa Lee
Leonard Ma
Charles Park
Nathan Roeters
Joy Sisson
Jeremy Walden

**Chair:** Raymond Jang
**Vice Chair:** Thuy Phuong Hoang

**Staff Resource:** Doreen Leong

**Mandate:** To ensure that registrants are qualified to practice.

**Responsibilities:**

- Review all matters relating to applicants for registration and determine applicants' eligibility for registration including establishing the conditions and requirements for registration.
- Grant registration, including reinstatement and registration renewal, to all individuals who satisfy the Registration Committee that they are qualified to be a registrant, including payment of required fees.
- Develop policies and requirements with respect to the registration of new, renewing and reinstating registrants.
- Set, administer and maintain policies on all matters related to assessment competencies, standards, principles, selection or design and processes.
- Establish sub-committees and ad hoc working groups for Board appointment, to develop, administer and maintain assessments for the purposes of the registration processes.
- Inform registrants, other stakeholders and the Health Professions Review Board, as required about the registration process and outcomes.

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**Relevant Statistical information:**

**Registration Committee**

- Number of meetings: 2 (in-person); 7 (tele-conference)

**Registrant Data:**

**Total number of new Full Pharmacists – 399**

- By pre-registration category:
  - UBC Students – 206
  - Pharmacists from other provinces (AIT) – 129
  - International Pharmacy Graduates - 45
  - New graduates from other provinces – 15
  - US Pharmacists – 3
  - New graduates from the US – 1

**Total number of new Pharmacy Technicians - 116**

- By pre-registration category:
  - New technician graduates - 99
  - Technicians from other provinces – 14
  - Currently in practice – 3

**Total reinstated Full Pharmacists – 48**

- By reinstatement category:
  - Reinstatement less than 6 years as a FMR/NP Pharmacists – 24
  - Reinstatement through the AIT – 24

**Total reinstated Pharmacy Technicians – 4**

- By reinstatement category:
  - Reinstatement less than 6 years as a FMR/NP Technicians – 3
  - Reinstatement through the AIT – 1

College of Pharmacists of British Columbia

**Accomplishments:**

- Key policies, processes and exam results reviewed and approved including the International Pharmacy Technician regulation requirements, Exam Appeal Policy, English Language Proficiency Policy and Jurisprudence Exam results.
- Applications reviewed whereby applicant had issues related to the statutory declaration:
    - Pharmacist Reinstatement Application, less than 6 years in Non-practising or former pharmacist register (N=2)
    - Pharmacist Pre-registration - International Pharmacy Graduate application (N=2)
    - Pharmacy Technician Pre-registration Application (N=2)
    - Pharmacy Technician Pre-registration Application to extend December 31, 2015 deadline (N=4)
    - Pharmacy Technician Reinstatement Application, less than 6 years in Non-practising or former pharmacy technician register (N=1)
- Other application reviewed:
    - Pharmacy Technician Jurisprudence Exam – Exam accommodation (N=1)
    - Pharmacy Technician Jurisprudence Exam – Additional sitting (N=3)
- Developed the intranasal drug administration educational module and integrated with registration re-certification process

**Goals for Next Fiscal Year:**

- Annual review of all registration policies
- Review and recommend bylaw changes related to pre-registration and registration requirements, number of assessment attempts and transfer from former category to non-practising register and from former to reinstatement category
- Review and recommend bylaw changes related to changes to the Standards, Limits and Conditions for Injection Authority
- Finalize the requirements and processes for International Pharmacy Technician Registration
- Develop and tested online registration pre-registration process

College of Pharmacists of British Columbia

# BOARD MEETING
# April 21, 2017

## 2b.vi. Privacy Policy

## DECISION REQUIRED

### Recommended Board Motion:
*Approve the College of Pharmacists of British Columbia Privacy Policy as circulated.*

### Purpose
To formalize the College's privacy practices in a Privacy Policy.

### Background
The Office of the Privacy Commissioner states that "public bodies should take all reasonable steps to ensure, and be able to demonstrate, *Freedom of Information and Protection of Privacy Act* (FIPPA) compliance and good practices". Written policies and procedures formalize the organization's practices.

### Discussion
Key privacy issues addressed in the policy include:

- Authority for collection, use and disclosure of personal information
- Requirements for consent and notification
- Accuracy of personal information
- Individual access to and correction of personal information
- Retention and disposal of personal information
- Responsible use of information and information technology; and
- A process for handling privacy-related complaints.

### Recommendation
That the Board approves the attached Privacy Policy.

| Appendix | |
|---|---|
| 1 | College of Pharmacists of British Columbia Privacy Policy |

# College of Pharmacists of BC Privacy Policy

## Privacy

### Our commitment to you

The College of Pharmacists of BC (College) is committed to protecting your privacy. We seek to use best practices in doing so. We collect, use and disclose personal information in accordance with our province's *Health Professions Act* (HPA), *Pharmacy Operations and Drug Scheduling Act* (PODSA), *Freedom of Information and Protection of Privacy Act* (FIPPA) and other applicable legislation.

Some of the personal information that we hold is publicly available under section 22(1) of the HPA and section 39(1)(2) of the College's HPA Bylaws.

### Accountability

We have designated staff who are responsible for making sure that we comply with privacy legislation. Our Registrar is ultimately accountable for the College's compliance with FIPPA**.**

If you have questions about our privacy practices, please contact our Privacy Officer. Please see below for our Privacy Officer's contact details.

### Identifying purposes

When we collect personal information we explain why we are collecting the information and our legal authority for doing so. For example, we collect (and, where applicable, use or disclose) personal information from our registrants (pharmacists, pharmacy technicians). We also collect personal information from people who apply for registration as a pharmacist or pharmacy technician, or who apply for a pharmacy licence. This is so we can operate our programs of registration and licensing for registrants and pharmacies. In these examples, our authority to collect personal information is found in section 26(c) of FOIPPA. We also have authority to collect personal information, in these and other cases, to:

- Meet our duty to serve and protect the public under section 16 of the HPA.
- Operate the College's programs, and carry out our activities, under the HPA, PODSA, our bylaws and any other applicable legal authority
- Perform criminal record checks on registrants or applicants as required by law.
- Consider and assess applications by individuals for registration as registrants under the HPA and the College's HPA Bylaws.
- Consider and assess application for licensure of a pharmacy under the PODSA and the College's PODSA Bylaws

- Maintain our register of registrants as required by section 21(2) of the HPA.
- Maintain and protect the College's systems, as well as provide system support for registrants, pharmacies and applicants when requested by them.
- Administer and implement the College's quality assurance program under sections 26.1 and 26.2 of the HPA and Part V of the HPA Bylaws
- Investigate and dispose of complaints against registrants under Part 3 of the HPA
- Comply with the procedures and requirements of the Health Professions Review Board, and participate in proceedings before the Review Board under Part 4.2 of the HPA.
- Contact registrants and pharmacies about our programs or activities and to obtain feedback on them.
- Obtain opinions and feedback from registrants and pharmacies on regulatory issues.
- Obtain information on the effectiveness of our communications to registrants, pharmacies and other stakeholders (e.g. date and time our electronic communications are opened or links within messages are opened) in order to tailor and adapt our communication messages and approaches.
- Send invitations to participate in third-party research to those registrants who have asked to receive those invitations.

This list is not exhaustive. There may be other situations where we collect, use and disclose personal information.

As part of a pharmacist's or pharmacy technician's registration, we share registrants' personal information with these organizations for the following purposes:

1. The BC Ministry of Health for the BC Provider Registry System. The Ministry uses registrants' information:

- to identify and authenticate pharmacists and pharmacy technicians, and to confirm the registration status of pharmacists and pharmacy technicians
- to obtain the contact information of registrants
- to administer and deliver health programs (for example, the Medical Services Plan and PharmaCare)
- for the purposes specified in section 5 or 18 of the E-Health (Personal Health Information Access and Protection of Privacy) Act
- for disclosure to healthcare providers such as health authorities, health care bodies, health professionals using electronic medical record systems or other persons as authorized by law
- for other purposes required or authorized by law

2. A registrant's employer, where required by Part 4 of the BC Criminal Records Review Act**.**

3. The Canadian Institute for Health Information, which uses pharmacists and pharmacy technicians' information:

- for health system uses such as statistical analysis and reporting
- to support the management, evaluation or monitoring of the allocation of resources to, or planning for, the health care system in Canada, including support for the improvement of the overall health of Canadians.

4. Service providers and contractors contracted to provide services to the College that require them to handle personal information. These service providers and contractors agree in writing to protect personal information and comply with FIPPA.

We also collect information from non-registrants. We explain the reasons when we collect the information.

**Collection methods**

When we need to collect personal information about someone, we usually get the information directly from that person. Here are some examples of where we may collect personal information from another source:

- So that we can assess the competency of a person applying for registration as a pharmacist or pharmacy technician in British Columbia and so that we can confirm that applicant's past employment;
- When we receive exam results and other information from the Pharmacy Examining Board of Canada (PEBC);
- To receive information on an internationally-educated pharmacist or pharmacy technician from the PEBC;
- To enable us to perform a criminal record check of a pharmacist or pharmacy technician or applicant;
- For the purposes of our investigating and disposing of a concern or a complaint about a registrant;
- As otherwise authorized by law or court order.

**Scope of collection, use, disclosure and retention**

We collect and use personal information that is needed to meet the purposes described above.

For credit and debit card payments made to the College, we designed our systems so that most credit and debit card information is collected directly on our behalf by our payment processor. Where we collect credit or debit card information ourselves, we shred the forms promptly upon processing the payment.

We only share pharmacists' and pharmacy technicians' and applicants' personal information with the organizations listed above, unless authorized or required by law or court order, or with the individuals' consent. When we send invitations to registrants to participate in third-party research or surveys, we do not share any personal information with that outside organization.

We keep personal information used to make a decision about an individual for a minimum of one year. Personal information may be kept for longer, for example if required by law for financial records. Personal information is retained and disposed of in accordance with the College's records retention and disposition schedules, which are developed and administered in accordance with generally-accepted records management practices.

Paper containing personal information is shredded by a service provider that provides a certificate of destruction. Personal information in online electronic form is deleted from our information systems.

**What personal information is being collected by our website?**

The information collected by the College includes:

- web browser and operating system you are using (e.g. Vista, XP, Safari)
- date and time of visit
- pages or services accessed
- If you were on another website before visiting the College website, the URL (web address) of that previous website if it referred you to the College website
- URL (web address) of the first website you visit immediately upon leaving the College website if you were referred to that website by the College website

The College, via its websites, will notify you if cookies will be collecting any additional information and in that case we will give you the right to decline to accept cookies of that kind. A cookie may remain on your computer after the Internet session finishes (until the cookie expires or is deleted by you).

**Accuracy and requesting correction of your personal information**

We make every reasonable effort to ensure that personal information is accurate and complete. We may contact you for an update if we become aware that your information is inaccurate.

It is your responsibility to contact us if your information needs to be updated. Pharmacists and pharmacy technicians are required by section 17 of the BC Criminal Records Review Act to report any new charges and convictions to the College that are relevant to their registration.

To access your personal information or request a correction of an error or omission:

- If you are a registrant, you can **login to your account** or contact our Registration Department at 604-733-2440 or toll free at 1-800-663-1940.

Members of the public:

- Please contact our Privacy Officer using the contact details below.

A correction request has to be in writing. You have to give us reasons why you believe the correction is reasonable. If we are satisfied that your request is reasonable, we will correct your information as soon as reasonably possible. If we decide not to correct your information, we will note your requested change on the information. We will also note why we did not correct your information as you asked. Correction requests will only be considered if they are about factual errors or omissions, not opinions or evaluations about the individual requesting the correction.

**Asking for a copy of your personal information**

You can ask us to give you a copy of your personal information that is in our custody or control.

To do this you have to contact us in writing. You must contact our Privacy Officer using the contact details below.

If we believe your request may involve someone else's personal information, or information protected under FIPPA, we may require you to make a formal request under FIPPA for access to your information. FIPPA gives us 30 business days to respond to a formal request, starting on the date your request is received. (It also allows that time to be extended.) Please note that in some cases FIPPA may require us to refuse you access to even your own personal information. We will give you written reasons for our decision.

Before disclosing your personal information, we will require you to verify your identity, so we can be sure that you are the individual whose information is being requested. This helps ensure we do not disclose your personal information to someone we should not give it to.

**Safeguards**

We are using reasonable security measures to protect the personal information we have collected, such as but not limited to physical and logical access controls and regular application of vendor-issued system updates.

**Changes to this Privacy Policy**

We may update this notice from time to time to reflect changes to our information practices. We will post any changes to this page.

**Questions and Complaints**

You may send your privacy-related questions, concerns or complaints to our Privacy Officer who is responsible for ensuring our compliance with this notice and with the appropriate privacy legislation.

Privacy Officer

200 – 1765 West 8th Avenue, Vancouver, BC, Canada V6J 5C6

Email: Privacy@bcpharmacists.org

If our Privacy Officer is unable to resolve a complaint, you may complain to the Information and Privacy Commissioner of British Columbia. That office's contact information is here:

**Mailing address**
Office of the Information and Privacy Commissioner for British Columbia
PO Box 9038 Stn. Prov. Govt.
Victoria B.C. V8W 9A4

**Location**
4th Floor, 947 Fort Street, Victoria BC V8V 3K3

**Telephone**
(250) 387-5629

**Legal Notice**

This policy does not create any legal rights, benefits, duties, obligations or requirements of any kind.

College of Pharmacists of British Columbia

# BOARD MEETING
# April 21, 2017

## 2b.vii. Audit & Finance Committee - Finance Report (January 2017)

## INFORMATION ONLY

### Purpose
To report on the highlights of the January 2017 financial reports.

### Background
The January 2017 financial reports reflect **eleven months** activity. Attached are the Statement of Financial Position, a summary Statement of Revenue and Expenditures and more detailed reports on Revenue and on Expenditures.

**Statement of Financial Position**
The College's cash position is well funded to meet payables owing with a balance of almost $700,000. Investments total more than $6 million. We have a busy renewal month in February which will fund the many year-end invoices and the three pay-period month of March. We will still receive PharmaNet revenues until later in the summer or fall which will help with cash flow for much of this coming fiscal year.

**Revenue**
Licensure revenues are almost right on budget, as is the *Other Revenue* category (Pharmanet, administrative fees, etc.)

**Expenses**
Total Year to Date Actual expenses are lower than budget. See the variance analysis which follows for details.

Variance analysis by department:

| Department | Budget | Actual | Comment |
|---|---|---|---|
| **Board & Registrar's Office** | $541,398 | $514,299 | Some expense categories are under budget but are off-set by the loyalty points legal costs. The invoices re the Organization Review will bring this department over budget. |
| **Grant distribution** | $406,301 | $225,567 | Both ADAPT and the physical assessment course will have one final round of invoices. However, the Enhanced PharmaNet Adverse Drug Event grant has run into some delays and will be carried over into future years. |
| **Registration & Licensure** | $237,420 | $274,938 | This variance is primarily due to consulting re Pharmacist Prescriber and PODSA. |
| **Quality Assurance** | $538,047 | $448,007 | The e-library portion will be under-budget as we discontinued the subscriptions as of Dec. 31st. |
| **Practice Review** | $270,646 | $123,281 | The Consulting Services budget was barely used. |
| **Complaints Resolution** | $348,729 | $334,123 | Legal and outside contractors' fees depend upon the timing of Discipline Hearings. |
| **Policy and Legislation** | $157,850 | $181,152 | Due to timing of legal expenditures. The PODSA ownership changes will require significant legal review but that may carry over into the new year. |
| **Public Engagement (Communications)** | $421,355 | $204,756 | This budget line will remain under budget. Some forums or town halls will not be held. Stakeholder engagement activities have been a high |

| | | | |
|---|---|---|---|
| | | | priority but are much less costly. |
| **Finance and Administration** | $1,431,949 | $1,665,106 | This category has been busy due to the IT upgrades. Some activities were accelerated as other departments were under budget. |
| **Salaries and benefits** | $4,708,397 | $4,528,436 | Due to timing of recruitment and staff turnover. |
| **Amortization** | $377,783 | $332,725 | Timing – as some calculations are done at year end. |

| **Appendix** | |
|---|---|
| 1 | Statement of Financial Position |
| 2 | Statement of Revenue and Expenditures |
| 3 | Statement of Revenue |
| 4 | Statement of Expenses |

**College of Pharmacists of BC**
**Statement of Financial Position**
**As of January 31, 2017**

| | |
|---|---|
| **ASSETS** | |
| **Current** | |
| Cash and Cash Equivalents | 678,601 |
| Investments | 6,009,618 |
| Receivables | 378,124 |
| Prepaid and deposits | 139,655 |
| | 7,205,998 |
| Investment in College Place Joint Venture | 1,608,629 |
| Development costs | 431,249 |
| Property and Equipment | 857,702 |
| | 2,897,580 |
| **Total Assets** | **10,103,577** |
| **LIABILITIES AND NET ASSETS** | |
| **Liabilities** | |
| **Current** | |
| Payables and Accruals | 972,874 |
| Deferred Revenue | 2,863,384 |
| Deferred Contributions | 191,185 |
| | 4,027,444 |
| Capital lease obligations | 56,334 |
| **Total Liabilities** | **4,083,778** |
| **Net Assets** | |
| Unrestricted Fund | 3,060,757 |
| Reserves - Capital Assets and Bldg | 500,000 |
| Reserves - Joint Venture | 500,000 |
| Reserves - Automation | 750,000 |
| Reserves - Legal | 750,000 |
| Reserves - Grants | 500,000 |
| Reserves - Operating | 1,500,000 |
| Retained Earnings | (1,540,958) |
| **Total Net Assets** | 6,019,799 |
| **Total Liabilities and Net Assets** | **10,103,577** |

**College of Pharmacists of BC**
**Statement of Revenue and Expenses**
**For the 11 months ended January 31, 2017**

| | Budget YTD Jan 2017 | Actual YTD Jan 2017 | Variance (Budget vs. Actual) $ | Variance (Budget vs. Actual) % |
|---|---|---|---|---|
| **Revenue** | | | | |
| **Licensure revenue** | 5,273,442 | 5,162,600 | (110,842) | (2%) |
| **Non-licensure revenue** | 2,176,153 | 2,128,831 | (47,321) | (2%) |
| **Transfer from Balance Sheet** | 1,990,279 | 1,712,055 | (278,224) | (14%) |
| **Total Revenue** | **9,439,874** | **9,003,486** | **(436,387)** | (5%) |
| **Total Expenses Excluding Amortization** | 9,062,091 | 8,499,664 | 562,427 | 6% |
| **Deficiency of revenue over expenses before amortization expenses** | **377,783** | **503,822** | **126,039** | 33% |
| **Amortization** | 377,783 | 332,725 | 45,058 | 12% |
| **Total Expenses Including Amortization** | **9,439,874** | **8,832,390** | **607,485** | 6% |
| **Surplus of Revenue over Expenses** | **(0)** | **171,097** | **171,097** | |

**College of Pharmacists of BC**
**Statement of Revenue**
**For the 11 months ended January 31, 2017**

| | Budget YTD Jan 2017 | Actual YTD Jan 2017 | Variance (Budget vs. Actual) $ | Variance (Budget vs. Actual) % |
|---|---|---|---|---|
| **Revenue** | | | | |
| **Licensure revenue** | | | | |
| Pharmacy fees | 1,699,861 | 1,684,376 | (15,485) | (1%) |
| Pharmacists fees | 3,048,884 | 2,974,996 | (73,888) | (2%) |
| Technician fees | 524,697 | 503,228 | (21,469) | (4%) |
| | **5,273,442** | **5,162,600** | **(110,842)** | **(2%)** |
| **Non-licensure revenue** | | | | |
| Other revenue | 1,586,177 | 1,612,279 | 26,102 | 2% |
| Grant Revenue | 215,635 | 143,750 | (71,885) | (33%) |
| Investment income | 145,174 | 145,524 | 350 | 0% |
| College Place joint venture income | 229,167 | 227,278 | (1,889) | (1%) |
| | **2,176,153** | **2,128,831** | **(47,321)** | **(2%)** |
| **Transfer from Balance Sheet** | **1,990,279** | **1,712,055** | **(278,224)** | **(14%)** |
| **Total Revenue** | **9,439,874** | **9,003,486** | **(436,387)** | **(5%)** |

**College of Pharmacists of BC**
**Statement of Expenses**
**For the 11 months ended January 31, 2017**

| | Budget YTD Jan 2017 | Actual YTD Jan 2017 | Variance (Budget vs. Actual) $ | Variance (Budget vs. Actual) % |
|---|---|---|---|---|
| **Expenses** | | | | |
| Board and Registrar's Office | 541,398 | 514,299 | 27,099 | 5% |
| Finance and Administration | 1,431,949 | 1,665,106 | (233,157) | (16%) |
| Grant Distribution | 406,301 | 225,567 | 180,734 | 44% |
| Registration, Licensure and Pharmanet | 237,420 | 274,938 | (37,518) | (16%) |
| Quality Assurance | 538,047 | 448,007 | 90,039 | 17% |
| Practice Reviews | 270,646 | 123,281 | 147,364 | 54% |
| Complaints Resolution | 348,729 | 334,123 | 14,606 | 4% |
| Policy and Legislation | 157,850 | 181,152 | (23,302) | (15%) |
| Public Engagement | 421,355 | 204,756 | 216,599 | 51% |
| Salaries and Benefits | 4,708,397 | 4,528,436 | 179,961 | 4% |
| **Total Expenses Excluding Amortization** | **9,062,091** | **8,499,664** | **562,427** | **6%** |
| **Amortization** | **377,783** | **332,725** | **45,058** | **12%** |
| **Total Expenses** | **9,439,874** | **8,832,390** | **607,485** | **6%** |

College of Pharmacists of British Columbia

# BOARD MEETING
# April 21, 2017

**2.b.viii. Governance Committee**
**a) Committee Member Appointments**

## DECISION REQUIRED

### Recommended Board Motion:

*Approve committee member appointments for terms beginning May 1, 2017, as circulated.*

### Purpose
To appoint new members, and to re-appoint existing members to College Committees.

### Background
The College committees are a vital resource to the Board that provide essential advice, expertise, and recommendations that ultimately inform Board policies and decisions. Every year, current members that are eligible for re-appointment, based on the committee's terms of reference, are asked if they would like to be considered for re-appointment. In addition, the College issues a call for applications from pharmacists, pharmacy technicians and the public. This year, interested candidates were required to submit a current resume in addition to completing the standard committee member volunteer application in order to be considered for placement on a College committee. Applications and resumes were reviewed and a slate was recommended for consideration by the Governance Committee. The following factors were considered in developing the list:

- Composition requirements from terms of reference
- Type of practice (community/hospital/others)
- Previous/type of volunteer experience
- Geographic area of practice
- Specialty areas of practice
- Relevant education
- Technician and pharmacist balance
- Continuing and new member balance

After review of the recommended slate, the Governance Committee recommends approval by the Board of the attached committee member appointments for terms beginning May 1, 2017.

| Appendix | |
|---|---|
| 1 | 2017 Committee Appointments |

**AUDIT AND FINANCE COMMITTEE**

| Name | Type | Term | Term Length (Yrs) | |
|---|---|---|---|---|
| Mary O'Callaghan | Staff | | | |
| George Walton | Chair/Public Board | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Mona Kwong | Vice-Chair/Pharmacist Board | Thru to November 16, 2017 | n/a | n/a |
| Norman Embree | Public Board | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Anar Dossa | Pharmacist Board | Thru to November 16, 2017 | n/a | n/a |

**COMMUNITY PHARMACY ADVISORY COMMITTEE**

| Name | Type | Term | Term Length (Yrs) | |
|---|---|---|---|---|
| Ashifa Keshavji | Staff | | | |
| Tara Oxford | Chair/Pharmacist Board | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Fady Moussa | Vice-Chair/Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Mohinder Jaswal | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Aaron Sihota | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Elijah Ssemaluulu | Pharmacist | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| Cindy Zhang | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Dana Elliott | Pharmacy Technician | May 1, 2017 – April 30, 2020 | 3 | NEW |

**DISCIPLINE COMMITTEE**

| Name | Type | Term | Term Length (Yrs) | |
|---|---|---|---|---|
| David Pavan | Staff | | | |
| Jeremy Walden | Chair/Public Board | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| Christopher Kooner | Pharmacist | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| Derek Lee | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Annette Robinson | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Amparo Yen | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Suzanne Coughtry | Pharmacy Technician | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Baldeep Dhillon | Pharmacy Technician | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Anneke Driessen | Public | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| James Ellsworth | Public | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| Nerys Hughes | Public | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Howard Kushner | Public | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Leza Muir | Public | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Carol Williams | Public | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| Heather Baxter | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | NEW |
| Peter Lam | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | NEW |
| Omar Saad | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | NEW |
| Sophie Sanfacon | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | NEW |
| Gurinder Saran | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | NEW |
| Rapinder Chahal | Pharmacy Technician | May 1, 2017 – April 30, 2020 | 3 | NEW |

Note: Vice-Chair to be determined

**DRUG ADMINISTRATION COMMITTEE**

| Name | Type | Term | Term Length (Yrs) | |
|---|---|---|---|---|
| Doreen Leong | Staff | | | |
| Cameron Zaremba | Chair/Pharmacist | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| Omar Alasaly | Vice-Chair/Pharmacist | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| Jagpaul Deol | Pharmacist | May 1, 2017 – April 30, 2019 | 2 | Re-appointment |
| Aileen Mira | Pharmacist | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| Elizabeth Brodkin | Public | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| Mitch Moneo | Public | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| Chris Salgado | Public | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |

**ETHICS ADVISORY COMMITTEE**

| Name | Type | Term | Term Length (Yrs) | |
|---|---|---|---|---|
| David Pavan | Staff | | | |
| Sorell Wellon | Chair/Pharmacy Technician Board | May 1, 2017 – April 30, 2020 | 3 | NEW |
| Cristina Alarcon | Vice-Chair/Pharmacist | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| Shivinder Badyal | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Tara Lecavalier | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Jing-Yi Ng | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Robyn Miyata | Pharmacy Technician | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| Vanessa Lee | Pharmacy Technician | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Alison Dempsey | Public | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Patricia Gerber | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | NEW |
| Robson Liu | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | NEW |
| Jamie Graham | Public | May 1, 2017 – April 30, 2020 | 3 | NEW |

**GOVERNANCE COMMITTEE**

| Name | Type | Term | Term Length (Yrs) | |
|---|---|---|---|---|
| David Pavan | Staff | | | |
| Norman Embree | Chair/Public Board | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Mona Kwong | Vice-Chair/Pharmacist Board | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| George Walton | Public Board | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Sorell Wellon | Pharmacy Technician Board | May 1, 2017 – April 30, 2020 | 3 | NEW |

**HOSPITAL PHARMACY ADVISORY COMMITTEE**

| Name | Type | Term | Term Length (Yrs) | |
|---|---|---|---|---|
| Ashifa Keshavji | Staff | | | |
| Arden Barry | Chair/Pharmacist Board | May 1, 2017 – April 30, 2020 | 3 | NEW |
| Elissa Aeng | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Lily Cheng | Pharmacist | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| Anca Cvaci | Pharmacist | May 1, 2017 – April 30, 2019 | 2 | Re-appointment |
| Karen Dahri | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Ashley Fairfield | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Karen LaPointe | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Fruzsina Pataky | Pharmacist | May 1, 2017 – April 30, 2019 | 2 | Re-appointment |
| Jennifer Dunkin | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Aleisha Enemark | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Aita Munroe | Pharmacy Technician | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Kristoffer Scott | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | NEW |
| Rapinder Chahal | Pharmacy Technician | May 1, 2017 – April 30, 2020 | 3 | NEW |

Note: Vice-Chair to be determined

**INQUIRY**

| Name | Type | Term | Term Length (Yrs) | |
|---|---|---|---|---|
| David Pavan | Staff | | | |
| Wui Ming Chang | Chair/Pharmacist Board | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| John Hope | Vice-Chair/Pharmacist | May 1, 2017 – April 30, 2019 | 2 | Re-appointment |
| Carla Ambrosini | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Sally Chai | Pharmacist | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| Sunny Gidda | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Susan Troesch | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Cynthia Widder | Pharmacist | May 1, 2017 – April 30, 2019 | 2 | Re-appointment |
| Karen Callaway | Pharmacy Technician | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| Alana Ridgeley | Pharmacy Technician | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Dorothy Barkley | Public | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| Michael Dunbar | Public | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Norman Embree | Public Board | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| George Kamensek | Public | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| Tricia Kean | Public | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| James Mercer | Public | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Alison Rhodes | Public | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Ann Wicks | Public | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Joy Bhimji | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | NEW |
| Kristoffer Scott | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | NEW |
| Fatima Ladha | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | NEW |
| Janice Munroe | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | NEW |
| Dinah Purewal | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | NEW |
| Joyce Wong | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | NEW |
| Marco Yeung | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | NEW |

**JURISPRUDENCE EXAM SUBCOMMITTEE**

| Name | Type | Term | Term Length (Yrs) | |
|---|---|---|---|---|
| Doreen Leong | Staff | | | |
| Christopher Szeman | Chair/Pharmacist Board | May 1, 2017 – April 30, 2020 | 3 | NEW |
| Roberta Walker | Vice-Chair/Pharmacy Technician | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| Melanie Johnson | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Anthony Seet | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Asal Taheri | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| David Wang | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Kent Ling | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | NEW |
| Ali Meghji | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | NEW |
| Angel Cao | Pharmacy Technician | May 1, 2017 – April 30, 2020 | 3 | NEW |

**LEGISLATION REVIEW COMMITTEE**

| Name | Type | Term | Term Length (Yrs) | |
|---|---|---|---|---|
| Christine Paramonczyk | Staff | | | |
| Jeremy Walden | Chair/Public Board | May 1, 2017 – April 30, 2019 | 2 | Re-appointment |
| Mona Kwong | Pharmacist Board | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Sorell Wellon | Pharmacy Technician Board | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Chris Szeman | Pharmacist Board | May 1, 2017 – April 30, 2020 | 3 | NEW |

**PRACTICE REVIEW**

| Name | Type | Term | Term Length (Yrs) | |
|---|---|---|---|---|
| Ashifa Keshavji | Staff | | | |
| Kris Gustavson | Chair/Public Board | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Michael Ortynsky | Vice-Chair/Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Fady Moussa | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Perry Tompkins | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Patrick Chai | Pharmacy Technician | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Aleisha Enemark | Pharmacy Technician | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Helen Singh | Pharmacy Technician | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Kate Cockerill | Public | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Joanne Konnert | Public | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Alison Rhodes | Public | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Marilyn Chadwick | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | NEW |

**QUALITY ASSURANCE**

| Name | Type | Term | Term Length (Yrs) | |
|---|---|---|---|---|
| Ashifa Keshavji | Staff | | | |
| Frank Lucarelli | Chair/Pharmacist Board | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Gary Jung | Vice-Chair/Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Hani Al-Tabbaa | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Sunny Gidda | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Dorothy Zahn | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Baldeep Dhillon | Pharmacy Technician | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Tessa Cheng | Public | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Norman Embree | Public Board | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Rebecca Siah | Public | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |

**RESIDENTIAL CARE ADVISORY COMMITTEE**

| Name | Type | Term | Term Length (Yrs) | |
|---|---|---|---|---|
| Ashifa Keshavji | Staff | | | |
| Sorell Wellon | Chair/Pharmacy Technician Board | May 1, 2017 – April 30, 2020 | 3 | NEW |
| Wui Ming Chang | Pharmacist Board | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Joyce Quon | Pharmacist | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| Alvin Singh | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Ivana Vojvodic | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | NEW |
| Aaron Tejani | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | NEW |
| Lanai Vek | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | NEW |

**REGISTRATION**

| Name | Type | Term | Term Length (Yrs) | |
|---|---|---|---|---|
| Doreen Leong | Staff | | | |
| Jeremy Walden | Chair/Public Board | May 1, 2017 – April 30, 2019 | 2 | Re-appointment |
| Phuong Hoang | Vice-Chair/Pharmacist | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| Carolyn Cheung | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Derek Lee | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Charles Park | Pharmacist | May 1, 2017 – April 30, 2019 | 2 | Re-appointment |
| Ashley Foreman | Pharmacy Technician | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| Vanessa Lee | Pharmacy Technician | May 1, 2017 – April 30, 2020 | 3 | Re-appointment |
| Laura Bickerton | Public | May 1, 2017 – April 30, 2019 | 2 | Re-appointment |
| Nathan Roeters | Public | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| Joy Sisson | Public | May 1, 2017 – April 30, 2018 | 1 | Re-appointment |
| Michelle Ho Chung | Pharmacist | May 1, 2017 – April 30, 2020 | 3 | NEW |
| Dana Elliott | Pharmacy Technician | May 1, 2017 – April 30, 2020 | 3 | NEW |

College of Pharmacists of British Columbia

# BOARD MEETING
# April 21, 2017

## ix. Practice Review Committee Update

## INFORMATION ONLY

### Purpose

To provide the Board with an update on the Practice Review Program (PRP).

**Business Stream:**

| Update | Next Steps |
|---|---|
| Phase 1 – Community Practice<br>• Conducted February and March reviews (Appendix 1)<br>• Scheduled pharmacies for April and May reviews<br>• Drafting PRP data report<br>• PRC approval of new focus areas for Pharmacy Technicians<br>  o Drafting new review form | Phase 1 – Community Practice<br>• Schedule pharmacies for June 2017 reviews<br>• Finalize PRP data report<br>• Board approval of new focus areas and review form for Pharmacy Technicians<br>• Develop Release 2 of Phase 1: Residential Care, packaging, compounding and other ancillary forms (contingent on resources) |
| Phase 2 – Hospital Practice<br>• Finalized review tool for Compliance Officers (excel database)<br>• First onsite review took place on April 3rd, 2017<br>• Scheduled pharmacies for May and June 2017 reviews | Phase 2 – Hospital Practice<br>• Schedule pharmacies for July 2017 reviews<br>• Monitor Risk Register which identifies and tracks implementation issues |

College of Pharmacists of British Columbia

# BOARD MEETING
# April 21, 2017

**Communications / Stakeholder Stream:**

| Update | Next Steps |
|---|---|
| General<br>• Finalized and posted new PRP video | General |
| Phase 1 – Community Practice<br>• New PRP Insights articles posted (Appendix 2)<br>• Posted registrant support tools for preparation and remediation | Phase 1 – Community Practice<br>• Continue to draft monthly PRP Insights articles based on findings from reviews |
| Phase 2 – Hospital Practice<br>• Posted resources for pharmacy managers and registrants prior to launch | Phase 2 – Hospital Practice<br>• Begin drafting PRP Insights articles |

**Legislation Stream:**

| Update | Next Steps |
|---|---|
| General<br>• Phase 1 review forms amended to reflect new legislation (security bylaws)<br>o In force as of April 21st, 2017<br>• Provided feedback on legislation based on findings from reviews | General<br>• Continue to provide feedback on legislation based on findings from reviews |

**Enforcement Stream:**

| Update | Next Steps |
|---|---|
| General<br>• Sharing PRP Information as needed<br>• Working with Complaints Resolution team to review selected pharmacies (to prevent overlap) | General<br>• Continue to share PRP information as needed<br>• Continue to work with Complaints Resolution team to review selected pharmacies (to prevent overlap) |

College of Pharmacists of British Columbia

# BOARD MEETING
# April 21, 2017

**IT Stream:**

| Update | Next Steps |
|---|---|
| Phase 1 – Community Practice<br>• Ongoing application enhancements<br>o Made changes to the Action Item Follow Up module based on registrant feedback | Phase 1 – Community Practice<br>• Continue with application enhancements<br>• Build reports for administrative use |
| Phase 2 – Hospital Practice<br>• Provide support as needed | Phase 2 – Hospital Practice<br>• Provide support as needed |

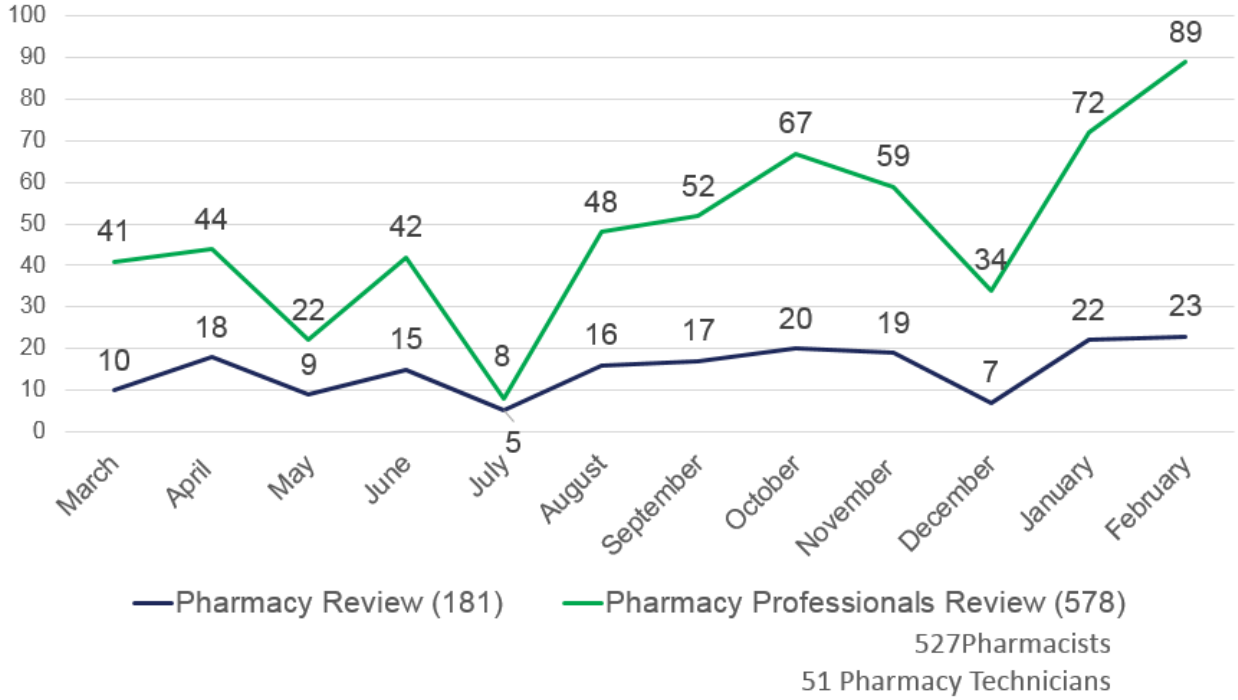
| Appendix | |
|---|---|
| 1 | Phase 1 – Operational Statistics |
| 2 | Phase 1 – Insights Articles for Readlinks |

**Appendix 1**

**PRP Phase 1: Community Practice Operational Statistics**

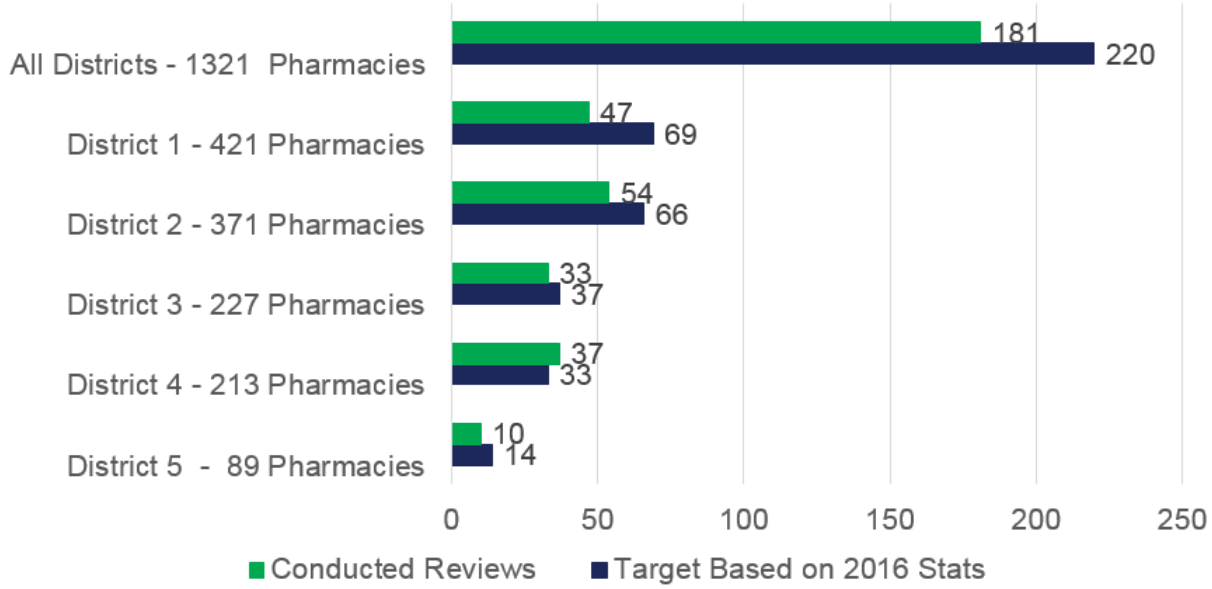
2016-17 Fiscal Year Progress: March 1st, 2016 – February 28th, 2017

Conducted Pharmacy Reviews and Pharmacy Professionals Reviews




2016-17 Fiscal Year Progress: March 1st, 2016 – February 28th, 2017

Conducted Pharmacy Reviews by District



**PRP Phase 1: Community Practice Insights Articles**

**New Article:** March 2017 Compliance Officers on their personal approach to practice reviews


# COMPLIANCE OFFICERS TALK ABOUT THEIR PERSONAL APPROACH TO PRACTICE REVIEWS

Practice reviews are conducted by the College's Compliance Officers, employed for their expertise in various areas of pharmacy practice. Compliance Officers are there to work with you and your colleagues to ensure the highest quality pharmacy service is being provided to patients.

Each Compliance Officer has his/her own personal approach to the review process and philosophy on how to work with pharmacy professionals while conducting a review. While a Practice Review should never be a cause for undue stress or concern, having a better idea of what to expect can help you and your staff prepare for assessment.

Practice Reviews are not disciplinary. Compliance Officers use industry experience, clear requirements and their own personal philosophy to work with registrants on practice reviews to ensure the consistent delivery of pharmacy services across BC.

We spoke to some of our Compliance Officers to gain some insight into their own approach to conducting a practice review to give you a better idea of what to expect.

*I like to observe and be as unobtrusive as possible. I've always worked in busy pharmacies and know how stressful it can get, so I try not to let my presence add to that stress. At the same time, I like to be there for the registrants and be able to answer any questions or give practical tips on how to implement policies and procedures that work with their practice.*

– MARK CHAN

*In order to make the most of the practice review, I encourage registrants to practice as they usually would on any other day. As it is not a pass/fail program, my goal is to observe and provide useful feedback that would be applicable to your usual day-to-day practice. My approach to reviews is as a peer and a collaborator. Having gone through my own practice review a couple of years ago, I know it can be a stressful situation and I hope to make registrants feel at ease during my visits. While I am on site, I encourage registrants to approach me with any questions or concerns they may have and discussions regarding any aspect of the review are welcomed.*

– MONICA CHENG

*I prefer to approach the professionals' review from an educational perspective. I believe strongly that the best way to fulfill our College regulatory mandate is by working closely with each registrant to ensure that they are aware of legislated requirements, and have the knowledge and tools to ensure that hey work within these guidelines to ensure safe and efficient service to the public.*

– DWAIN NOTTEBROCK

*The first point I always try to emphasize is that there is no passing (or failing) mark on this whole review process and that it is not meant to be punitive. To me, the overall intent of the program is to ensure the delivery of safe and effective pharmaceutical care to the general public and in order to do so, pharmacy professionals needs to be held accountable to a minimum standard of care which is outlined the respective bylaws.*

*With that in mind, I conduct my reviews in two general phases: an initial assessment and then a subsequent discussion. On the pharmacy review, if non-compliances are noted, it is up to the pharmacy manager to decide how to implement his or her action plan. On the professionals review, I try to encourage registrants to practice 'normally' because then it allows myself as an assessor to observe what their day-to-day practice is like. If there are aspects of practice that are different than current legislative expectations, then it provides a platform to potentially discuss change and move pharmacy practice forward.*

– JOHN THAI

LEARN MORE ABOUT THE PRACTICE REVIEW PROGRAM AND HOW TO PREPARE FOR A REVIEW AT

**BCPHARMACISTS.ORG/PRP**

**New Article:** [February 2017 Meet our Compliance Officers]


# MEET OUR COMPLIANCE OFFICERS

In 2015, the College of Pharmacists of BC introduced the Practice Review Program in order to conduct in-person reviews of a pharmacy professional's practice and the pharmacy where they work. The program's goal is to protect public safety by improving compliance with the College Bylaws and Professional Practice Policies and ensuring consistent delivery of pharmacy services across BC.

Practice Reviews are conducted by, registered pharmacy professionals known as **Compliance Officers**.

The College currently employs 8 Compliance Officers, all of whom have been chosen for their expertise in the various areas of pharmacy practice. Compliance Officers work with pharmacy professionals to help pharmacy professionals identify opportunities to improve their practice and ensure they provide quality pharmacy service to patients.

Take a moment to get to know our Compliance Officers...

**Mark Chan** graduated from UBC and started as a community pharmacist on Vancouver Island, working at various locations throughout Victoria. Since then, he's had the pleasure of being able to experience a variety of different practice settings by taking on the role of pharmacy manager at busy community pharmacies in Nanaimo, Surrey and West Vancouver. He's also worked as a Certified Diabetes Educator and a Practice Educator for UBC students, allowing him to balance managerial and administrative duties in a more clinical setting.

**Monica Cheng** is a UBC graduate and has been a registered pharmacist with the College of Pharmacists of BC since 2008. Prior to joining the PRP team as a Compliance Officer, she worked for several years as a community pharmacist and pharmacy manager in downtown Vancouver. During her time in community pharmacy, she also served as a practice educator for UBC students and international pharmacy graduates.

**Dwain Nottebrock** comes from a long line of healthcare professionals and has been interested in healthcare for as long as he can remember. He's a University of Saskatchewan graduate and has worked as a pharmacy manager at numerous community pharmacies. With a strong interest in alternative pharmacy services, Dwain has worked on the BC Medication Management Project (BCMMP) and been both anticoagulation and injection certified for many years.

**David Morhun** has 23 years of pharmacy, management, administration and IT experience. He's held numerous positions in Residential Care environments, Regional Health Authorities, Government and Retail (both corporate and independent). His strong IT background allows him to act as a liaison with many local, provincial and federal healthcare-related departments.

**James Van** was drawn to pharmacy because of the way it mixes patient interaction with the practice of health science. In addition to working as an Assistant Pharmacy Manager at numerous community pharmacies, James has held positions as a Certified Immunization Trainer; Assistant Editor for The Canadian Pharmacy Technician's Letter Publication and Clinical Lab Instructor at UBC's School of Pharmacy.

**Jonathan Lau** graduated from UBC Pharmacy in 2001. After completing his hospital residency in 2002, he worked as a clinical pharmacist and has since covered a number of different clinical areas including pediatrics, general medicine and outpatient oncology. Before joining the College as a Hospital Inspector in 2012, Jonathan worked as a Dispensary and Parenteral Services Supervisor at a hospital pharmacy.

**John Thai** has spent the majority of his pharmacy career working in the retail sector as a staff pharmacist or as relief coverage at various community pharmacies which included major chains as well as smaller independents. His experience gives him an intimate knowledge of most pharmacy software systems.

**Bethany Gamache** is a registered Pharmacy Technician. She received her Pharmacy Technician Certification in Kelowna in 2001 before starting her career in hospital pharmacy. In 2003 she moved to Vancouver where she worked as a hospital pharmacy technician before becoming an IV Orientation Leader, and assisting with the development of their IV training program. She joined the College as a Hospital Compliance Officer and Practice Review Coordinator in July 2015 and still works on a casual-basis as a Technician 2A at a hospital pharmacy in Vancouver.

LEARN MORE ABOUT THE PRACTICE REVIEW PROGRAM AND HOW TO PREPARE FOR A REVIEW AT

**BCPHARMACISTS.ORG/PRP**

**Previous Articles:**

**January 2017:** Managing Return-to-Stock Medications

**October 2016:** When Are CPP Forms Required for Residential Care Facilities, Hospices and Hospitals

**June 2016:** Privacy, Confidentiality and Security of Patient Health Information

**March 2016:** Expiry Dates of Compounding Materials and Products

**November 2015:** Signing Narcotic Records

**August 2015:** Policy and Procedure Manual

**June 2015**: Retaining Prescriptions

**March 2015:** Drug Product Distribution Requirements

College of Pharmacists of British Columbia

# BOARD MEETING
# April 21, 2017

## 2.b.x. Cannabis for Medical Purposes

## INFORMATION ONLY

I participated in a strategy session of the Council of Pharmacy Registrars of Canada (CPRC) on March 30th, 2017 to discuss the various considerations for pharmacy involvement with cannabis when used for medical purposes.

Registrars from all of the jurisdictions attended the meeting in Toronto. It was facilitated by an external facilitator. The meeting started with a panel presentation with Dr. Mark Ware, Member of the Task Force on Cannabis Legalization and Regulation, Dr. Phil Emberley, Director of Professional Affairs, CPhA, and Jenna Hall, Health Canada (by teleconference). They provided context and background to the current situation. Following the panel, the CPRC discussed evidence and therapeutics, professional practice and distribution issues surrounding the use of cannabis for medical purposes.

The challenges facing cannabis's medical use include the lack of pharmaceutical grade evidence to support its safe and effective use, as well as the lack of availability of a product that can meet the Canadian product standards. In addition, cannabis for recreational use is being considered and may be available by July 1st, 2018.

A position statement for consideration by the NAPRA Board was developed and will be taken to the Board on April 27th. This statement will serve as a basis for consideration of provincial Colleges.

Respectfully submitted,

Bob Nakagawa, B.Sc.(Pharm.), RPEBC, ACPR, FCSHP, R.Ph.
Registrar

College of Pharmacists of British Columbia

# Board Meeting

*Friday, April 21, 2017*

*CPBC Office, 200-1765 West 8th Avenue, Vancouver*

AGENDA

| | | | |
|---|---|---|---|
| **11:00am - 11:10am** | **1.** | Welcome & Call to Order | Chair Dossa |
| | **2.** | Consent Agenda<br>a) Items for further discussion<br>b) Approval of Consent Items | Chair Dossa |
| | **3.** | Confirmation of Agenda **[DECISION]** | Chair Dossa |
| **11:10am - 12:30pm** | **4.** | Legislation Review Committee:<br>a) HPA Bylaws - Filing (Application Committee) **[DECISION]**<br>b) Compounding - Implementation Plan **[DECISION]**<br>c) Fees and Forms<br>i) HPA - Filing (Fees) **[DECISION]**<br>ii) PODSA - Public Posting (Fees and Forms) **[DECISION]**<br>d) PODSA Bylaws - Public Posting (Telepharmacy) **[DECISION]** | Jeremy Walden |
| **12:30pm - 1:30pm** | | ***LUNCH*** | |
| | **4.1** | Registrar's Evaluation **[DECISION]** | Vice-Chair Kwong |
| **1:30pm - 1:50pm** | **5.** | Scope of PODSA Modernization - Phase 1 | Doreen Leong |
| **1:50pm - 2:10pm** | **6.** | Governance Committee:<br>a) Update<br>b) Committee Terms of Reference **[DECISION]** | Norm Embree |
| **2:10pm - 2:15pm** | **7.** | Items brought forward from Consent Agenda | |
| | | ***CLOSING COMMENTS, ROUND TABLE EVALUATION OF MEETING, AND ADJOURNMENT*** | |

College of Pharmacists of British Columbia

# a) HPA Bylaws – Filing (Application Committee)

College of Pharmacists of British Columbia

# Amendments to *Pharmacy Operations and Drug Scheduling Act* (PODSA)

**Background**

- On May 19, 2016 the amendments to PODSA were given Royal Assent.
- These amendments:
  - Apply to pharmacy ownership;
  - Allow the College to require information about pharmacy owners;
  - Allow the College determine their suitability for pharmacy ownership; and
  - Hold owners accountable for providing safe and effective care by ensuring their pharmacies are compliant with legislative requirements for pharmacies in BC.

College of Pharmacists of British Columbia

# New - Application Committee

**Establishing the Application Committee**

- **The amendments to PODSA include the definition of a new committee called, the Application Committee.**
- It will be responsible for:
  - Reviewing applications which do not meet the eligibility criteria;
  - Requesting additional information or evidence, if required;
  - Issuing a pharmacy licence with or without conditions; and
  - Refusing to issue, renew or reinstate a pharmacy licence.
- Bylaws under the ***Health Professions Act*** are needed to establish the committee and determine its composition.

College of Pharmacists of British Columbia

# Health Professions Act (HPA) Bylaws – Application Committee

**Composition of the Application Committee**

- Existing committees in the HPA were reviewed.
- The standard composition for existing committees has been applied to the Application Committee. This composition is:
  - Consists of at least 6 persons appointed by the board.
  - At least 1/3 of the committee must be public representatives, at least one of whom is an appointed board member.
- The proposed bylaws also allows the Application Committee to meet in panels.

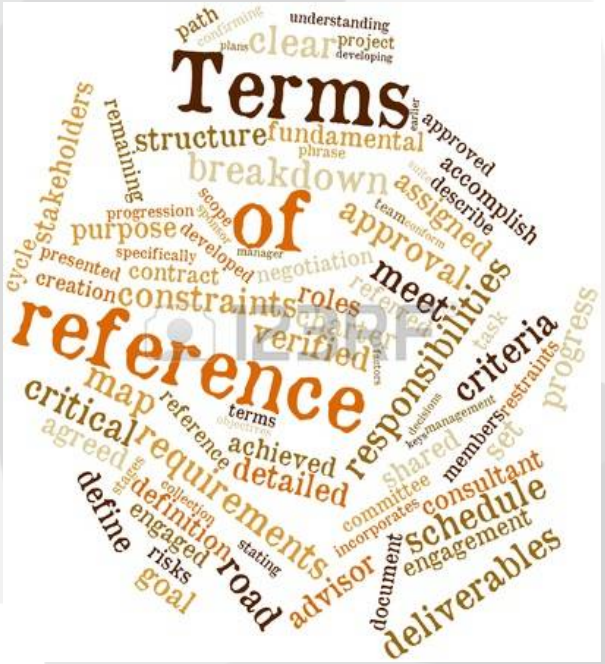
College of Pharmacists of British Columbia

# Public Posting – November 2016 to February 2017

- The Board approved these bylaws for public posting (90 days).
- The public posting period ended on February 16, 2017.
- No comments were received during this period.
- Therefore, no changes were made to the bylaws.

College of Pharmacists of British Columbia

# Terms of Reference for Application Committee




- The Terms of Reference of the Application Committee have been drafted to be aligned with the amendments to PODSA and the bylaws.

College of Pharmacists of British Columbia

# HPA Bylaws – Filing (Application Committee)

**MOTION 1:**

Approve the following resolution to amend the Health Professions Act Bylaws to establish the Application Committee:

*RESOLVED THAT, in accordance with the authority established in section 19(1) of the Health Professions Act, and subject to filing with the Minister as required by section 19(3) of the Health Professions Act, the board amend the bylaws of the College of Pharmacists of British Columbia, as set out in the schedule attached to this resolution.*

College of Pharmacists of British Columbia

# HPA Bylaws – Filing (Application Committee)

**MOTION 2:**

Approve the Terms of Reference of the Application Committee, as circulated.

College of Pharmacists of British Columbia

# BOARD MEETING
# April 21, 2017

## 4a. Legislation Review Committee
## Amendments to HPA bylaws – Application Committee

## DECISION REQUIRED

### Recommended Board Motion:

1) *Approve the following resolution to amend the Health Professions Act Bylaws to establish the Application Committee:*

*RESOLVED THAT, in accordance with the authority established in section 19(1) of the Health Professions Act, and subject to filing with the Minister as required by section 19(3) of the Health Professions Act, the board amend the bylaws of the College of Pharmacists of British Columbia, as set out in the schedule attached to this resolution.*

2) *Approve the Terms of Reference of the Application Committee, as circulated.*

### Purpose

To approve amendments to the *Health Professions Act* (HPA) bylaws, for filing with the Ministry of Health and to approve the Terms of Reference of the Application Committee, as circulated.

### Background

On May 19, 2016 amendments to the *Pharmacy Operations and Drug Scheduling Act* (PODSA) received Royal Assent[1]. The amendments to PODSA permit the College to know the identity of all pharmacy owners, determine their suitability for pharmacy ownership and hold them accountable for providing safe and effective care by ensuring their pharmacies are compliant with legislative requirements for pharmacies in British Columbia. [2]

[1] Pharmacy Operations and Drug Scheduling Amendment Act, 2016, https://www.leg.bc.ca/parliamentary-business/legislation-debates-proceedings/40th-parliament/5th-session/bills/progress-of-bills

[2] http://www.bcpharmacists.org/news/new-requirements-pharmacy-ownership-begin-march-1-2018

The PODSA amendments include the definition of a new committee called the Application Committee. Additionally, the amendments outline the powers and duties of that Committee. However, that Committee must be established and its composition must be determined in the HPA bylaws, in accordance with the bylaw making authority in section 19(1)(t) of the HPA. Accordingly, bylaws were drafted and at their November 2016 meeting, the Board approved publicly posting those proposed bylaws a for a ninety day period.

## Discussion

The proposed bylaws were subsequently posted for the ninety day public posting period on the College's website. The public posting period ended on February 16, 2017. No comments were received during this time; therefore, no further amendments are being proposed (see Appendix 1).

The Terms of Reference of the Application Committee (Appendix 2) have been drafted in accordance with the amendments to PODSA and the bylaws.

## Next Steps

As per section 19(3) of HPA, the next step in the process to finalize the bylaws, is that they must be filed with the Minister of Health. Once filed, the bylaws will come into effect sixty days from the filing request date to the Ministry of Health. If approved by the Board, the bylaw amendments will be in effect by mid-June 2017.

## Recommendation

The Board approve the amendments to the HPA bylaws (by approving the schedule to the resolution in Appendix 3), that establish and determine the composition of the Application Committee, for filing with the Ministry of Health. Additionally, to approve the Terms of Reference of the Application Committee, as circulated.

| **Appendix** | |
|---|---|
| 1 | HPA Bylaws Application Committee (track changes) |
| 2 | Terms of Reference of the Application Committee |
| 3 | Schedule to the Resolution |

## *Health Professions Act* – BYLAWS

### Table of Contents

11. Application for Reinstatement
12. Order to Attend a Discipline Committee Hearing
13. Application for Certification – Drug Administration

## Definitions

1. In these bylaws:

**"*Act*"** means the *Health Professions Act*;

**"appointed board member"** means

(a) a person appointed to the board under section 17(3)(b) of the *Act,* or

(b) prior to the first election referred to in section 17(2)(a) of the *Act*, a person appointed under section 17(2)(a) of the *Act* to represent the public on the first board;

**"ballot"** means an electronic ballot;

**"board"** means the board of the college;

**"board member"** means an appointed board member or an elected board member;

**"chair"** means the chair of the board elected under section 12;

**"child-resistant package"** means a package that complies with the requirements of the Canadian Standards Association Standard CAN/CSA-Z76.1-06, published in 2006 as amended from time to time;

**"controlled drug substance"** means a drug which includes a controlled substance listed in Schedule I, II, III, IV or V of the *Controlled Drugs and Substances Act* (Canada);

**"college"** means the College of Pharmacists of British Columbia continued under section 15.1(4) of the *Act*;

**"deliver"** with reference to a notice or other document, includes mail by post or electronically to, or leave with a person, or deposit in a person's mailbox or receptacle at the person's residence or place of business;

**"director"** has the same meaning as in section 1 of the *Pharmacy Operations and Drug Scheduling Act*;

**"dispense"** has the same meaning as in section 1 of the *Pharmacy Operations and Drug Scheduling Act;*

**"drug"** has the same meaning as in section 1 of the *Pharmacy*

*Operations and Drug Scheduling Act*;

**"elected board member"** means a full pharmacist board member or a pharmacy technician board member;

**"examination"** means an examination, given orally or in writing, or a practical examination, or any combination of these, and includes a supplemental examination;

**"full pharmacist"** means a member of the college who is registered in the class of registrants established in section 41(a);

**"full pharmacist board member"** means

(a) a full pharmacist elected to the board under section 17(3)(a) of the *Act* or appointed to the board under section 10, or

(b) prior to the first election referred to in section 17(2)(a) of the *Act*, a person appointed under section 17(2)(a) of the *Act* to represent the health profession on the first board;

**"hospital"** has the same meaning as in section 1 of the *Hospital Act*;

**"in good standing"** in respect of a registrant means

(a) the registration of the registrant is not suspended under the *Act*, and

(b) no limits or conditions are imposed on the registrant's practice of pharmacy under section 20(2.1), 20(3), 32.2, 32.3, 33, 35, 36, 37.1, 38, 39, or 39.1 of the *Act*;

**"limited pharmacist"** means a member of the college who is registered in the class of registrants established in section 41(b);

**"manager"** has the same meaning as in section 1 of the *Pharmacy Operations and Drug Scheduling Act*;

**"medication"** has the same meaning as "drug";

**"non-practising pharmacist"** means a member of the college who is registered in the class of registrants established in section 41(f);

**"owner"** has the same meaning as in section 1 of the *Pharmacy Operations and Drug Scheduling Act*;

**"personal information"** means "personal information" as defined in Schedule 1 of the *Freedom of Information and Protection of Privacy Act*;

**"pharmacy assistant"** has the same meaning as "support person" in section 1 of the *Pharmacy Operations and Drug Scheduling Act*;

**"pharmacy services"** means the services a registrant is authorized under the *Act* to provide;

**"pharmacy technician"** means a member of the college who is

registered in the class of registrants established in section 41(e);

**"pharmacy technician board member"** means a pharmacy technician elected to the board under section 17(3)(a) of the *Act* or appointed to the board under section 10;

**"practising pharmacist"** means a full pharmacist, limited pharmacist, temporary pharmacist or student pharmacist;

**"practitioner"** has the same meaning as in section 1 of the *Pharmacy Operations and Drug Scheduling Act*;

**"prescription"** has the same meaning as in section 1 of the *Pharmacy Operations and Drug Scheduling Act*;

**"public representative"** means a person who

(a) is not a registrant or former registrant, and

(b) has no close family or business relationship with a registrant or former registrant,

and includes an appointed board member;

**"quality assurance assessor"** means an assessor appointed under section 26.1(4) of the *Act*;

**"record"** means a "record" as defined in Schedule 1 of the *Freedom of Information and Protection of Privacy Act*;

**"Regulation"** means the Pharmacists Regulation, B.C. Reg. 417/2008;

**"student pharmacist"** means a member of the college who is registered in the class of registrants established in section 41(d);

**"temporary pharmacist"** means a member of the college who is registered in the class of registrants established in section 41(c);

**"vice-chair"** means the vice-chair of the board elected under section 12 of the *Act*.

## PART I – College Board, Committees and Panels
## Composition of Board

2. The board consists of

(a) 7 full pharmacist board members,

(b) 1 pharmacy technician board member, and

(c) the appointed board members.

## Composition of the Board – Transitional

2.1 Despite section 2, until the start of the November 2010 board meeting, the board consists of

(a) 7 full pharmacist board members, and

(b) the appointed board members

**Electoral Districts**

3. (1) For the purpose of elections of full pharmacist board members under section 17(3)(a) of the *Act*, electoral districts are established as follows:

(a) the province of British Columbia is divided into 7 electoral districts, the boundaries of which are set out in Schedule "B";

(b) the number of full pharmacist board members elected from each electoral district is 1;

(c) electoral district boundaries described in paragraph (a) may be changed only by special resolution amending Schedule "B";

(d) a full pharmacist who has only 1 place of practice which is not a hospital must be assigned to an electoral district from among Districts 1 to 5, according to the location of the full pharmacist's place of practice;

(e) a full pharmacist who has only 1 place of practice which is a hospital must be assigned to District 6 or 7, according to the location of the hospital;

(f) a full pharmacist who practices in more than 1 electoral district must be assigned to the electoral district in which the full pharmacist's primary place of practice is located;

(g) a full pharmacist who does not practice must be assigned to the electoral district within which he or she resides.

(2) For the purpose of election of pharmacy technician board members under section 17(3)(a) of the *Act*, the electoral district is the province of British Columbia.

**Notice of Election**

4. (1) An election under section 17(3)(a) of the *Act* must be held in each calendar year, by electronic means approved by the registrar, at a date determined by the registrar that is at least 21 days prior to the date of the November board meeting in that year.

(2) The registrar must deliver a notice of election in Form 1 to every full pharmacist and pharmacy technician assigned to the electoral districts which are to elect board members in the election, at least 60 days prior to the election date.

(3) The accidental omission to deliver notice of an election to, or the non-receipt of such a notice, by any person entitled to receive notice does not invalidate the election, any proceedings in relation thereto, or the results thereof.

**Eligibility and Nominations**

5. (1) To be eligible for election to the board under section 17(3)(a) of the *Act*, a registrant must be

(a) a full pharmacist or pharmacy technician,

(b) in good standing, and

(c) assigned to the electoral district in which he or she is nominated.

(2) A full pharmacist or pharmacy technician is not eligible to be elected to the board if he or she is employed by the college or is engaged in a contract or assignment providing goods or services to the college.

(3) A nomination for a full pharmacist board member must be endorsed by 3 full pharmacists who are in good standing and are assigned to the electoral district in which the nominee is standing for election.

(4) A nomination for a pharmacy technician board member must be endorsed by 3 pharmacy technicians who are in good standing.

(5) A nomination must be delivered to the registrar at least 45 days prior to the election date.

(6) A nomination must be in Form 2.

**Election Procedure**

6. (1) If there is only 1 nominee for a vacant position at the close of nominations, the nominee for that position is elected by acclamation.

(2) Only full pharmacists and pharmacy technicians, who are in good standing, are eligible to vote in an election under section 17(3)(a) of the *Act.*

(3) A full pharmacist or pharmacy technician eligible to vote under subsection (2) is eligible to vote only in the electoral district to which he or she is assigned for an election.

(4) The registrar must deliver to each full pharmacist and pharmacy technician who is eligible to vote the instructions for voting electronically in the election at least 30 days prior to the election date.

(5) Each full pharmacist and pharmacy technician who is eligible to vote is entitled to 1 ballot and may vote in favour of 1 candidate for the

vacant position.

(6) A ballot does not count unless it is cast no later than 5:00 p.m. Pacific Time on the election date.

(7) The candidate for a vacant position receiving the most votes on the return of the ballots is elected.

(8) In the case of a tie vote, the registrar must select the successful candidate by random draw.

(9) In the event that there are no nominees for a vacant position, the board may fill the vacant position in accordance with section 10.

(10) The registrar must supervise and administer all elections under section 17(3)(a) of the *Act* and may establish additional procedures consistent with these bylaws for that purpose.

(11) The registrar may determine any dispute or irregularity with respect to any nomination, ballot or election.

(12) The registrar must use Form 3 to certify newly elected members of the board under section 17.1(1) of the *Act*.

(13) If there is an interruption of electronic service during the nomination period or election, the registrar may extend the deadline for delivery of nominations or casting of ballots for such period of time as the registrar considers necessary in the circumstances.

**Terms of Office**

7. (1) The term of office for an elected board member is 2 years, commencing at the start of the November board meeting following that board member's election.

(2) An elected board member may serve a maximum of 3 consecutive terms.

(3) The terms of office of the elected board members from odd-numbered electoral districts must commence and end in odd-numbered years, and the terms of office of elected board members from even-numbered electoral districts must commence and end in even-numbered years.

(4) Subsections (1) to (3) do not apply prior to the first election referred to in section 17(2)(a) of the *Act*.

**Ceasing to Hold Office as a Board Member**

8. (1) An elected board member ceases to hold office if he or she

(a) ceases to be a full pharmacist or pharmacy technician, in good

standing,

(b) submits a written resignation to the chair,

(c) becomes an employee of the college or engaged in a contract or assignment providing goods or services to the college,

(d) is removed by a special resolution of the board, if notice of the proposal to remove the elected board member has been included with the notice of the board meeting, or

(e) is absent from 3 or more consecutive board meetings for reasons which the board finds unacceptable.

(2) Subsection (1) does not apply prior to the first election referred to in section 17(2)(a) of the *Act*.

**First Election and Terms of Office**

9. Despite section 7(1) and (3), the term of office for the first elected full pharmacist board members from Districts 2, 4 and 6 is 1 year, commencing at the start of the November 2009 board meeting.

**Vacancy**

10. (1) In the event of a vacancy in an elected board member position, the board may, by special resolution, appoint a full pharmacist or pharmacy technician, as applicable, eligible under section 5 for election to fill the position until the next election.

(2) Subsection (1) does not apply prior to the first election referred to in section 17(2)(a) of the *Act*.

**Remuneration of Board and Committee Members**

11. All board members and committee members are equally entitled to be

(a) remunerated for time spent on business of the college in the amount approved by the board from time to time, and

(b) reimbursed by the college for reasonable expenses necessarily incurred in connection with the business of the college.

**Chair and Vice-Chair**

12. (1) The chair must

(a) preside at all board meetings,

(b) sign certificates, diplomas and other instruments executed on behalf of the college as required, and

(c) act in accordance with the requirements of his or her office for the proper carrying out of the duties of the board.

(2) At the November board meeting in each calendar year, the board members must elect a chair by a majority vote in accordance with the following procedure:

(a) the acting chair for the meeting must call for nominations;

(b) if there is only 1 nominee, he or she is elected by acclamation;

(c) if there is more than 1 nominee, an election must be held by secret ballot, and the person with the most votes is elected;

(d) if there is a tie vote, there must be a second vote immediately following the first vote;

(e) if there is a second tie vote, the new chair must be selected by random draw.

(3) The chair's term of office as chair is 1 year, commencing at the election of the vice-chair under subsection (4), and ending at the start of the November board meeting in the next calendar year.

(4) Immediately following the election of the chair under subsection (2), the board members must elect a vice-chair by a majority vote in accordance with the procedure set out in subsection (2).

(5) The vice-chair's term of office as vice-chair is 1 year, commencing at his or her election under subsection (4), and ending at the start of the November board meeting in the next calendar year.

(6) The vice-chair must perform the duties of the chair in the chair's absence.

(7) In the absence of both the chair and the vice-chair, an acting chair for a board meeting must be elected by a majority vote of the board members present.

(8) Despite subsections (2) to (5), the board members must elect a chair and vice-chair in accordance with the procedure set out in subsection (2), each to serve a term ending at the start of the November 2009 board meeting.

**Board Meetings**

13. (1) The board must meet at least 4 times in each calendar year, including one meeting in November, and must provide reasonable notice of board meetings to board members, registrants and the public.

(2) The accidental omission to deliver notice of a board meeting to, or the non-receipt of a notice by, any person entitled to receive notice does not invalidate proceedings at that meeting.

(3) Despite subsection (1), the chair or registrar may call a meeting of the board without providing notice to registrants or the public if necessary

to conduct urgent business.

(4) The registrar must call a board meeting at the request of the chair or any 3 board members.

(5) The registrar must provide the following to members of the public on request:

(a) details of the time and place of a board meeting;

(b) a copy of the agenda;

(c) a copy of the minutes of any preceding board meeting.

(6) Subject to subsection (7), board meetings must be open to registrants and the public.

(7) The board may exclude any person from any part of a board meeting if it is satisfied that

(a) financial, personal or other matters may be disclosed of such a nature that the desirability of avoiding public disclosure of them in the interest of any person affected or in the public interest outweighs the desirability of adhering to the principle that meetings be open to the public,

(b) a person involved in a criminal proceeding or civil suit or proceeding may be prejudiced,

(c) personnel matters or property acquisitions will be discussed,

(d) the contents of examinations will be discussed,

(e) communications with the Office of the Ombudsman will be discussed, or

(f) instructions will be given to or opinions received from legal counsel for the college, the board, or a committee.

(8) If the board excludes any person from a part of a board meeting, it must have its reasons for doing so noted in the minutes of the meeting.

(9) The registrar must ensure that minutes are taken at each board meeting and retained on file, and must publish them on the college website.

(10) A majority of the total number of board members constitutes a quorum.

(11) The chair is entitled to vote on all motions, and is also entitled to speak in debate, but not in preference to other board members.

(12) A written resolution signed by all board members is valid and binding

and of the same effect as if such resolution had been duly passed at a board meeting.

(13) In case of an equality of votes the chair does not have a casting or second vote in addition to the vote to which he or she is entitled as a board member and the proposed resolution does not pass.

(14) The board may meet and conduct business using video-conferencing or tele-conference connections or by other electronic means when some or all of the board members are unable to meet in person.

(15) Except as otherwise provided in the *Act*, the regulations, or these bylaws, the most recent edition of Robert's Rules of Order governs the procedures at meetings of the board.

**Registration Committee**

14. (1) The registration committee is established consisting of at least 6 persons appointed by the board.

(2) At least 1/3 of the registration committee must consist of public representatives, at least one of whom must be an appointed board member.

**Inquiry Committee**

15. (1) The inquiry committee is established consisting of at least 6 persons appointed by the board.

(2) At least 1/3 of the inquiry committee must consist of public representatives, at least one of whom must be an appointed board member.

**Practice Review Committee**

15.1 (1) The practice review committee is established consisting of at least 6 persons appointed by the board.

(2) At least 1/3 of the practice review committee must consist of public representatives, at least one of whom must be an appointed board member.

(3) The practice review committee is responsible for monitoring standards of practice to enhance the quality of practice and reduce incompetent, impaired or unethical practice amongst registrants.

(4) The practice review committee may receive reports made to the registrar, inquiry committee or discipline committee in respect of

(a) matters specified in section 17(1) of the *Pharmacy Operations and Drug Scheduling Act,* including without limitation reports under section 18 of that Act, and

(b) matters specified in section 28(1) of the *Health Professions Act*, including without limitation reports under section 28(3) of that Act.

(5) Upon receipt of a report described in subsection (4), the practice review committee may

(a) review the report, and

(b) as it considers appropriate in the circumstances, refer a matter arising from that review to the inquiry committee, quality assurance committee or registrar.

**Application Committee**

15.2 (1) The application committee within the meaning of section 1 of the *Pharmacy Operations and Drug Scheduling Act [SBC 2003] c.77* is established consisting of at least 6 persons appointed by the board.

(2) At least 1/3 of the application committee must consist of public representatives, at least one of whom must be an appointed board member.

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**Discipline Committee**

16. (1) The discipline committee is established consisting of at least 6 persons appointed by the board.

(2) At least 1/3 of the discipline committee must consist of public representatives, at least one of whom must be an appointed board member.

**Quality Assurance Committee**

17. (1) The quality assurance committee is established consisting of at least 6 persons appointed by the board.

(2) At least 1/3 of the quality assurance committee must consist of public representatives, at least one of whom must be an appointed board member.

**Drug Administration Committee**

18. (1) The drug administration committee is established consisting of at least 4 and no more than 7 persons appointed by the board.

(2) The committee must include

(a) one full pharmacist,

(b) one medical practitioner confirmed by the College of Physicians and Surgeons of British Columbia as suitable for membership

on the committee,

(c) one registered nurse confirmed by the College of Registered Nurses of British Columbia as suitable for membership on the committee, and

(d) one person nominated by the Ministry of Health Services.

(3) The drug administration committee

(a) must review, develop and recommend to the board standards, limits and conditions respecting the performance by practising pharmacists of restricted activities under section 4(1) (c.1) of the Regulation for the purposes of preventing diseases, disorders and conditions, and

(b) may

(i) review the role of practising pharmacists in regard to the performance of restricted activities under section 4(1) (c.1) of the Regulation, and

(ii) make recommendations to the board, for submission to the Ministry of Health Services, respecting the standards, limits and conditions for practice and any other requirements it considers necessary or appropriate to support the performance by practising pharmacists of restricted activities under section 4(1) (c.1) of the Regulation for the purposes of treating diseases, disorders and conditions.

(4) The committee may consult, as it considers necessary or appropriate, with registrants or other individuals who have expertise relevant to drug administration or on any other matter considered by the committee.

**Committees**

19. (1) A person appointed to a committee established under these bylaws

(a) serves for a term determined by the board not exceeding 2 years, and

(b) is eligible for reappointment but may not serve more than 3 consecutive terms.

(2) A committee member may be removed by a majority vote of the board.

(3) The board must appoint a committee chair and a committee vice-chair from among the members of the committee.

(4) Each committee must submit a report of its activities to the board

annually or as required by the board.

(5) The registrar is an ex officio non-voting member of the committees established under these bylaws.

(6) The chair is a non-voting ex-officio member of all committees, except in respect of a committee to which he or she has been appointed under these bylaws, in which case he or she has the right to vote.

**Committee Panels**

20. (1) The registration committee, inquiry committee, practice review committee, application committee, discipline committee and quality assurance committee may meet in panels of at least 3 but not more than 5 persons, and each panel must include at least 1/3 public representatives.

(2) The chair of a committee referred to in subsection (1) must appoint the members of a panel and must designate a chair of the panel.

(3) A panel of a committee referred to in subsection (1) may exercise any power or perform any duty of that committee.

**Meetings of a Committee or Panel**

21. (1) A majority of a committee constitutes a quorum.

(2) All members of a panel constitute a quorum.

**PART II – College Administration**
**Registrar/Deputy Registrar**

22. (1) The registrar is authorized to establish, by bylaw, forms for the purposes of the bylaws, and to require the use of such forms by registrants.

(2) If a deputy registrar is appointed by the board,

(a) the deputy registrar is authorized to perform all duties and exercise all powers of the registrar, subject to the direction of the registrar, and

(b) if the registrar is absent or unable to act for any reason, the deputy registrar is authorized to perform all duties and exercise all powers of the registrar.

**Seal**

23. (1) The board must approve a seal for the college.

(2) The seal of the college must be affixed, by those persons designated by the board, to the documents determined by the board.

**Fiscal Year**

24. The fiscal year of the college commences on March 1st and ends on the last day of February of the following year.

**Banking**

25. The board must establish and maintain such accounts with a chartered bank, trust company or credit union as the board determines to be necessary from time to time.

**Payments and Commitments**

26. The board must approve an operating and capital budget for each fiscal year, and may amend the approved budget from time to time.

**Investments**

27. The board may invest funds of the college in accordance with the board's investment policy which must be consistent with sections 15.1 and 15.2 of the *Trustee Act.*

**Auditor**

28. (1) The board must appoint a chartered accountant or a certified general accountant to be the auditor.

(2) The registrar must submit the financial statement to the auditor within 60 days of the end of the fiscal year.

(3) A copy of the auditor's report must be included in the annual report.

**Legal Counsel**

29. The board or, with the approval of the registrar, a committee or panel, may retain legal counsel for the purpose of assisting the board, a committee or a panel in exercising any power or performing any duty under the *Act*.

**General Meetings**

30. (1) General meetings of the college must be held in British Columbia at a time and place determined by the board.

(2) The first annual general meeting must be held before October 1, 2010, and after that an annual general meeting must be held at least once in every calendar year and not more than 20 months after the holding of the last preceding annual general meeting.

(3) The following matters must be considered at an annual general meeting:

(a) the financial statements of the college;

(b) the annual report of the board;

(c) the report of the auditor.

(4) Every general meeting, other than an annual general meeting, is an extraordinary general meeting.

(5) The board

(a) may convene an extraordinary general meeting by resolution of the board, and

(b) must convene an extraordinary general meeting within 60 days after receipt by the registrar of a request for such a meeting signed by at least ten percent of all full pharmacists and pharmacy technicians, who are in good standing.

**Notice of General Meetings**

31. (1) The registrar must deliver notice of an annual or extraordinary general meeting to every board member and registrant at least 21 days prior to the meeting.

(2) Notice of a general meeting must include

(a) the place, day and time of the meeting,

(b) the general nature of the business to be considered at the meeting,

(c) any resolutions proposed by the board, and

(d) any resolutions proposed under section 32 and delivered to the registrar prior to the mailing of the notice.

(3) The accidental omission to deliver notice of a general meeting to, or the non-receipt of a notice by, any person entitled to receive notice does not invalidate proceedings at that meeting.

(4) General meetings must be open to the public.

(5) The registrar must

(a) provide reasonable notice of each general meeting to the public, and

(b) provide to members of the public on request a copy of the notice given under subsection (1) in respect of the meeting.

**Resolutions**

32. Any 3 full pharmacists or pharmacy technicians, who are in good

standing, may deliver a written notice to the registrar at least 60 days prior to the date of an annual or an extraordinary general meeting requesting the introduction of a resolution.

**Voting at a General Meeting**

33. (1) A full pharmacist or pharmacy technician present at a general meeting is entitled to 1 vote at the meeting.

(2) In case of an equality of votes the chair of the general meeting does not have a casting or second vote in addition to the vote to which he or she is entitled as a full pharmacist or pharmacy technician, if any, and the proposed resolution does not pass.

(3) Except as these bylaws otherwise provide, the most recent edition of Robert's Rules of Order governs the procedures at an annual or extraordinary general meeting.

(4) A resolution passed at an annual or extraordinary general meeting is not binding on the board.

**Proceedings at General Meetings**

34. (1) Quorum is 25 registrants consisting of full pharmacists or pharmacy technicians, or both.

(2) No business, other than the adjournment or termination of the meeting, may be conducted at a general meeting at a time when a quorum is not present.

(3) If at any time during a general meeting there ceases to be a quorum present, business then in progress must be suspended until there is a quorum present.

(4) In the case of a general meeting other than an extraordinary general meeting under section 30(5)(b),

(a) if there is no quorum within 30 minutes from the time appointed for the start of the meeting, or

(b) if there is no quorum within 30 minutes from any time when there is no quorum during the meeting,

the meeting must be adjourned to one month later, at the same time and place, and those full pharmacists and pharmacy technicians who attend that later meeting will be deemed to be a quorum for that meeting.

(5) In the case of an extraordinary general meeting under section 30(5)(b),

(a) if there is no quorum within 30 minutes from the time appointed

for the start of the meeting, or

(b) if there is no quorum within 30 minutes from any time when there is no quorum during the meeting,

the meeting must be adjourned and cancelled and no further action may be taken in respect of the request under section 30(5)(b) for that meeting.

(6) In the absence of both the chair and the vice-chair of the board, an acting chair for a general meeting must be elected by a majority vote of the full pharmacists and pharmacy technicians present.

(7) A general meeting may be adjourned from time to time and from place to place, but no business may be transacted at an adjourned meeting other than the business left unfinished at the meeting from which the adjournment took place.

(8) When a meeting is adjourned in accordance with subsection (4) or by resolution, notice of the rescheduled meeting must be delivered in accordance with section 31.

**Notice to Public Representatives**

35. Every notice or mailing to registrants must also be provided to public representatives serving on the board or a committee.

**PART III – College Records**
**Body Responsible for Administering the *Freedom of Information and Protection of Privacy Act***

36. (1) The registrar is the "head" of the college for the purposes of the *Freedom of Information and Protection of Privacy Act.*

(2) The registrar may authorize the deputy registrar, a person employed by the college or a person who has contracted to perform services for the college to perform any duty or exercise any function of the registrar that arises under the *Freedom of Information and Protection of Privacy Act.*

**Fees for Information Requests**

37. Subject to section 75 of the *Freedom of Information and Protection of Privacy Act*, an applicant who requests access to a college record under section 5 of the *Freedom of Information and Protection of Privacy Act* must pay the fees set out in the Schedule of Maximum Fees in B.C. Reg. 323/93 for services required to comply with the information request.

**Disclosure of Annual Report**

38. The registrar must make each annual report under section 18(2) of

the *Act* available electronically and free of charge on the college website, must notify registrants that the report is available, and must provide a paper copy of the report to any person on request upon payment of the fee set out in Schedule "D".

**Disclosure of Registration Status**

39. (1) If an inquiry about the registration status of a person is received by the board or the registrar, the registrar must disclose, in addition to the matters required by section 22 of the *Act*,

(a) whether the discipline committee has ever made an order relating to the person under section 39 of the *Act* and the details of that order,

(b) whether the person has ever consented to an order under section 37.1 of the *Act* and the details of that order, and

(c) whether the person has ever given an undertaking or consented to a reprimand under section 36 of the *Act* and the details of that undertaking or reprimand.

(2) When acting under subsection (1), the registrar must not release the name of, or information which might enable a person to identify

(a) a patient, or

(b) another person, other than the registrant, affected by the matter,

except with the consent of the patient or the other person.

**Manner of Disposal of College Records Containing Personal Information**

40. The board must ensure that a college record containing personal information is disposed of only by

(a) effectively destroying a physical record by utilizing a shredder or by complete burning,

(b) erasing information recorded or stored by electronic methods on tapes, disks or cassettes in a manner that ensures that the information cannot be reconstructed,

(c) returning the record to the person the information pertains to, or

(d) returning the record to the registrant who compiled the information.

**PART IV – Registration**
**Classes of Registrants**

41. The following classes of registrants are established:

(a) full pharmacist;

(b) limited pharmacist;

(c) temporary registrant;

(d) student pharmacist;

(e) pharmacy technician;

(f) non-practising registrant.

**Full Pharmacist Registration**

42. (1) For the purposes of section 20(2) of the *Act*, the requirements for full pharmacist registration are

(a) graduation with a degree or equivalent qualification from a pharmacy education program recognized by the board for the purpose of full pharmacist registration and specified in Schedule "C",

(b) successful completion of the jurisprudence examination required by the registration committee,

(c) successful completion of an English language proficiency examination acceptable to the registration committee, if the person has not graduated from a pharmacy education program in Canada or the United States accredited by the Canadian Council for Accreditation of Pharmacy Programs or the Accreditation Council for Pharmacy Education,

(d) successful completion of the structured practical training required by the registration committee, if any,

(e) successful completion of the Pharmacy Examining Board of Canada Evaluating Examination, if the person has not graduated from a pharmacy education program in Canada or the United States accredited by the Canadian Council for Accreditation of Pharmacy Programs or the Accreditation Council for Pharmacy Education,

(f) successful completion of the Pharmacy Examining Board of Canada Qualifying Examination - Part I and Part II,

(g) evidence satisfactory to the registration committee that the person is of good character and fit to engage in the practice of pharmacy, and

(h) receipt by the registrar of

(i) a signed application for full pharmacist registration in

Form 4,

(ii) the application fee specified in Schedule “D”,

(iii) a notarized copy, or other evidence satisfactory to the registration committee, of the person’s degree or equivalent qualification, and that he or she is the person named therein,

(iv) a statutory declaration in Form 5,

(v) if applicable, the fee for the jurisprudence examination specified in Schedule “D”,

(vi) a criminal record check authorization in the form required by the *Criminal Records Review Act*,

(vii) if the person has engaged in the practice of pharmacy or another health profession in another jurisdiction, an authorization for a criminal record check in that jurisdiction,

(viii) a letter or certificate, in a form satisfactory to the registration committee and dated within three months prior to the date of the application, of the person’s good standing from each body responsible for the regulation of the practice of pharmacy or another health profession in a Canadian or foreign jurisdiction where the person is, or has been, authorized to engage in the practice of pharmacy or another health profession,

(ix) a certified passport size photograph of the person taken within one year prior to the date of application,

(x) a notarized copy, or other evidence satisfactory to the registration committee, of the person’s Canadian citizenship or authorization to work in Canada, and

(xi) proof of professional liability insurance as required under section 81.

(1.1) If an applicant for registration does not complete the requirements for full registration in subsection (1) within 12 months from the date of application, the applicant must provide

(a) a letter or certificate, in a form satisfactory to the registration committee and dated within three months prior to the date of full registration, of the person’s good standing from each body responsible for the regulation of the practice of pharmacy or another health profession in a Canadian or foreign jurisdiction where the person is, or has been, authorized to engage in the practice of pharmacy or another health profession, and

(b) a notarized copy, or other evidence satisfactory to the

registration committee, of the person's Canadian citizenship or authorization to work in Canada.

(2) Despite subsection (1), the person may be granted full pharmacist registration if he or she

(a) is registered in another Canadian jurisdiction as the equivalent of a full pharmacist and has provided notarized evidence, or other evidence satisfactory to the registration committee, of such registration and that he or she is the person named therein, and

(b) meets the requirements established in subsection (1)(g) and (h)(i) to (iv) and (vi) to (xi).

(3) Despite subsection (1), the registration committee has discretion, in satisfying itself under section 20 of the *Act* that the person meets the conditions or requirements for registration as a full pharmacist member of the college, to consider whether the person's knowledge, skills and abilities are substantially equivalent to the standards of academic or technical achievement and the competencies or other qualifications established in subsection (1)(a), and to grant full pharmacist registration on that basis, if the person also meets the requirements established in subsection (1)(b) to (h).

(4) A full pharmacist may use only the abbreviation "R.Ph.".

(5) A full pharmacist must not

(a) delegate any aspect of practice to a pharmacy technician, or

(b) authorize a pharmacy technician to perform or provide any aspect of practice under supervision.

**Certification of Practising Pharmacists for Drug Administration**

43. (1) A practising pharmacist may apply to the registrar under this section for certification that the practising pharmacist is qualified and competent to perform a restricted activity under section 4(1) (c.1) of the Regulation.

(2) The registrar must grant certification under this section if the practising pharmacist has

(a) provided evidence satisfactory to the registrar that the practising pharmacist has

(i) successfully completed within the year prior to application an education program in drug administration, approved by the board for the purposes of section 4.1(c) of the Regulation and specified in Schedule "C",

(ii) a current certificate in cardiopulmonary resuscitation from a program approved by the board and specified in Schedule “C”, and

(iii) a current certificate in first aid from a program approved by the board and specified in Schedule “C”,

(b) submitted a signed application for certification in Form 13, and

(c) paid the fee specified in Schedule “D”.

(3) If certification is granted under this section, the registrar must enter a notation of certification for drug administration in the register in respect of the practising pharmacist.

(4) To maintain certification under this section, a practising pharmacist must declare upon registration renewal

(a) that he or she has successfully completed a continuing education program in drug administration approved by the board and specified in Schedule “C” if an injection has not been administered in the preceding three years, and

(b) that he or she has successfully completed a continuing education program in administering a drug by intranasal route approved by the board and specified in Schedule “C” if a drug has not been administered by intranasal route in the preceding three years, and

(c) maintain current certification in cardiopulmonary resuscitation from a program approved by the board and specified in Schedule “C”, and

(d) maintain current certification in first aid from a program approved by the board and specified in Schedule “C”.

(5) The registrar must remove a practising pharmacist’s notation of certification from the register if the practising pharmacist fails to meet any of the requirements in subsection (4), and the practising pharmacist must not again perform a restricted activity under section 4(1) (c.1) of the Regulation until

(a) the requirements in subsection (4) are met to the satisfaction of the registrar, and

(b) the registrar has re-entered a notation of certification for drug administration in the register in respect of the practising pharmacist.

**Intranasal Drug Administration**

43.1 A practising pharmacist who has been certified under section 43(1) must complete the program specified in Schedule C on intranasal

drug administration prior to administering an intranasal drug.

**Limited Pharmacist Registration**

44. (1) An applicant under section 42 or 52 may be granted limited pharmacist registration for a period of up to one year if

(a) the applicant

(i) does not meet the requirements established in section 42(1)(b)(c)(e) and (f) or (3), or section 52(2)(a) and (c), as applicable,

(ii) meets the requirements established in section 42(1)(d), or section 52(2)(b), as applicable, and

(iii) is capable, in the opinion of the registration committee, of practising as a limited pharmacist without any risk to public health and safety, or

(b) the applicant

(i) meets the requirements established in section 42(1)(b)(c)(e) and (f) or (3), or section 52(2)(a) and (c), as applicable,

(ii) does not meet the requirements established in section 42(1)(d), or section 52(2)(b), as applicable, and

(iii) is capable, in the opinion of the registration committee, of practising as a limited pharmacist without any risk to public health and safety.

(2) Limited pharmacist registration may be renewed twice, but in any case, the total period of registration in this class must not exceed 3 years.

(3) Full pharmacist registration may be granted to a limited pharmacist who has met all the requirements in section 42(1) or (3), or section 52, as applicable.

(4) A limited pharmacist may provide pharmacy services as if he or she is a full pharmacist, but only under the supervision of a full pharmacist approved by the registration committee for that purpose.

(5) A limited pharmacist must not delegate any aspect of practice.

(6) A limited pharmacist may use only the title “pharmacist (limited)” and must not use any abbreviations.

**Temporary Registration**

45. (1) Despite sections 42 and 47, a person may be granted temporary pharmacist registration or temporary pharmacy technician

registration, for a period of up to 90 days, if

(a) an emergency has been declared by the registrar in accordance with criteria established by the board,

(b) the person

(i) is registered in another jurisdiction in Canada or the United States as the equivalent of a full pharmacist or a pharmacy technician, and

(ii) has provided notarized evidence, or other evidence satisfactory to the registration committee, of such registration and that the person is the person named therein.

(2) The registration of a temporary pharmacist or temporary pharmacy technician may be renewed once for an additional period of up to 90 days.

(3) A temporary pharmacist may provide services as if he or she is a full pharmacist, and may apply for certification, and be certified, under section 43.

(4) A temporary pharmacy technician may provide services as if he or she is a pharmacy technician,

(5) A temporary pharmacist may use only the title “pharmacist (temporary)” and must not use any abbreviations.

(6) A temporary pharmacy technician may use only the title “pharmacy technician (temporary)” and must not use any abbreviations.

**Student Pharmacist Registration**

46. (1) A person may be granted student pharmacist registration if the person

(a) is enrolled as a student in a pharmacy education program recognized by the board for the purpose of full pharmacist registration and specified in Schedule ”C”,

(b) provides evidence satisfactory to the registration committee that the person is of good character and fit to engage in the practice of pharmacy, and

(c) has delivered to the registrar

(i) a signed application for registration in Form 6,

(ii) the application fee specified in Schedule “D”,

(iii) a notarized copy, or other evidence satisfactory to the registration committee of the person’s enrolment and

educational standing, and that he or she is the person named therein,

(iv) a statutory declaration in Form 5,

(v) a criminal record check authorization in the form required under the *Criminal Records Review Act*,

(vi) if the person has engaged in the practice of pharmacy or another health profession in another jurisdiction, an authorization for a criminal record check in that jurisdiction,

(vii) a letter or certificate, in a form satisfactory to the registration committee and dated within three months prior to the date of the application, of the person's good standing from each body responsible for the regulation of the practice of pharmacy or another health profession in a Canadian or foreign jurisdiction where the person is, or has been, authorized to engage in the practice of pharmacy or another health profession,

(viii) a certified passport size photograph of the person taken within one year prior to the date of application, and

(ix) a notarized copy, or other evidence satisfactory to the registration committee, of the person's Canadian citizenship or authorization to work in Canada.

(2) A person described in subsection (1)(a) must be registered under this section

(a) within 6 months of their enrolment as a student in the pharmacy education program, and

(b) before undertaking a period of structured practical training or providing pharmacy services.

(3) A person who is enrolled as a student in a pharmacy education program that is not recognized by the board for the purpose of registration may be granted student registration if the applicant meets all requirements established in subsection (1)(b) and (c).

(4) A person described in subsection (3) must be registered under this section before undertaking a period of structured practical training, or providing pharmacy services.

(5) A student pharmacist may only provide pharmacy services while under the supervision of a full pharmacist

(5.1) Despite subsection (5), a student pharmacist may only perform a restricted activity under section 4(1)(c.1) of the Regulation while under the supervision of

(a) a full pharmacist who is certified under section 43, or

(b) a person who is

(i) not a member of the college,

(ii) registered as a member of another college established or continued under the Act, and

(iii) authorized under the Act to perform the restricted activity in the course of practising the designated health profession for which the other college is established or continued.

(6) The registration of a student pharmacist may be renewed if he or she

(a) remains enrolled in a pharmacy education program described in subsection 1(a),

(b) applies in writing in a form acceptable to the registration committee,

(c) pays any outstanding fine, fee, debt or levy owed to the college, and

(d) pays the fee specified in Schedule "D".

(7) A student pharmacist must not delegate any aspect of practice.

(8) A student registrant may use only the title "pharmacist (student)" and must not use any abbreviations.

**Pharmacy Technician Registration**

47. (1) For the purposes of section 20(2) of the *Act,* the requirements for pharmacy technician registration are

(a) graduation with a diploma or certificate from a pharmacy technician education program recognized by the board for the purpose of pharmacy technician registration and specified in Schedule "C",

(b) successful completion of the jurisprudence examination required by the registration committee,

(c) successful completion of an English language proficiency examination acceptable to the registration committee, if the person has not graduated from a pharmacy technician education program in Canada accredited by the Canadian Council for Accreditation of Pharmacy Programs.

(d) successful completion of the structured practical training required by the registration committee, if any,

(e) successful completion of the Pharmacy Examining Board of

Canada Evaluating Examination, if the person has not graduated from a pharmacy technician education program in Canada accredited by the Canadian Council for Accreditation of Pharmacy Programs.

(f) successful completion of the Pharmacy Examining Board of Canada Pharmacy Technician Qualifying Examination – Part I and Part II,

(g) evidence satisfactory to the registration committee that the person is of good character and fit to engage in practice as a pharmacy technician, and

(h) receipt by the registrar of

(i) a signed application for registration in Form 7,

(ii) the application fee specified in Schedule "D",

(iii) a notarized copy, or other evidence satisfactory to the registration committee, of the person's diploma, certificate or equivalent qualification, and that he or she is the person named therein,

(iv) a statutory declaration in Form 5,

(v) if applicable, the fee for the jurisprudence examination specified in Schedule "D",

(vi) a criminal record check authorization in the form required by the *Criminal Records Review Act*,

(vii) if the person has practised as a pharmacy technician or in another health profession in another jurisdiction, an authorization for a criminal record check in that jurisdiction,

(viii) a letter or certificate, in a form satisfactory to the registration committee and dated within three months prior to the date of the application, of the person's good standing from each body responsible for the regulation of the practice of pharmacy or another health profession in a Canadian or foreign jurisdiction where the person is, or has been, authorized to practise as a pharmacy technician or in another health profession,

(ix) a certified passport size photograph of the person taken within one year prior to the date of application,

(x) a notarized copy, or other evidence satisfactory to the registration committee, of the person's Canadian citizenship or authorization to work in Canada, and

(xi) proof of professional liability insurance as required under

section 81.

(1.1) If an applicant for registration does not complete the requirements for full registration in subsection (1) within 12 months from the date of application, the applicant must provide

(a) a letter or certificate, in a form satisfactory to the registration committee and dated within three months prior to the date of full registration, of the person's good standing from each body responsible for the regulation of the practice of pharmacy or another health profession in a Canadian or foreign jurisdiction where the person is, or has been, authorized to engage in the practice of pharmacy or another health profession, and

(b) a notarized copy, or other evidence satisfactory to the registration committee, of the person's Canadian citizenship or authorization to work in Canada.

(2) Despite subsection (1), the person may be granted pharmacy technician registration if he or she

(a) is registered in another Canadian jurisdiction as the equivalent of a pharmacy technician and has provided evidence, satisfactory to the registration committee, of such authorization and that he or she is the person named therein, and

(b) meets the requirements established in subsection (1)(g) and (h)(i) to (iv) and (vi) to (xi).

(3) Despite subsection (1), the registration committee has discretion, in satisfying itself under section 20 of the *Act* that the person meets the conditions or requirements for registration as a pharmacy technician member of the college, to consider whether the person's knowledge, skills and abilities are substantially equivalent to the standards of academic or technical achievement and the competencies or other qualifications established in subsection (1)(a), and to grant full pharmacy technician registration on that basis, if the person also meets the requirements established in subsection (1)(b) to (h).

(4) Despite subsection (1), the person may be granted pharmacy technician registration if he or she

(a) applies on or before December 31, 2015,

(b) has worked for at least 2000 hours as the equivalent of a pharmacy assistant in the 3 year period immediately preceding the date of application,

(c) has

(i) successfully completed the Pharmacy Examining Board of Canada Evaluating Examination, or

(ii) been certified as the equivalent of a pharmacy technician in

the Province of Ontario or Province of Alberta prior to January 1, 2009, or in another jurisdiction recognized by the registration committee, or

(iii) successfully completed an accredited pharmacist degree program in Canada or in the continental United States,

(d) has successfully completed the pharmacy technician bridging programs, and

(e) meets the requirements in subsection (1)(b) to (d) and (f) to (h).

(5) A pharmacy technician must not

(a) perform a restricted activity under section 4(1)(a) or (c.1) of the Regulation,

(b) act under section 25.92 of the *Act,* or

(c) be appointed as a pharmacy manager.

(6) A pharmacy technician may use only the title "pharmacy technician" and may use only the abbreviation "R.Ph.T.".

**Non-Practising Registration**

48. (1) A full pharmacist or pharmacy technician may be granted non-practising registration if the registrar has received

(a) a signed application for non-practising registration in Form 8,

(b) the registration fee specified in Schedule "D",

(c) a statutory declaration in Form 5, and

(d) a criminal record check authorization in the form required under the *Criminal Records Review Act*.

(2) A non-practising registrant must not provide pharmacy services in British Columbia.

(3) A non-practising registrant who was formerly a full pharmacist may use only the title "pharmacist (non-practising)" and must not use any abbreviations.

(4) A non-practising registrant who was formerly a pharmacy technician may use only the title "pharmacy technician (non-practising)" or "technician (non-practising)" and must not use any abbreviations.

**Certificate of Registration and Registration Card**

49. (1) The registrar must issue a certificate in Form 9 to a person who is granted full pharmacist or pharmacy technician registration.

(2) A registration card must be issued to a person who is granted

registration, and is valid from the date issued until the date shown on the card.

**Examinations**

50. (1) An applicant who fails a required examination under this Part, may write the examination again to a maximum of 4 times except where the Pharmacy Examining Board of Canada for its examinations, determines otherwise.

(2) If an invigilator has reason to believe that an applicant has engaged in improper conduct during the course of an examination, the invigilator must make a report to the registration committee, and may recommend that the registration committee take one or more of the following courses of action:

(a) fail the applicant;

(b) pass the applicant;

(c) require the applicant to rewrite the examination;

(d) disqualify the applicant from participating in any examination for a period of time.

(3) After considering a report made under subsection (2), the registration committee may take one or more of the courses of action specified in subsection (2).

(4) An applicant disqualified under subsection 2(d) must be provided with written reasons for disqualification.

**Registration Renewal**

51. (1) To be eligible for a renewal of registration, a registrant must

(a) provide the registrar with a completed Form 10,

(b) pay the registration renewal fee specified in Schedule “D”,

(c) pay any other outstanding fine, fee, debt or levy owed to the college,

(d) attest that he or she is in compliance with the *Act*, the regulations, and these bylaws, and is in compliance with any limits or conditions imposed on his or her practice under the *Act*,

(e) meet all applicable requirements of the quality assurance program under Part V,

(f) if certified under section 43, meet all applicable requirements of section 43(4),

(g) provide proof of professional liability insurance as required

under section 81, and

(h) provide an authorization for a criminal record check in the form required under the *Criminal Records Review Act*, if the college does not have a valid authorization on file.

(2) Form 10 must be delivered to each registrant no later than 30 days before the registration renewal date and must describe the consequences of late payment and non-payment of fees.

(3) Each registrant must submit the monies required under subsection (1) and a completed Form 10 to the college on or before the registration expiry date.

(4) On receipt of the monies required under subsection (1) and a completed Form 10, the registrar must issue a receipt stating that the registrant is, subject to his or her compliance with the *Act*, the regulations, and the bylaws, entitled to practice the profession of pharmacy or practise as a pharmacy technician, as applicable, in the Province of British Columbia as a member of the college.

(5) If a registrant fails to submit the monies required under subsection (1) and a completed Form 10 on or before the registration expiry date, he or she ceases to be registered.

(6) In this section, ”registrant” does not include a student pharmacist.

**Reinstatement**

52. (1) The registration of a former registrant or a non-practising registrant, whose registration is not suspended or cancelled under the *Act* and who has been out of practice for more than 90 days but less than 6 years must, subject to sections 20 and 39 of the *Act*, be reinstated by the registration committee if the former registrant or non-practising registrant

(a) has met all the applicable requirements of the quality assurance program approved by the board, and

(b) has delivered to the registrar

(i) a signed application for reinstatement in Form 11,

(ii) a statutory declaration in Form 5,

(iii) an authorization for a criminal record check in the form required by the *Criminal Records Review Act*, and

(iv) the registration reinstatement fee and transfer fee, if applicable, specified in Schedule “D”.

(2) The registration of a former registrant or a non-practising registrant, whose registration is not suspended or cancelled under the *Act* and

who has been out of practice for 6 years or more must, subject to sections 20 and 39 of the *Act*, be reinstated by the registration committee if the former registrant or non-practising registrant

(a) successfully completes the jurisprudence examination required by the registration committee,

(b) successfully completes the structured practical training required by the registration committee,

(c) successfully completes the Pharmacy Examining Board of Canada Qualifying Examination - Part II, and

(d) has delivered to the registrar

(i) a signed application for reinstatement in Form 11,

(ii) a statutory declaration in Form 5,

(iii) an authorization for a criminal record check in the form required by the *Criminal Records Review Act*, and

(iv) the registration reinstatement and transfer fee, if applicable specified in Schedule "D".

**Reinstatement Following Late Registration Renewal**

53. The registration of a former registrant who ceased to be registered under section 51(5) must, subject to sections 20 and 39 of the *Act*, be reinstated by the registration committee if the former registrant

(a) applies for reinstatement in Form 11 not later than 90 days following the expiry of his or her registration,

(b) meets the requirements of section 52(1),

(c) is not in contravention of the *Act*, the regulations, or these bylaws, and

(d) pays the registration reinstatement and late registration renewal fees specified in Schedule "D".

**Registration Information**

54. (1) For the purposes of section 21(2)(f) of the *Act*, the registrar must enter and maintain on the register the most recent electronic mail address for each registrant.

(2) A registrant must notify the registrar immediately of any change of name, address, telephone number, electronic mail address, names and addresses of the pharmacies where the registrant provides pharmacy services, or any other registration information previously provided to the registrar.

**PART V – Quality Assurance**

**Quality Assurance Program**

55. (1) In this Part, **"program"** means the quality assurance program established by the board in accordance with this section.

(2) The program consists of the following:

(a) continuing professional development;

(b) assessment of professional performance.

**Continuing Professional Development**

56. (1) Each full pharmacist and pharmacy technician must complete learning activities for the purpose of continuing professional development, in accordance with the policy approved by the board.

(2) Each full pharmacist and pharmacy technician must

(a) keep records in a form satisfactory to the quality assurance committee of the learning activities that the full pharmacist or pharmacy technician undertakes for the purpose of meeting the requirement established in subsection (1), and

(b) provide, on the request of and in accordance with the direction of the quality assurance committee, copies of the records referred to in paragraph (a).

(3) The quality assurance committee may conduct a review of the records provided under subsection 2(b).

**Assessment of Professional Performance**

56.1 (1) The quality assurance committee may require a full pharmacist or pharmacy technician to undergo an assessment of professional performance

(a) upon referral from the practice review committee under section 15.1(5), or

(b) if the quality assurance committee determines an assessment is appropriate in the circumstances upon a review of records conducted under section 56(3).

(2) For the purpose of an assessment under subsection (1) the quality assurance committee or an assessor appointed by the quality assurance committee may do one or more of the following:

(a) conduct an interview of the full pharmacist or pharmacy technician;

(b) assess the practice competency of the full pharmacist or pharmacy technician;

(c) require the full pharmacist or pharmacy technician to undergo any other type of assessment determined by the quality assurance committee to be appropriate in the circumstances.

## PART VI – Inquiries and Discipline
## Consent Orders

57. The record of an undertaking or consent given under section 36 of the *Act*, a consent order under section 37.1 of the *Act*, or an agreement under section 32.2(4)(b) or 32.3(3)(b) of the *Act*, must

(a) include any consent to a reprimand or to any other action made by the registrant under section 32.2(4)(b), 32.3(3)(b), 36 or 37.1 of the *Act*,

(b) include any undertaking made by the registrant under section 36 of the *Act*,

(c) specify the length of time that an undertaking specified in paragraph (b) is binding on the registrant,

(d) specify the procedure that the registrant may follow to be released from an undertaking specified in paragraph (b), and

(e) subject to sections 22 and 39.3 of the *Act* and sections 39(1) and 60(1), specify which limits or conditions of the undertaking, consent order or agreement may be published, disclosed to the public, or both.

### Notice of Disciplinary Committee Action Under Section 39.1 of *Act*

57.1 The discipline committee must deliver notice to a registrant not fewer than 14 days before making an order under section 39.1 of the *Act* in respect of the registrant.

### Citation for Disciplinary Hearing

58. (1) On the direction of a panel of the discipline committee, the registrar may join one or more complaints or other matters which are to be the subject of a discipline hearing in one citation as appropriate in the circumstances.

(2) On the direction of a panel of the discipline committee, the registrar may sever one or more complaints or other matters which are to be the subject of a discipline hearing as appropriate in the circumstances.

(3) On the direction of a panel of the discipline committee, the registrar may amend a citation issued under section 37 of the *Act*.

(4) If a citation is amended under subsection (3) prior to a discipline hearing, the amended citation must be delivered to the respondent by personal service or sent by registered mail to the respondent at the

last address for the respondent recorded in the register not fewer than 14 days before the date of the hearing.

(5) If a citation is amended under subsection (3) prior to a discipline hearing, and the amended citation changes the date, time or place of the hearing, the registrar must notify any complainant of the amendment not fewer than 14 days before the date of the hearing.

**Hearings of Discipline Committee**

59. (1) No person may sit on the discipline committee while he or she is a member of the inquiry committee.

(2) No member of the discipline committee may sit on the panel hearing a matter in which he or she:

(a) was involved as a member of the inquiry committee, or

(b) has had any prior involvement.

(3) Information about the date, time and subject matter of the hearing must be provided to any person on request.

(4) The discipline committee must provide notice by registered mail or by personal service to a person who is required to attend a hearing under section 38(6) of the *Act* in Form 12.

(5) All discipline hearings must be recorded and any person may obtain, at his or her expense, a transcript of any part of the hearing which he or she was entitled to attend.

**Notice of Disciplinary Decision**

60. (1) In addition to any notification required under section 39.3 of the *Act* with respect to any of the actions referred to in section 39.3(1)(a) to (e) of the *Act*, the registrar

(a) must notify all registrants,

(b) must notify the regulatory bodies governing the practice of pharmacy or the services of pharmacy technicians in every other Canadian jurisdiction, and

(c) may notify any other governing body of a health profession inside or outside of Canada.

(2) Notification provided to all registrants under subsection (1)(a)

(a) must include all information included in the public notification under section 39.3 of the *Act*, and

(b) unless otherwise directed by the inquiry committee or the discipline committee, as the case may be, must exclude any information withheld from the public notification under section

39.3(3) or (4) of the *Act*.

(3) Unless otherwise directed by the inquiry committee or the discipline committee, as the case may be, notification provided to other regulatory or governing bodies under subsection (1)(b) or (c) may include information that has been withheld from the public notification under section 39.3(3) or (4) of the *Act*.

**Retention of Discipline Committee and Inquiry Committee Records**

61. Records of the inquiry committee and discipline committee must be retained permanently.

**Registrant Under Suspension**

62. (1) If the registration of a registrant is suspended, the registrant must

(a) not engage in the practice of pharmacy or provide the services of a pharmacy technician,

(b) not hold himself or herself out as a registrant,

(c) not hold office in the college,

(d) not be a manager,

(e) not make appointments for patients or prospective patients,

(f) remove the registrant's name and any sign relating to the registrant's practice from any premises where the registrant practiced pharmacy or provided the services of a pharmacy technician and any building in which any such premises are located,

(g) not contact or communicate with patients or prospective patients, except for the following purposes:

(i) to advise a patient or a prospective patient of the fact and duration of the suspension, and

(ii) to advise a patient or prospective patient that another registrant will continue to act or provide services in the suspended registrant's place, or

(iii) to refer a patient or prospective patient to another registrant, who is in good standing.

(h) pay any fee required by the college when due in order to remain a registrant and any other outstanding fine, fee, debt or levy owed to the college, and

(i) immediately surrender his or her registration card to the registrar.

(2) No registrant or former registrant is entitled to any refund of any fine, fee, debt or levy paid to the college solely on the basis that it was paid during or in relation to a period of suspension from practice.

(3) During the period of suspension,

(a) a suspended full pharmacist may permit another full pharmacist in good standing to practice pharmacy, and

(b) a suspended pharmacy technician may permit a full pharmacist or another pharmacy technician, in good standing, to provide pharmacy services,

in the premises where the full pharmacist or pharmacy technician formerly practiced pharmacy or provided pharmacy services, as applicable.

**Fines**

63. The maximum amount of a fine that may be ordered by the discipline committee under section 39(2)(f) of the *Act* is $100,000.

**PART VII –Registrant Records**
**Definitions**

64. In this Part, **"patient's representative"** means

(a) a "committee of the patient" under the *Patient's Property Act*,

(b) the parent or guardian of a patient who is under 19 years of age,

(c) a representative authorized by a representation agreement under the *Representation Agreement Act* to make or help in making decisions on behalf of a patient,

(d) a decision maker or guardian appointed under section 10 of the *Adult Guardianship Act*, or

(e) a temporary substitute decision maker chosen under section 16 of the *Health Care (Consent) and Care Facility (Admission) Act*.

**Purpose for which Personal Information may be Collected**

65. No registrant may collect personal information regarding a patient without the patient's consent unless

(a) the information relates directly to and is necessary for providing health care services to the patient or for related administrative purposes, or

(b) the collection of that information is expressly authorized by or under an enactment.

**Source of Personal Information**

66. (1) A registrant must collect personal information about a patient directly from the patient, unless the patient otherwise consents.

(2) Despite subsection (1), a registrant may collect personal information about a patient from another person if he or she has reasonable grounds to believe

(a) that the patient has been made aware of the matters set out in section 67(1) and has authorized collection of the personal information from another person,

(b) that the patient is unable to give his or her authority and the registrant, having made the patient's representative aware of the matters set out in section 67(1), collects the information from the representative or the representative authorizes collection from another person,

(c) that compliance with subsection (1) would:

(i) prejudice the best interests of the patient,

(ii) defeat the purpose or prejudice the use for which the information is collected, or

(iii) prejudice the safety of any person,

(d) that compliance with subsection (1) is not reasonably practicable in the circumstances of the particular case,

(e) that the collection is for the purpose of assembling a family or genetic history of a person and is collected directly from that person,

(f) that the information is publicly available,

(g) that the information:

(i) will not be used in a form in which the patient concerned is identified, or

(ii) will be used for statistical or research purposes and will not be published in a form that could reasonably be expected to identify the patient.

(h) that non-compliance with subsection (1) is necessary if the information is about law enforcement or anything referred to in sections 15(1) or (2) of the *Freedom of Information and Protection of Privacy Act*.

**Collection of Personal Information**

67. (1) If a registrant collects personal information directly from a patient, or from a patient's representative, the registrant must take such steps as

are, in the circumstances, reasonable to ensure that the patient or patient's representative is aware of

(a) the fact that the personal information is being collected,

(b) the purpose for which the personal information is being collected,

(c) the intended recipients of the personal information,

(d) whether or not the supply of the personal information is voluntary or mandatory and, if mandatory, the legal authority for collecting the personal information,

(e) the consequences, if any, for that patient if all or any part of the requested personal information is not provided, and

(f) the rights of access to personal information provided in section 80.

(2) The steps referred to in subsection (1) must be taken before the personal information is collected or, if that is not practicable, as soon as practicable after the personal information is collected.

(3) A registrant is not required to take the steps referred to in subsection (1) in relation to the collection of personal information from a patient, or the patient's representative, if the registrant has taken those steps in relation to the collection, from the patient or patient's representative, of the same information or information of the same kind for the same or a related purpose, on a recent previous occasion.

(4) Despite subsection (1), a registrant is not required to comply with subsection (1) if the registrant believes on reasonable grounds

(a) that non-compliance is authorized by the patient concerned,

(b) that compliance would:

(i) prejudice the interests of the patient concerned, or

(ii) defeat the purpose or prejudice the use for which the information is collected,

(c) that compliance is not reasonably practicable in the circumstances of the particular case, or

(d) that the information is about law enforcement or anything referred to in sections 15(1) or (2) of the *Freedom of Information and Protection of Privacy Act*.

**Manner of Collection of Personal Information**

68. Personal information must not be collected by a registrant

(a) by unlawful means, or

(b) by means that in the circumstances intrude to an unreasonable extent upon the personal affairs of the patient concerned.

**Accuracy of Personal Information**

69. The registrant must make every reasonable effort to ensure that personal information collected about patients is current and is legibly, accurately and completely recorded.

**Right to Request Correction of Personal Information**

70. (1) A person who believes there is an error or omission in a record containing his or her personal information may request that the registrant having the record in his or her custody or control correct the information.

(2) If, after receiving a request for correction under subsection (1), the registrant disagrees that there is an error or omission in the record, the registrant must note the request in the record with particulars of the correction that was sought.

**Use of Personal Information**

71. A registrant may use personal information about a patient only

(a) for the purpose of providing health care services to, or performing health, care services for, the patient, or for a related administrative purpose, or

(b) for a use or disclosure consistent with a purpose specified in paragraph (a)

(i) if the patient has consented to the use, or

(ii) for a purpose for which that information may be disclosed by the registrant under section 72 or otherwise under the *Act*.

**Disclosure of Personal Information**

72. A registrant must maintain confidentiality of personal information about a patient, and may disclose personal information about a patient only

(a) if the patient concerned has consented to the disclosure,

(b) for the purpose of providing health care services to, or performing health care services for, the patient, or for a related administrative purpose, or for a disclosure consistent with either purpose,

(c) for the purpose of complying with an enactment of, or an

arrangement or agreement made under an enactment of, British Columbia or Canada,

(d) for the purpose of complying with a subpoena, warrant or order issued or made by a court, person or body with jurisdiction to compel the production of information,

(e) to an employee of, or contractor providing services to, the registrant, if the information is necessary for the performance of the duties of, or for the protection of the health or safety of, the employee or contractor,

(f) to a lawyer acting for the registrant, for use in civil or criminal proceedings involving the registrant,

(g) if necessary to comply with the *Coroners Act*,

(h) if necessary to comply with the *Ombudsman Act*,

(i) for the purposes of

(i) collecting a debt or fine owing by a patient to the registrant, or

(ii) making a payment owing by the patient to a registrant,

(j) to an auditor, the college or any other person or body authorized by law, for audit purposes,

(k) if the registrant believes on reasonable grounds that there is a risk of significant harm to the health or safety of any person and that the use or disclosure of the information would reduce that risk,

(l) so that the next of kin or a friend of an injured, ill or deceased individual may be contacted,

(m) in accordance with the *Act*, the regulation, or these bylaws, or

(n) as otherwise required by law.

**Definition of Consistent Purpose**

73. A use or disclosure of personal information is consistent with the purposes of providing health care services to a patient or related administrative purposes under sections 71 and 72 if the use or disclosure has a reasonable and direct connection to either purpose.

**Storage of Personal Information**

74. A registrant must ensure that all records pertaining to his or her practice, and containing personal information about patients are safely and securely stored

(a) at the pharmacy, or

(b) off site.

**Manner of Disposal of Records**

75. A registrant must ensure that records referred to in section 74 are disposed of only by

(a) transferring the record to another registrant, or

(b) effectively destroying a physical record by utilizing a shredder or by complete burning, or

(c) erasing information recorded or stored by electronic methods on tapes, disks or cassettes in a manner that ensures that the information cannot be reconstructed.

**Registrant Ceasing to Practice**

76. (1) Except where records must be retained for the purpose of Part 3 of the *Act* and Part 3 of the *Pharmacy Operations and Drug Scheduling* Act, in any case where a pharmacy is closed or a registrant ceases to practise, for any reason, the records referred to in section 74 must be transferred in accordance with this Part, and the college must be notified and provided with a written summary of the steps taken to transfer those records.

(2) A registrant must make appropriate arrangements to ensure that, in the event that the registrant dies or becomes unable to practise for any reason and is unable to dispose of records referred to in section 74 those records will be safely and securely transferred to another registrant.

(3) A registrant who transfers records containing personal information about a patient transferred in accordance with subsection (1) or (2) must notify the patient.

**Protection of Personal Information**

77. (1) A registrant must protect personal information about patients by making reasonable security arrangements against such risks as unauthorized access, collection, use, disclosure or disposal.

(2) A registrant must take reasonable measures to ensure that a third party, including a volunteer, employee or contractor of the registrant, or a limited pharmacist does not access, collect, use, disclose, store or dispose of personal information about patients except in accordance with this Part.

**Contracts for Handling Personal Information**

78. A registrant must ensure that, if personal information about patients is transferred to any person or service organization for processing, storage or disposal, a contract is made with that person which

includes an undertaking by the recipient that confidentiality and physical security will be maintained.

**Remedying a Breach of Security**

79. A registrant must take appropriate measures to remedy any unauthorized access, use, disclosure or disposal of personal information about patients under this Part as soon as possible after the breach is discovered, including

(a) taking steps to recover the personal information or to ensure its disposal if it cannot be recovered,

(b) taking steps to ensure that any remaining personal information is secured,

(c) notifying

(i) anyone affected by the unauthorized access including patients and other health care providers,

(ii) the college, and

(iii) law enforcement officials, if criminal action may have contributed to the unauthorized action, and

(d) modifying existing security arrangements to prevent a re-occurrence of the unauthorized access.

**Patient Access to Personal Information**

80. (1) For the purposes of this section, **"**access to" means the opportunity to examine or make copies of the original record containing personal information about a patient.

(2) If a patient or a patient's representative makes a request for access to personal information about the patient, the registrant must comply as soon as practical but not more than 45 days following the request by

(a) providing access to the patient or patient's representative,

(b) providing access to the remainder of the personal information if that information excepted from disclosure under subsection (3) can reasonably be severed, or

(c) providing written reasons for the refusal of access to the personal information or to any portion thereof.

(3) The registrant may refuse to disclose personal information to a patient or a patient's representative

(a) if there is a significant likelihood of a substantial adverse effect on the physical, mental or emotional health of the patient,

(b) if there is a significant likelihood of harm to a third party, or

(c) if the disclosure could reasonably be expected to disclose personal information regarding another individual.

(4) If a patient or a patient's representative requests a copy of an original record containing personal information about the patient to which a registrant has given the patient or patient's representative access, a copy must be provided if it can reasonably be reproduced.

(5) A registrant may charge a reasonable fee for the reproduction of personal information which does not exceed the fee specified in Schedule "G".

(6) Subject to subsection (3), a patient under 19 years of age may have access to a record if, in the opinion of the registrant, the patient is capable of understanding the subject matter of the record.

(7) Except if authorized by the patient, a registrant must not provide access to the records of a patient who is under 19 years of age to the guardian or parent of the patient if the subject matter of the record is health care which was provided without the consent of a parent or guardian in accordance with the requirements of section 17 of the *Infants Act.*

**Part VIII – General**
**Liability Insurance**

81. (1) Each registrant, other than a student registrant or a non-practising registrant, must obtain and at all times maintain professional liability insurance coverage with a limit of liability not less than $2,000,000 insuring against liability arising from an error, omission or negligent act of the registrant.

(2) Each registrant, other than a student registrant or a non-practising registrant, must obtain and at all times maintain professional liability insurance coverage with a limit of liability not less than $2,000,000 insuring against liability arising from an error, omission or negligent act of an employee of the registrant.

**Part IX – Marketing and Advertising**

**Definitions**

82. In this Part:

**"advertisement"** means the use of space or time in a public medium, or the use of a commercial publication such as a brochure or handbill, to communicate with the general public, or a segment thereof, for the purpose of promoting professional services or enhancing the image of the advertiser;

**"marketing"** includes

(a) an advertisement,

(b) any publication or communication in any medium with any patient, prospective patient or the public generally in the nature of an advertisement, promotional activity or material, a listing in a directory, a public appearance or any other means by which professional services are promoted, and

(c) contact with a prospective client initiated by or under the direction of a registrant.

**Marketing and Advertising**

83. (1) When advertising pharmacy services that are required by legislation, the statement, “Required in all British Columbia Pharmacies”, must accompany the advertising and must be of the same size and prominence as all other print in the advertising.

(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”.

(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 advertisement, and both figures must be featured equally.

(4) Schedule I drug price advertising must not include any reference to the safety, effectiveness or indications for use of the advertised prescription drug products or compare the fees charged by the registrant with those charged by another registrant.

(5) Any marketing undertaken or authorized by a registrant in respect of his or her professional services must not be

(a) false,

(b) inaccurate,

(c) reasonably expected to mislead the public, or

(d) unverifiable.

(6) Marketing violates subsection (5) if it

(a) is calculated or likely to take advantage of the weakened state, either physical, mental or emotional, of the recipient or intended recipient,

(b) is likely to create in the mind of the recipient or intended recipient an unjustified expectation about the results which the registrant can achieve,

(c) implies that the registrant can obtain results

(i) not achievable by other registrants,

(ii) by improperly influencing a public body or official, or any corporation, agency or person having any interest in the welfare of the recipient,

(iii) by any other improper means, or

(d) compares the quality of services provided with those provided by another registrant, or a person authorized to provide health care services under another enactment, or another health profession.

(7) The home page of any pharmacy that advertises on a website must clearly show

(a) that the pharmacy is licensed in British Columbia,

(b) the contact information for the college,

(c) a notice to patients that pharmacy practice issues may be reported to the college,

(d) the physical location of the pharmacy operation,

(e) the 10 digit pharmacy telephone number, and

(f) the name of the pharmacy's manager.

**Part X – Patient Relations**
**Patient Relations Program**

84. (1) The board must establish a patient relations program to seek to prevent professional misconduct, including professional misconduct of a sexual nature.

(2) For the purposes of the patient relations program, the board must

(a) establish and maintain procedures by which the college deals with complaints of professional misconduct of a sexual nature,

(b) monitor and periodically evaluate the operation of procedures established under subsection (a), and

(c) develop guidelines for the conduct of registrants with their patients.

(3) The registrar must provide information to the public regarding the college's complaint, investigation, and discipline processes.

(4) In this section, "**professional misconduct of a sexual nature**" means

(a) sexual intercourse or other forms of physical sexual relations between the registrant and the patient,

(b) touching of a sexual nature, of the patient by the registrant, or

(c) behavior or remarks of a sexual nature by the registrant towards the patient,

but does not include touching, behavior and remarks by the registrant towards the patient that are of a clinical nature appropriate to the service being provided.

## Part XI – Standards of Practice

### Community Pharmacy, Hospital Pharmacy, Residential Care Facilities and Homes

85. Standards, limits, and conditions for the practice of the health profession of pharmacy and the provision of pharmacy technician services by registrants, referred to in section 19(1)(k) of the *Act* are established in Parts 1 to 3 of Schedule "F".

### Drug Administration

86. Standards, limits, and conditions respecting practising pharmacists and drug administration, referred to in section 19(1)(k) of the *Act*, are established in Part 4 of Schedule "F".

## Part XII – Standards of Professional Ethics
## Code of Ethics

87. Standards of professional ethics for registrants, including standards for the avoidance of conflicts of interest, referred to in section 19(1)(l) of the *Act,* are established in Schedule "A".

# APPLICATION COMMITTEE

## Background

The Board is required to establish an Application Committee.

## Authority

Health Professions Act (HPA) sections 19(1)(t) and HPA Bylaws sections 15.2, 19 and 20.
Pharmacy Operations and Drug Scheduling Act (PODSA) sections 1, 4(2), 4(3), 4(4), 4(5), 4.1 and 5.1(b).

## Mandate

To review pharmacy licence applications that have been referred to the committee and determine whether to issue, renew or reinstate a licence with or without conditions.

## Responsibilities

- Review applications for a pharmacy licence as referred by the Registrar that do not meet the eligibility criteria defined in PODSA.
- Request additional information or evidence, if required to make a decision.
- Issue, renew or reinstate a pharmacy licence, with out without conditions, to applicants who satisfy the Application Committee they are eligible to hold a pharmacy licence.
- Refuse to issue, renew or reinstate a pharmacy licence, to applicants who do not satisfy the Application Committee that they are eligible to hold the pharmacy licence.
- Develop conditions with respect to issuing, renewing and reinstating a pharmacy licence.
- Establish sub-committees and ad-hoc working groups for Board appointment, to review, develop, administer and establish requirements for the purposes of the application process.
- Inform applicants, about the results of the licensure decision made by the Application Committee.

## Reporting relationship

The committee as a whole reports through the chair to the Board. The committee must submit a report of its activities to the Board annually, or as required by the Board.

## Membership

- At least six full pharmacists or pharmacy technicians appointed by the Board (there must be representation from both groups of registrants).
- At least 1/3 of its members must consist of public representatives, at least one of whom must be an appointed Board member.

## Panels

- The committee may meet in panels of at least 3 persons but not more than 5 persons, and each panel must include at least 1/3 public representatives.
- The chair of the Application Committee must appoint the members of a panel and must designate a chair of the panel.
- The panel may exercise any power, duty or function of the Application Committee.

## Term of appointment

- Appointments are determined by the Board and will not exceed 2 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.
- A registrant appointed to the committee ceases to be a member if they are no longer a full pharmacist or pharmacy technician in good standing or if they become a College employee.
- Any committee member may resign upon written notification to the registrar. Committee members who are absent for more than three committee meetings per year automatically forfeit membership on the committee. The chair has the discretion to approve, in advance, an extended absence of any committee member.

## Committee officers

Board appoints a committee chair and vice-chair from among the members of the committee.

## Voting rights

Each member, including each public representative, is entitled to one vote on all matters coming before the committee or a panel of the committee.

## Meeting procedures

| | |
|---|---|
| *Schedule:* | At least three times annually. |
| *Format:* | In person, by teleconference, or by videoconference. |
| *Agenda:* | Developed by College staff in consultation with the committee chair with input from committee members. |
| *Panels:* | The committee chair, who also designates the panel chair, must appoint panel members. A panel of a committee may exercise any power, duty or function of that committee. |
| *Attendees:* | Only Application Committee members and College staff are entitled to attend committee and panel meetings, unless specifically invited by the committee or panel chair as a guest. |
| *Quorum:* | A majority of the committee or all members of a panel. |
| *Minutes:* | Drafted by College staff for review and approval at next committee meeting; filed at the College office. |
| *Secretariat Support:* | Provided by the College, including meeting coordination, preparation and distribution of materials and drafting meeting minutes. |

## Conflict-of-interest disclosure

Members must declare conflicts of interest prior to the discussion of individual files or at any time a conflict of interest or potential conflict of interest arises.

A conflict of interest refers to situations in which personal, occupational or financial considerations may affect or appear to affect the objectivity or fairness of decisions related to the committee activities. A conflict of interest may be real, potential or perceived in nature. Individuals must declare potential conflicts to the chair of the committee and must either absent themselves from the discussion and voting, or put the decision to the committee on whether they should absent themselves.

## Confidentiality

Each committee member must sign a confidentiality agreement at the time of each appointment indicating their agreement to maintain the confidentiality, security and integrity of all materials during and after their term on the committee.

## Remuneration

Committee members may claim honouraria and expense reimbursement in accordance with the Board's policy and guidelines for claiming committee expenses.

## Amendment to terms of reference

The Board may amend committee terms of reference at any time and from time to time.

## Schedule of Amendments

*Health Professions Act* - Bylaws are amended to establish and determine the composition of the Application Committee as follows:

1. The following new section has been added to Part I – College Board, Committees and Panels:

   Application Committee

   15.2 (1) The application committee within the meaning of section 1 of the *Pharmacy Operations and Drug Scheduling Act [SBC 2003] c.77* is established consisting of at least 6 persons appointed by the board.

   (2) At least 1/3 of the application committee must consist of public representatives, at least one of whom must be an appointed board member.

2. Subsection 20(1) has been amended to include “application committee” as follows:

   20. (1) The registration committee, inquiry committee, practice review committee, application committee, discipline committee and quality assurance committee may meet in panels of at least 3 but not more than 5 persons, and each panel must include at least 1/3 public representatives.

College of Pharmacists of British Columbia

# b) Compounding – Implementation Plan

College of Pharmacists of British Columbia

# Adopting Standards

- The College of Pharmacists of BC has explicit bylaw making authority to establish standards, limits or conditions for the practice of pharmacy
- To adopt standards created by another body such as NAPRA, due diligence is required to ensure the appropriateness of the standards to the practice of pharmacy in BC.

College of Pharmacists of British Columbia

# Subject Matter Expert - Dana Lyons

- Dana is a registered Pharmacy Technician with the Alberta College of Pharmacists.
- She is a specialist in implementation and management of sterile compounding processes and validation.
- She is also currently leading the implementation of these Model Standards in pharmacies across Alberta.

College of Pharmacists of British Columbia

# Subject Matter Expert Role:

- Assess the suitability of the newly released NAPRA Model Standards to pharmacy practice in BC.
- Review existing references to compounding in the College's bylaws and policies.
- Conduct a gap analysis.
- Provide recommendations regarding the adoption and implementation of the new standards.

College of Pharmacists of British Columbia

# What is compounding?

- Compounding is defined as the combining of mixing together of two or more ingredients to create a final product in an appropriate form for administration.
- Healthcare professionals who provide compounding related services and products to patients/clients must be able to demonstrate that a **patient-healthcare professional relationship** exists.

College of Pharmacists of British Columbia

# Compounding Incidents

**Marchese Hospital Solutions**

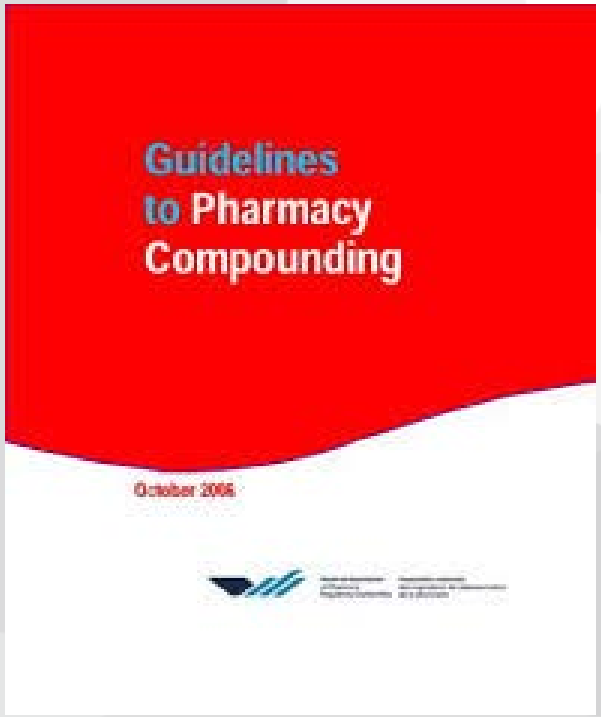
- In 2013 Marchese Hospital Solutions supplied nearly 1,200 Canadian cancer patients in hospital in Ontario and New Brunswick with weaker-than-prescribed doses of chemotherapy drugs.
- Hospitals have said the saline bags that the chemotherapy cocktails came in were overfilled, diluting the concentration of the cancer-fighting drugs by as much as 20 per cent.

**New England Compounding Centre**

- Over 50 people died and over 800 people were infected from a fungal meningitis outbreak where patients were infected from receiving contaminated steroid injections mixed at New England Compounding Centre in 2012.

College of Pharmacists of British Columbia

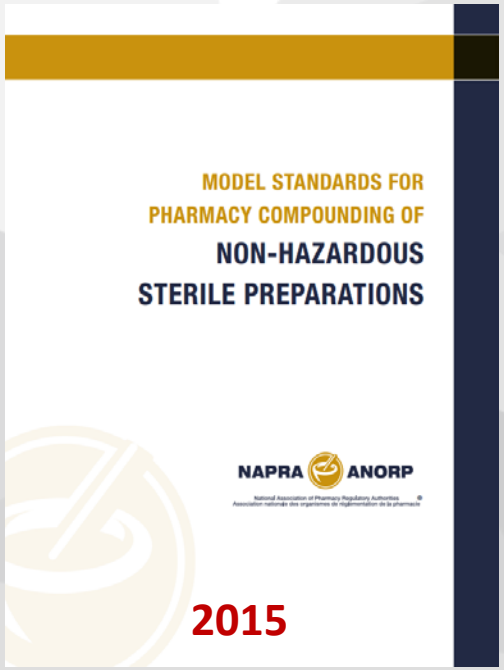
# NAPRA Compounding Standards

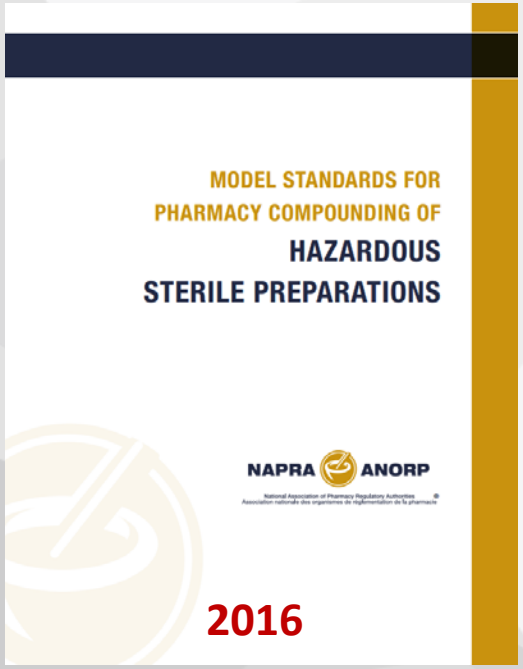



- NAPRA has previously established compounding standards: “Guidelines to Pharmacy Compounding” (2006).
- Evolving practice and increased awareness of the inherent dangers of compounding sterile preparations for the health of both patients and compounding personnel, led to the need to review these guidelines.

College of Pharmacists of British Columbia

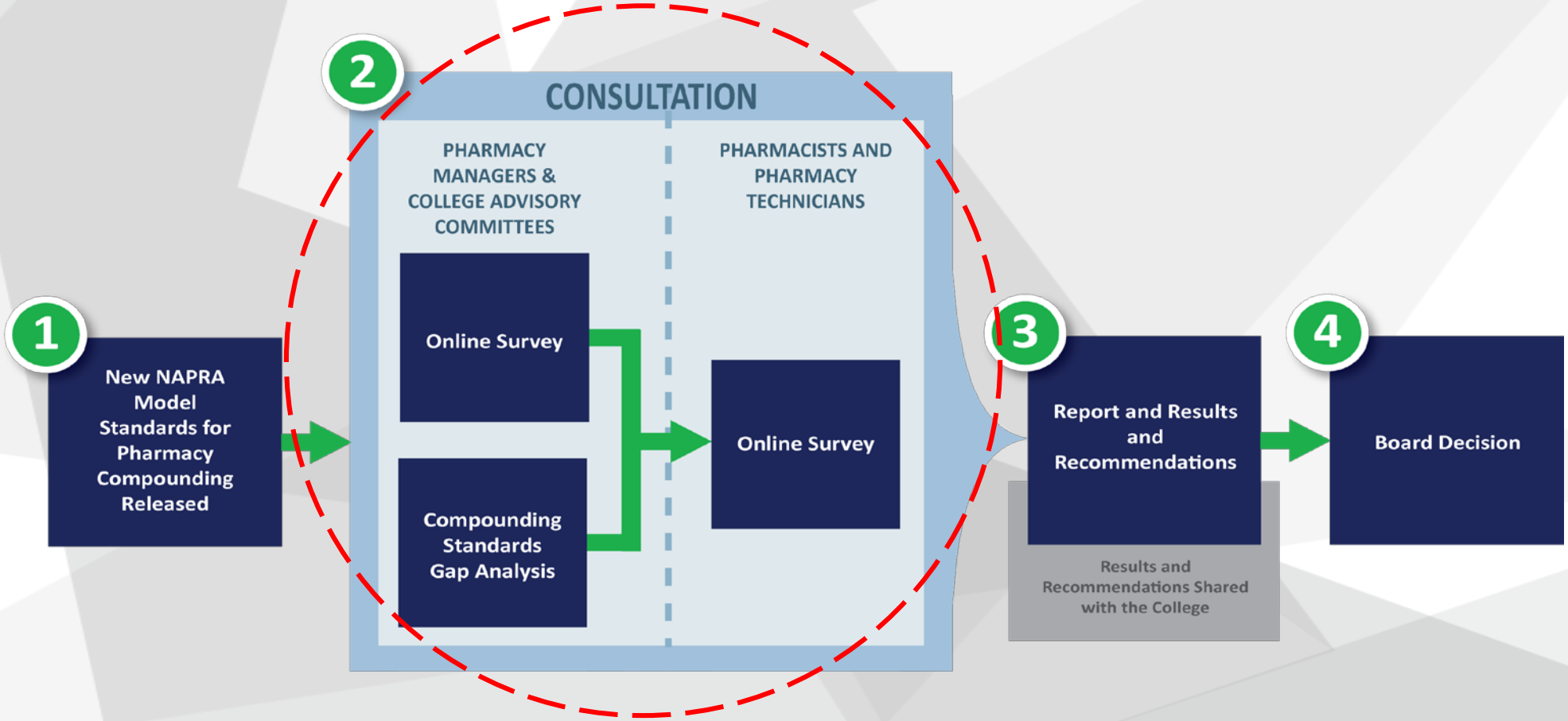
# New NAPRA Model Standards for Sterile Compounding



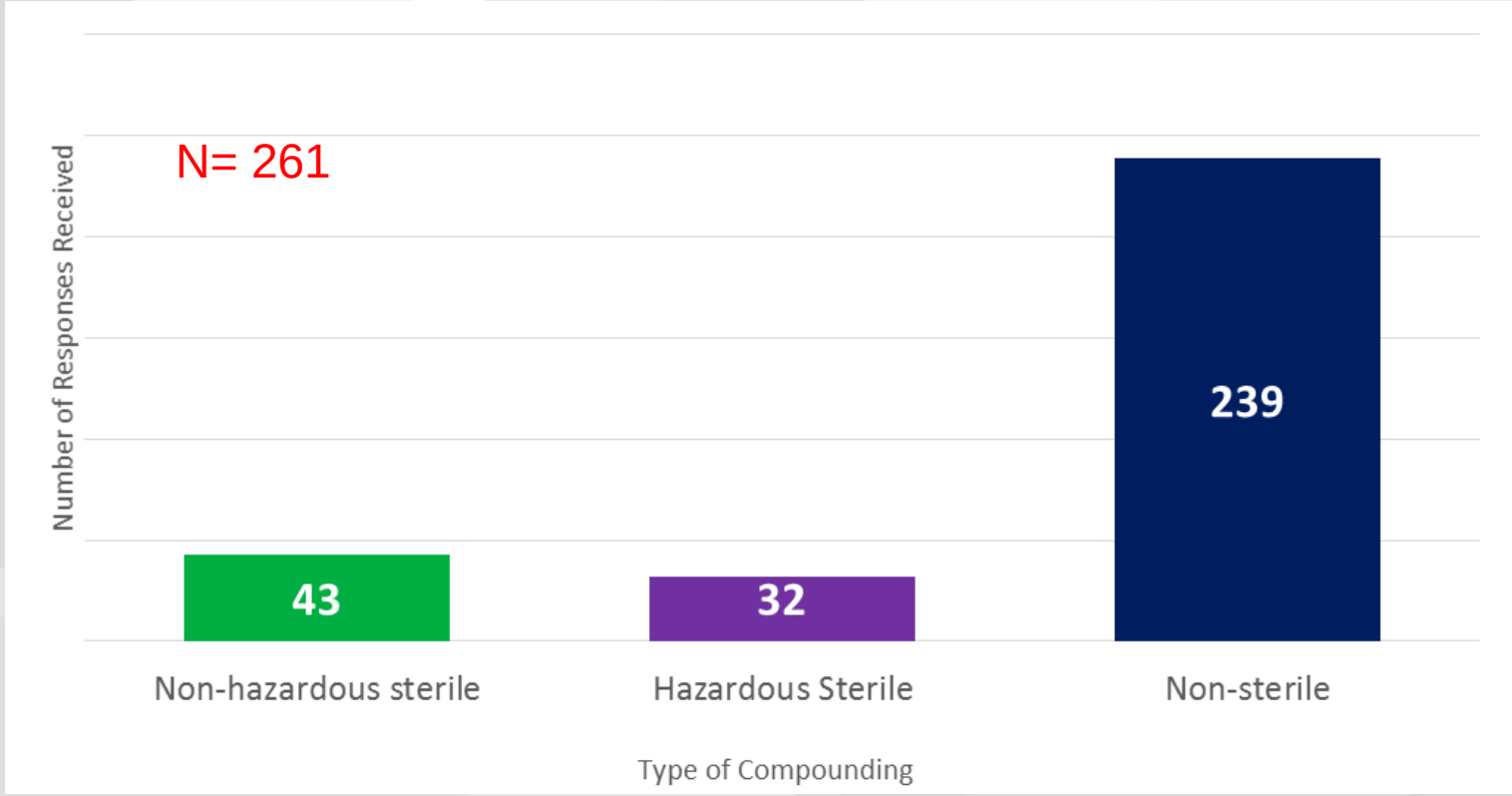
College of Pharmacists of British Columbia

# Consultation and Engagement Process



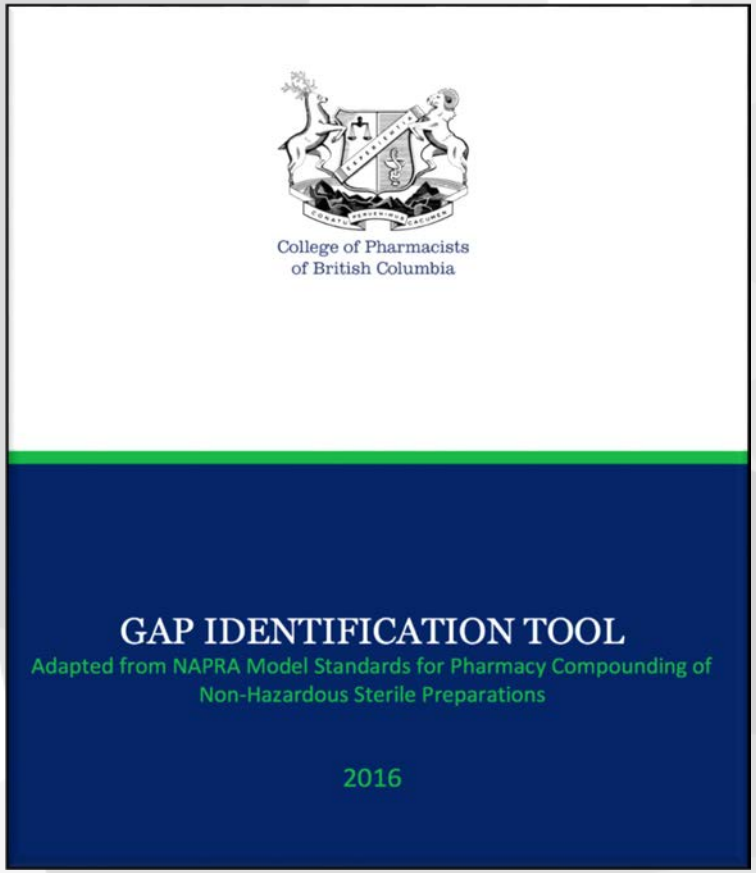
College of Pharmacists of British Columbia

# Online Survey – Do you compound, if so what type of compounding are you engaged in?



College of Pharmacists of British Columbia

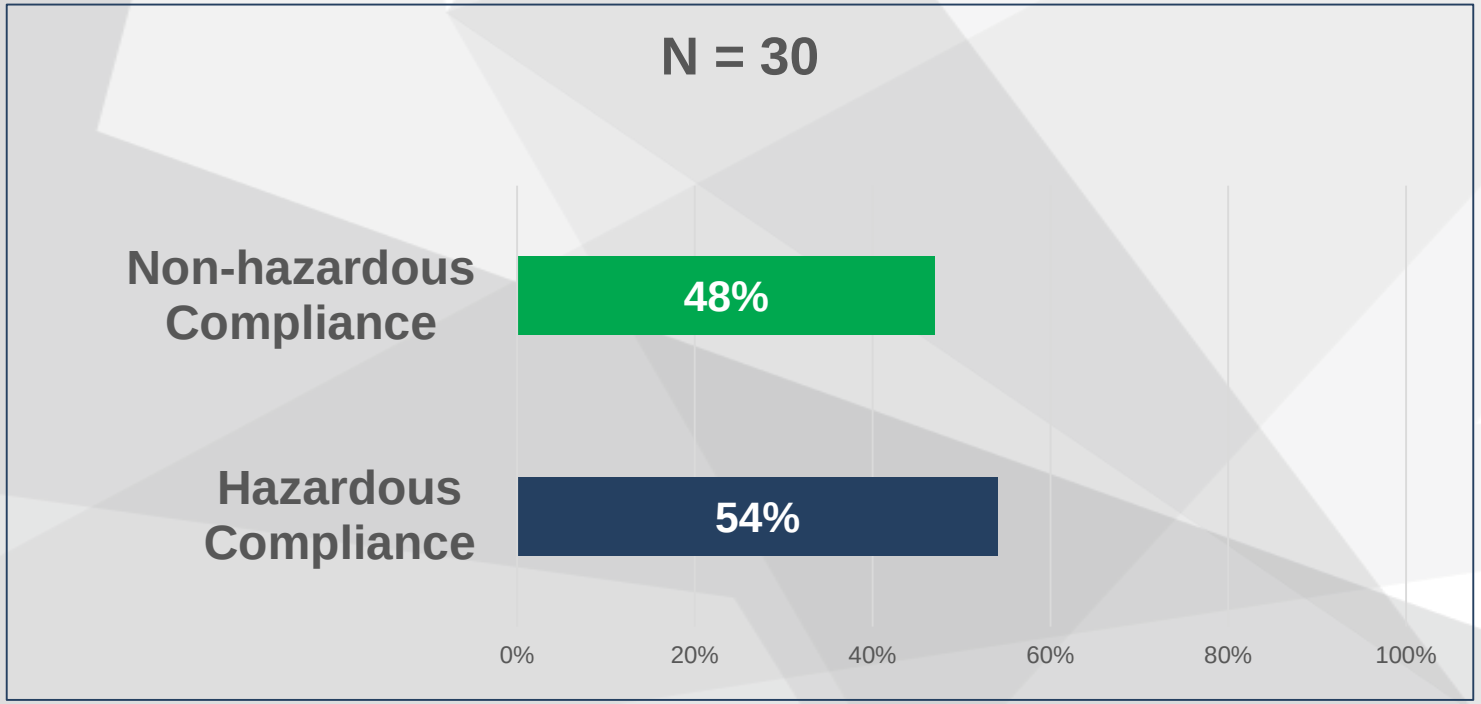
# Gap Analysis




- Based on must/shall statements from NAPRA Model Standards
- Developed for both released Model Standards

College of Pharmacists of British Columbia

# Gap Analysis Survey Results: Self-Reported Compliance



College of Pharmacists of British Columbia

# Barriers Cited by Registrants

| Barriers |
| --- |
| • Gaps in knowledge |
| • Financial constraints |
| • Restrictive beyond-use dates |
| • Communication |

College of Pharmacists of British Columbia

# Mitigation Strategies

| Mitigation Strategies |
| --- |
| • Phased in approach for implementation |
| • Frequent communication by the College on implementation timelines |

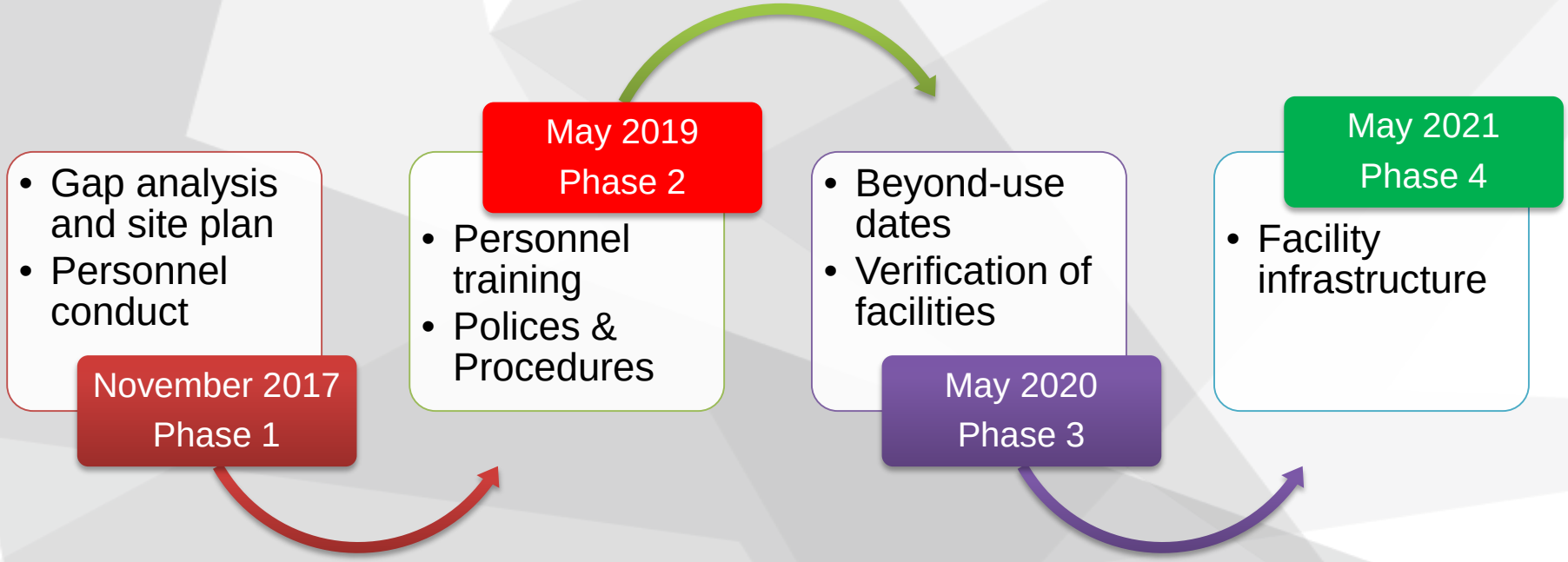
College of Pharmacists of British Columbia

# Risks

| Risk of Adopting too Quickly | Risks of Adopting too Slowly |
|---|---|
| • Facilities will fail | • Risk to public safety |
| • Confidence in College will lower | • Risk to staff who lack control over compounding environments |
| • Supply concerns (new purchases) | • Loss of momentum |
| • Overwhelm frontline staff | • Loss of public respect |
| • Loss of economies of scale | • Standards may continue to change |
| • Patient access to compounding decreased | |
| • Opportunity to gain knowledge and train will be lost | |

College of Pharmacists of British Columbia

# Implementation Strategy



College of Pharmacists of British Columbia

# Adoption of NAPRA Model Standards Across Canada

- **To date, five other provincial pharmacy regulatory authorities have adopted the two Model Standards:**
  - Alberta
  - Ontario
  - Manitoba
  - Nova Scotia
  - Newfoundland and Labrador

- **Alberta, Ontario and Manitoba have established multi-year implementation phases.**

College of Pharmacists of British Columbia

# Other Provinces: Multi-Year Implementation Phases

| Ontario | Deadline |
|---|---|
| All requirements | January 1, 2019 |

| Alberta | Phase Deadline |
|---|---|
| Phase 1 | July 1, 2018 |
| Phase 2 | January 1, 2019 |
| Phase 3 | Not yet approved by Council. |

| Manitoba | Phase Deadline |
|---|---|
| Phase 1 | June 1, 2018 |
| Phase 2 | June 1, 2019 |
| Phase 3 | January 1, 2021 |

| BC Proposed Phases | |
|---|---|
| Phase | Deadline |
| Phase 1 | November 2017 |
| Phase 2 | May 2019 |
| Phase 3 | May 2020 |
| Phase 4 | May 2021 |

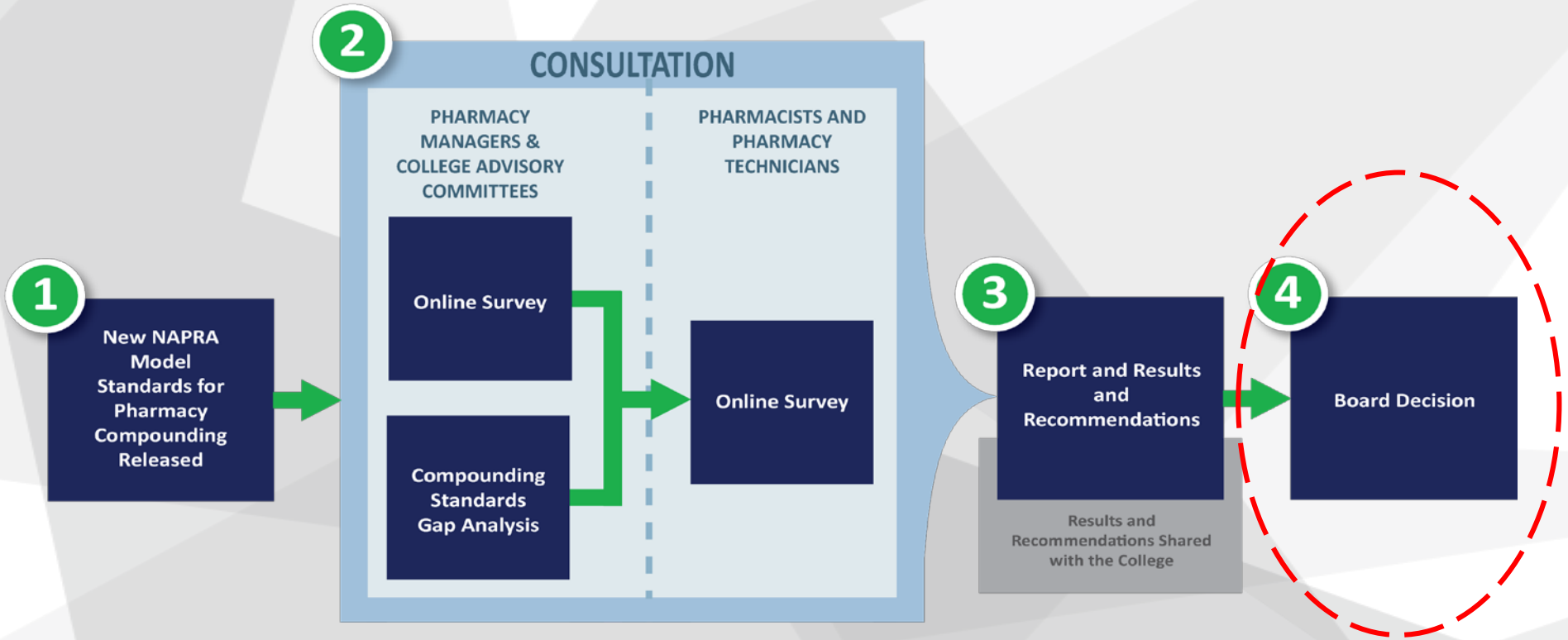
College of Pharmacists of British Columbia

# Existing Bylaws and PPP's

- The existing compounding bylaws and policies will remain in place until the implementation deadline of May 2021 (i.e., after the four-year implementation period is complete).
- Some existing compounding references in the College's PPPs are outdated.
- With approval from the Board, new bylaws to adopt the Model Standards will be drafted to be effective as of May 2021, and all existing references will be repealed at that time.

College of Pharmacists of British Columbia

# Engagement Process Next Steps



College of Pharmacists of British Columbia

# Questions

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# Compounding – Implementation Plan

**MOTION 1:**

Approve the four-year implementation plans to adopt the *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations* and the *Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations*, with the following recommended phases:

- Phase 1 (gap analysis and site plan, personnel conduct): November 2017
- Phase 2 (personnel training, policies and procedures): May 2019
- Phase 3 (beyond-use dates, verification of facilities): May 2020
- Phase 4 (facility infrastructure): May 2021

College of Pharmacists of British Columbia

# Compounding – Implementation Plan

**MOTION 2:**

Direct the Registrar to draft bylaws to adopt the *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations* and the *Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations*, to be effective for May 2021, which will officially establish minimum requirements to be applied in compounding sterile preparations.

College of Pharmacists of British Columbia

# BOARD MEETING
# April 21, 2017

## 4. Legislation Review Committee
## b) Compounding – Implementation Plan

## DECISION REQUIRED

### Recommended Board Motions:

1. Approve the four-year implementation plans to adopt the *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations* and the *Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations*, with the following recommended phases:

    - Phase 1 (gap analysis and site plan, personnel conduct): November 2017
    - Phase 2 (personnel training, policies and procedures): May 2019
    - Phase 3 (beyond-use dates, verification of facilities): May 2020
    - Phase 4 (facility infrastructure): May 2021

2. Direct the registrar to draft bylaws to adopt the Model Standards, to be effective for May 2021, which will officially establish minimum requirements to be applied in compounding sterile preparations.

### Purpose

To seek approval for the four-year implementation plans to adopt the *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations* and the *Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations,* and to direct the Registrar to draft bylaws to officially adopt them (effective May 2021).

### Background

Compounding, in respect to a drug, is defined as mixing together of one or more other ingredients[1]. Evolving practice and increased awareness of the inherent dangers of compounding sterile preparations for the health of both patients and compounding personnel, led the National Association of Pharmacy Regulatory Authorities (NAPRA) to develop a suite of

[1] http://www.bclaws.ca/civix/document/id/lc/statreg/417_2008

new model standards for pharmacy compounding. These model standards will set national standards for pharmacy compounding, and are expected to be adopted by pharmacy regulatory authorities across Canada.

NAPRA recently released two of the three model standards documents for pharmacy compounding. The two released documents are: *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations*[2] and *Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations*[3] (the Model Standards). The final document for non-sterile preparations is expected to be released later in 2017. The release of all three model standards documents will replace NAPRA's Guidelines to Pharmacy Compounding (2006), which was adopted by the Board in 2010.

The Model Standards have been adapted from standards originally developed by the Order of Pharmacists in Quebec, which in turn are based on the General Chapter of the United States Pharmacopeia – National Formulary (USP). The USP standards amongst others (i.e., the Canadian Society of Hospital Pharmacists) are the existing standards of practice for sterile compounding in community and hospital pharmacies in British Columbia. See Appendix 1 for a summary of the existing standards of practice for pharmacy compounding, as referenced in College bylaws and professional practice policies.

The Model Standards will come into effect in each province/territory once they have been adopted by the respective provincial/territorial pharmacy regulatory authorities.

## Discussion

The College of Pharmacists of BC has explicit bylaw making authority to establish standards, limits or conditions for the practice of pharmacy.[4] It cannot "simply" adopt the standards established by another organization. Therefore, in order to adopt standards created by another body such as NAPRA, due diligence is required to ensure that the NAPRA Model Standards are appropriate for BC. Accordingly, Dana Lyons, a subject matter expert in compounding, was

[2] http://napra.ca/Content_Files/Files/Mdl_Stnds_Pharmacy_Compounding_NonHazardous_Sterile_Preparations_Nov2016_Revised.pdf

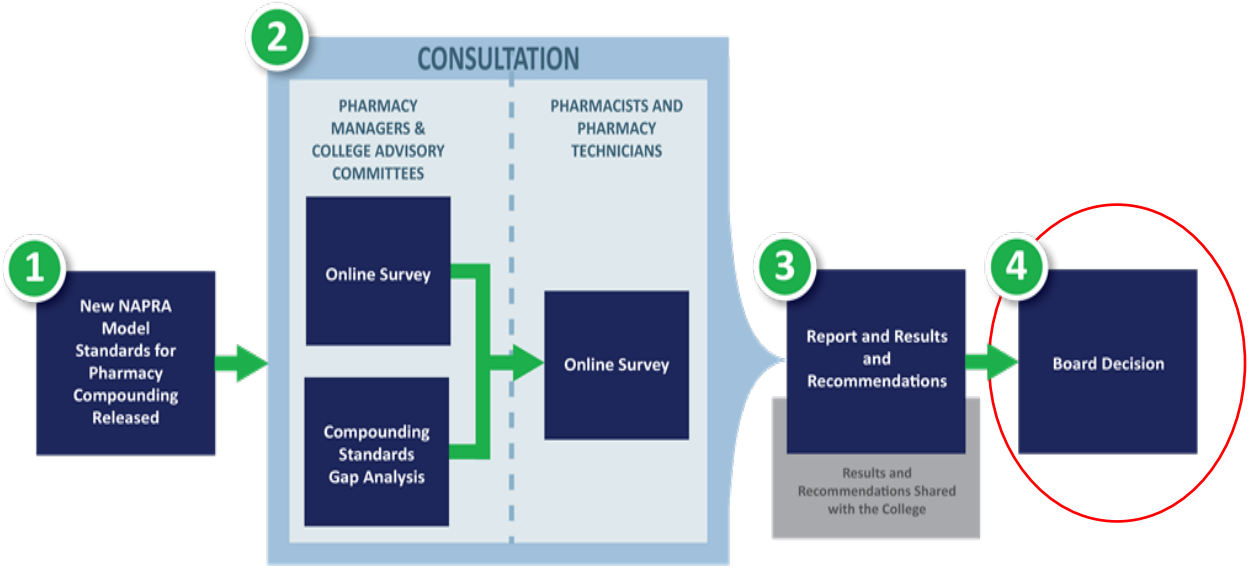
[3] http://napra.ca/Content_Files/Files/Mdl_Stnds_Pharmacy_Compounding_Hazardous_Sterile_Preparations_Nov2016_Revised.pdf

[4] *Health Professions Act*:
19(1) A board may make bylaws, consistent with the duties and objects of a college under section 16, that it considers necessary or advisable, including bylaws to do the following:
(k) establish standards, limits or conditions for the practice of the designated health profession by registrants;

contracted by the College to recommend a plan for adoption and implementation of the two released Model Standards in BC.

Dana Lyons is a registered with the Alberta College of Pharmacists as a Pharmacy Technician, and is a specialist in implementation and management of sterile compounding processes and validation. Ms. Lyons is currently leading the implementation of these standards in pharmacies across Alberta.

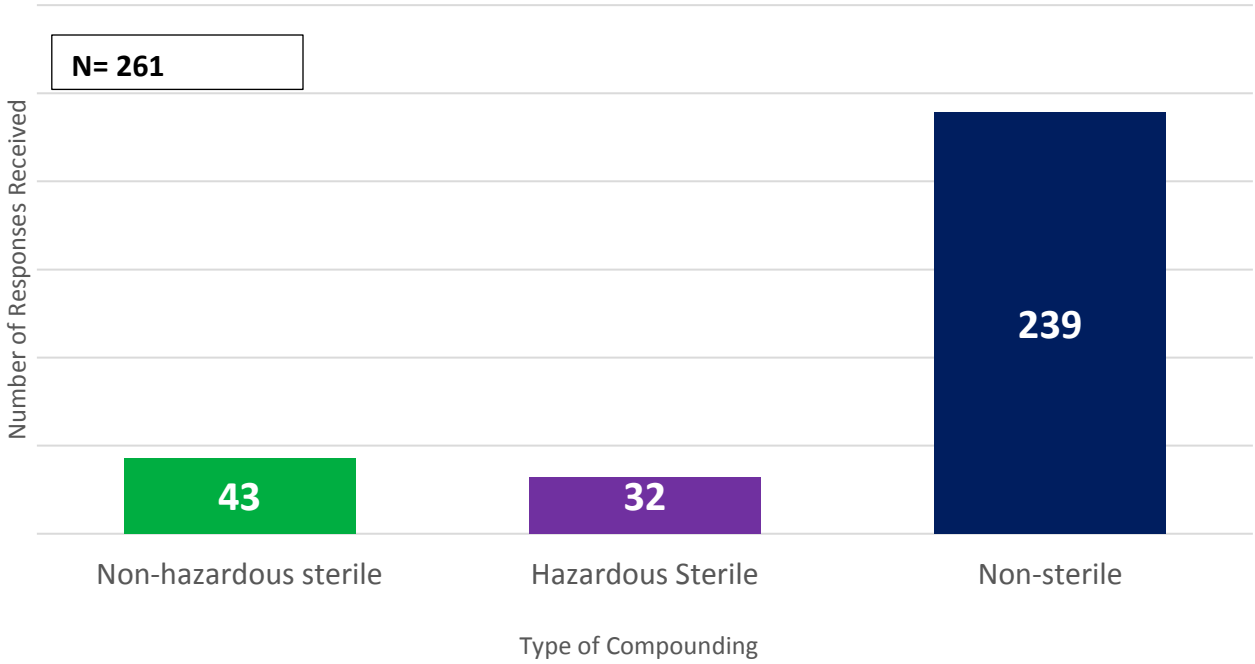
**Consultation and Engagement**
To inform the adoption and implementation of the two released Model Standards, a multi-step engagement process was developed (see below).




The first step of this process was reaching out to pharmacy managers through an online survey to determine how many pharmacies (community and hospital) are engaged in non-hazardous sterile compounding, hazardous sterile compounding and non-sterile compounding. There was a total of 261 responses received to this survey.

The responses received suggest that most pharmacies compound non-sterile preparations (over 90% of responses received indicated that they compound non-sterile preparations). Also, from the responses received, it can be noted that more non-hazardous sterile compounding takes place than hazardous sterile compounding. Please note that pharmacies can be involved in any combination of the three types of compounding. For example, a pharmacy could be engaged in non-hazardous and non-sterile compounding. Chart 1 below illustrates the results of the survey responses.

Chart 1: Summary of Survey Results for Types of Compounding




Following this survey, a Gap Analysis Survey was developed to determine any gaps in practice in meeting the minimum standards in the Model Standards. The Gap Analysis Survey included a series of questions developed from the required minimum standards described in the Model Standards. The Tool was sent out to pharmacy managers, pharmacists and pharmacy technicians to determine how their current-day practice meets or does not meet the standards indicated in the Model Standards.

**Gap Analysis Results**

The questions in the Gap Analysis Survey for the Model Standards (non-hazardous sterile compounding) included the standards in the document which used mandatory language (i.e., "must" and "shall"). Based on the responses received, the self-reported compliance with these standards was 48%. This means that the current gap in meeting them is 52%.

The results from the Gap Analysis Survey for the Model Standards (hazardous sterile compounding), indicated that the self-reported compliance with the mandatory standards in the document to be 54%. Therefore, the current gap in meeting them is 46%.

The second step of the consultation process involved an in-person engagement session with those pharmacy managers, pharmacists and pharmacy technicians, who an expressed interest in attending a consultation, during the online survey noted above. This step included a review of the gap survey results and a workshop-style session where each participant was placed in a

small group and worked through a series of questions developed to understand where potential barriers and challenges to meeting the Model Standards may exist.

The third step was to engage more broadly with pharmacy managers, pharmacists and pharmacy technicians who are involved in compounding sterile preparations (non-hazardous and hazardous). To do this, a survey was developed for each of the Model Standards. The survey was designed to understand what knowledge gaps front-line compounders might be facing and also to understand challenges and barriers from their perspective.

**Barriers Brought Forward in In-Person Engagement and Surveys**

In both the engagement and survey, the top barrier to implementing the Model Standards was the cost of compliance. It was raised that the Model Standards will require some organizations to renovate pharmacies to meet the new minimum standards. The proposed four-year phased implementation plans will allow for at least two budgeting cycles to occur while these standards to be implemented, to address the capital infrastructure cost concerns.

Another identified barrier to implementation is specific to the beyond-use dates (BUD)[5]. The Model Standards require a more stringent way of assigning a BUD. It was raised that this could result in drug wastage and costs to patients, as the BUD setting in the Model Standards may be shorter than how they are currently set. Existing standards referenced in the College's bylaws do permit a less stringent approach; however, the approach included in the Model Standards is consistent with USP standards, which are also referenced in the College's bylaws.

The results of the Gap Analysis Surveys, engagement session and surveys informed the recommendations, timelines and mitigation strategies for successful implementation of the Model Standards, in Ms. Lyons reports which are in Appendix 2 and Appendix 3.

**Proposed Implementation Plans**

A four-year phased implementation is recommended for both Model Standards. The recommended deadlines for each phase are as follows:

- Phase 1: November 2017
- Phase 2: May 2019
- Phase 3: May 2020
- Phase 4: May 2021

[5] Beyond-use date (BUD): Date and time after which a compounded sterile product cannot be used and must be discarded (because of a risk of loss of sterility); assigned based on risk of contamination.

Each phase includes specific groupings of standards from the Model Standards (see table below and Appendix 2 and 3, for further details).

| Phase 1 | Phase 2 | Phase 3 | Phase 4 |
|---|---|---|---|
| • Define compounding risk level<br>• Complete gap survey and prioritize a site plan<br>• NAPRA standards:<br>- 6.3 (compounded sterile preparation log)<br>- 6.4 (patient file)<br>- 6.5 (personnel)<br>- 6.6 (aseptic compounding of sterile preparations)<br>- 6.7 (packaging)<br>- 6.8 (storage)<br>- 6.9 (transport and delivery of compounded sterile preparations)<br>- 6.10 (recall of sterile products of final compounded sterile preparations) | • NAPRA standards:<br>- 5.1 (personnel)<br>- 5.2 (policies and procedures)<br>- 5.4 (maintenance log)<br>- 6.2 (compounded sterile preparation protocols) | • NAPRA standards:<br>- 6.1 (beyond-use date)<br>- 6.11 (incident and accident management)<br>- 6.12 (waste management)<br>- 7.1 (program content)<br>- 7.2 (results and action levels)<br>- 7.3 (verification of equipment and facilities)<br>- 7.4 (quality assurance of personnel)<br>- 7.5 (quality assurance of compounded sterile preparation)<br>- 7.6 (documentation of quality control activities) | • NAPRA standard 5.3 (facilities and equipment) |

**Status of Other Provinces that have Adopted the Model Standards**

The two released Model Standards have been adopted by five other provincial pharmacy regulatory authorities (AB, ON, MB, NS, and NL) to date. AB, ON and MB have adopted the Model Standards through multi-year implementation phases. Appendix 4 lists the provinces

that have adopted the Model Standards to date and their implementation deadlines, as applicable.

**Bylaws Amendments Needed to Adopt the Model Standards**

The College's existing bylaws and policies (Appendix 1) will remain in place until the implementation deadline of May 2021 (i.e., after the four-year implementation period is complete). It should be noted that some of the existing references to compounding standards in the College's Professional Practice Polices are outdated references. However, updating them at this time would lead to further confusion for registrants given that the goal is for them to work towards meeting the Model Standards. Therefore, with approval from the Board, new bylaws to adopt the Model Standards will be drafted to be effective as of May 2021, and all existing references will be repealed at that time.

## Next Steps

- Develop bylaws to come into force by May 2021 and repeal existing standards referenced in bylaws and policies, as of that date (will be brought forward to a future Board meeting for approval).
- Develop communications to continually inform and notify registrants of the implementation phases and their respective deadlines.
- Compliance Officers assess the implementation of the Model Standards according to the phases in the implementation plans, through the Practice Review Program. As the bylaws are not to be in effect until 2021, Compliance Officers would only monitor and inform registrants of any instances of non-compliance. The bylaws would not be legally enforceable until 2021.

## Recommendation

The Board approve the implementation plans to adopt the Model Standards (non-hazardous and hazardous sterile preparations) and to direct the Registrar to draft bylaws adopting them.

| **Appendix** | |
|---|---|
| 1 | Existing College Sterile Compounding Standards |
| 2 | Report on Non-hazardous Model Standards Implementation |
| 3 | Report on Hazardous Model Standards Implementation |
| 4 | Other Jurisdictions that have Adopted the Released NAPRA Model Standards |

# Existing College Minimum Standards for Pharmacy Compounding

## Community

*Existing Policy*
*PPP-64 Guidelines to Pharmacy Compounding*. This policy states that the College of Pharmacists of BC adopts the NAPRA Guidelines to Pharmacy Compounding (2006) as the Standard of Practice for registrants.

## Hospital

*Existing Policies*
*PPP-61 Hospital Pharmacy Published Standards*. This policy states that sterile products must be prepared in accordance with two CSHP Official publications – Guidelines for Preparation of Sterile Products in Pharmacies and Handling and Disposal of Hazardous Pharmaceuticals (including cytotoxic drugs).

*PPP-57 Standards for Pharmacy Assistant Verification of Sterile Products in Hospital Pharmacy Practice*. This policy outlines what can be delegated to pharmacy assistants regarding sterile compounding.

*Existing Bylaws*
Health Professions Act – Bylaws Schedule F (Part 2 – Hospital Pharmacy Standards of Practice) under the Drug Distribution section 3(3) is the following statement:

> **Sterile products must be prepared and distributed in an environment that is in accordance with:**
> 1. The CSHP Guidelines for Preparation of Sterile Products in Pharmacies.
> 2. The USP Pharmaceutical Compounding – Sterile Products Guidelines, and
> 3. Such other published standards approved by the Board from time to time

Health Professions Act – Bylaws Schedule F (Part 2 – Hospital Pharmacy Standards of Practice) under the Drug Distribution section 3(4) is the following statement:

> **Hazardous drugs** must be handled and prepared in accordance with the Requirements for the Safe Handling of Antineoplastic Agents in Health Care Facilities published by the Workers Compensation Board of British Columbia and such other published standards approved by the board from time to time.

# Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations Engagement Summary and Recommendations

## Consultation and Implementation Approach

Part 1 of 2

This report is part 1 of the consultation reports. Part 2 is a report for Hazardous Sterile Preparations.


### Abstract

This report and the seven recommendations within was completed with the engagement and consultation of pharmacy registrants. This report (part 1), and part 2 together, are intended to inform and support implementation for all sterile compounding activities in the province of British Columbia.



Dana Lyons RPhT

September 2016

# Table of Contents

# Executive Summary

In light of the new NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations (NAPRA), and the historically ineffective nature of voluntary guidelines, it was likely that some form of enforceable sterile compounding standards similar to those in the United States would come into place in Canada. Despite a growing awareness of the importance of good sterile compounding practices, there remains a troubling disconnect between practice guidelines and actual practice. Developing an effective compounding strategy is critical to ensuring patients have access to properly compounded medications, but because each organization's needs differ, a one-size-fits-all solution cannot be applied to every hospital practice environment where compounding takes place. The responsibility to plan and become compliant involves facility infrastructure to changing historic personnel practices and cleaning routines.

Consultation with registrants including leaders and managers, frontline pharmacists and pharmacy technicians who compound in both hospital and community resulted in seven recommendations. Out of those seven recommendations is the proposed plan to adopt NAPRA Model Standards in four phases. Each phase has key NAPRA requirements attached to it with specific timelines.

To ensure we achieve compliance it is recommended that we measure compliance as we implement the four-phase model with completion of the phases targeted for May 2021.

Of a pharmacy professional's countless responsibilities, perhaps none is more critical to positive patient outcomes than ensuring patients receive safe medications, compounded according to established standards.

## 1.0 Scope

The scope of this initiative is to review what the current policies, standards and bylaws are that guide sterile compounding practices in hospital and community pharmacy in the province of British Columbia. This work includes a confirmation and review of what current state practice is and the potential gaps in practice. Pharmacy leaders have been engaged and consulted for recommendations on implementation timelines of the NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations. As well, sought input from these leaders on challenges and barriers to implementation balanced with potential ideas to overcome these challenges to fully understand the whole compounding picture. The data gathered was used to put forward recommendations, timelines and mitigation strategies for successful implementation of the NAPRA Model Standards in British Columbia.

## 2.0 Current Bylaws and Practice Guidelines

### 2.1 Community Pharmacy

The policy documents in place to guide sterile compounding practice in the Community Pharmacy setting include:

I. Professional Practice Policy – 64 (Guidelines to Pharmacy Compounding)

The following key statement is found within this policy: ***The Board of the College of Pharmacists of BC adopts the NAPRA Guidelines to Pharmacy Compounding as the Standard of Practice for registrants.***

The NAPRA document referenced in the Professional Practice Policy is based on eight performance indicators.

1. Knowledge and expertise to compound
2. Confirm the need to compound
3. Access to equipment
4. Quality ingredients
5. Labelling
6. Suitable containers
7. Storage
8. Documentation checking, duplicating and tracing.

Within this NAPRA 2006 document, there are three key points specific to sterile compounding practice and they are:

1. Pharmacists engaging in sterile compounding should be knowledgeable and obtain specialized technical training in this area.
2. Carefully established standards for the operation of cleanrooms and the preparation of sterile products should be documented in accordance with a recognized source. (E.g. Canadian Society of Hospital Pharmacists) (CSHP).
3. Sterility testing shall be done according to a clearly defined standard (E.g. United States Pharmacopeia) (USP) and the product assigned an estimated expiry date.

**2.2 Hospital Pharmacy**

**The policy documents that currently guide the compounding practices in hospital pharmacy are:**

I. Professional Practice Policy – 61 (Hospital Pharmacy Published Standards)
II. Professional Practice Policy – 57 (Standards for Pharmacy Assistant Verification of Sterile Products in Hospital Pharmacy Practice)

Within the professional practice policy documents, the following statement can be found: **Sterile Products must be prepared in accordance with the published standards noted below:**

1. CSHP Official Publications – Guidelines for Preparation of Sterile Products in Pharmacies
2. CSHP Official Publications – Handling and Disposal of Hazardous Pharmaceuticals (including cytotoxic drugs)

**Bylaw documents for Hospital Pharmacy include**:

I. Health Professions Act – Bylaws Schedule F (Part 2 – Hospital Pharmacy Standards of Practice)

Within the Health Professions Act – Bylaws Schedule F (Part 2 – Hospital Pharmacy Standards of Practice) under the Drug Distribution section 3 is the following statement:

> **Sterile products must be prepared and distributed in an environment that is in accordance with:**
>
> 1. The CSHP Guidelines for Preparation of Sterile Products in Pharmacies.
> 2. The USP Pharmaceutical Compounding – Sterile Products Guidelines, and
> 3. Such other published standards approved by the Board from time to time

**CSHP Guidelines**

The CSHP Guidelines for Preparation of Sterile Products in Pharmacies was published in 1996. The scope of this guideline was intended to be used in situations where pharmacies are involved in the preparation of sterile products for patients (e.g., hospitals, community pharmacies, nursing homes, home health care and others). This document was retired in 2014 after the CSHP guideline was published.

**USP Chapter <797> Standards**

The other choice for published guidelines referenced in the bylaws and currently the standard in British Columbia is USP Chapter <797> Pharmaceutical Compounding – Sterile Preparations. Chapter <797> was first published in 2004 and has specific requirements for the following areas:

- Design of the Facility
- Environmental and Engineering Controls
- Environmental Testing
- Personnel Training and Competency Testing
- Standard Operating Procedures and Documentation
- Quality Assurance
- Patient Monitoring and Adverse Events Reporting
- Storage and Dating

The aspects of compounding and the minimum requirements to perform this regulated task safely should be the same in all pharmacy practice settings. Therefore, the current bylaws and standards guiding sterile compounding in Community and Hospital practice must be the same.

**Recommendation #1**

The College creates Bylaws and Professional Practice Policies that guide the act of sterile compounding for any pharmacy registrant including the location where sterile compounding is taking place.

## 3.0 Current State of Compliance with Bylaws and Professional Practice Policies

The College protects public health by registering and regulating pharmacists and pharmacy technicians and the places where they practice. For hospital practice, College Inspectors review compliance approximately every three years and for community pharmacy inspections occur on a six-year cycle.

### 3.1 Community Pharmacy Compliance

Community pharmacy inspections do not currently include any sterile compounding-related practice or premise.

### 3.2 Hospital Compliance

Inspectors use a checklist for the many different practice areas they are reviewing in one visit. The criteria for sterile compounding compliance consists of twenty-three points.

Compliance with current standards appears to be lagging. One assumption may be that the inspection criteria is missing practice-related questions. Currently, the inspector's checklist is focused on the facility requirements and not the practice side of sterile compounding.

Other noted deficiencies with the inspector's checklist is the lack of quality assurance checks, in particular, beyond-use dates and environmental monitoring of all components required in the current USP <797> document. With the newly regulated status of pharmacy technicians, this might be an opportunity to review and improve the criteria for compliance.

**Recommendation #2**

Inspector checklists for sterile compounding should include a balance of the many components of sterile compounding including facility design, personnel metrics and quality assurance indicators.

## 4.0 Consultation and Engagement

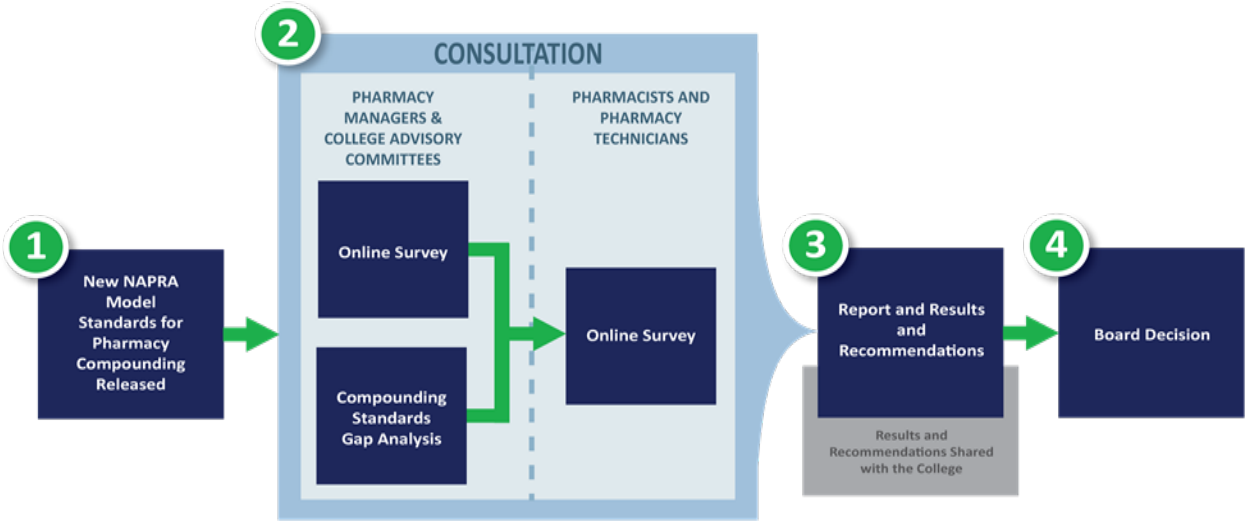
### 4.1 Method

A multi-step consultation process was designed to reach the many stakeholders including, leaders and pharmacy managers, as well as front-line pharmacists and pharmacy technicians all impacted by the change in sterile compounding standards.

The first step was to consult and engage with registrants who are leaders or managers and operate facilities or pharmacies where sterile compounding takes place. The registrants self-identified and chose to participate in the consultation session. Using “shall” statements from the NAPRA Model Standards, a 33-question survey on sterile compounding practices was sent to the pharmacy leaders and managers to complete. The second step of the consultation process involved a face-to-face engagement session for those that completed the gap survey. This step included a review of the gap survey results, following which the registrants participated in a workshop-style session where each person was placed in a small group and together worked through eight questions developed to understand where the barriers and challenges might exist. The third step was to engage all compounders who compound sterile preparations. To do this, a nine-question survey was developed. This survey was designed to understand what knowledge gaps front-line compounders might be facing and also to understand challenges and barriers from their perspective.

The results of the consultation session and surveys were used to make the recommendations in this report, understand barriers and identify risks. Mitigation strategies for a successful implementation are also an outcome of the consultation process.

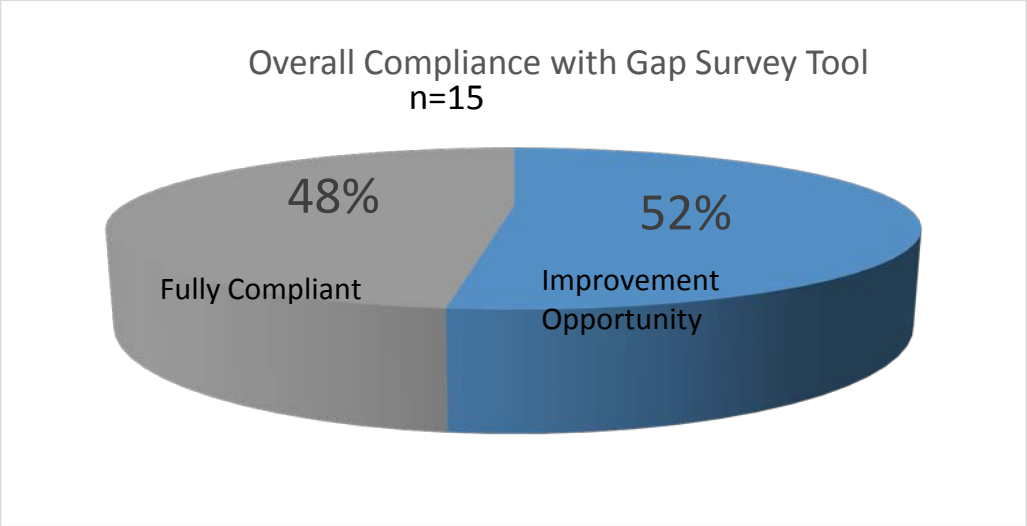
**4.2 Consultation Process**




## 5.0 Practice Gap

When looking at practice gaps, we needed to understand what gap we currently have with current standards, and then how does that gap widen with the introduction of new standards. Using the 33-question gap survey results (n=15), we can start to understand the gap in practice versus NAPRA.

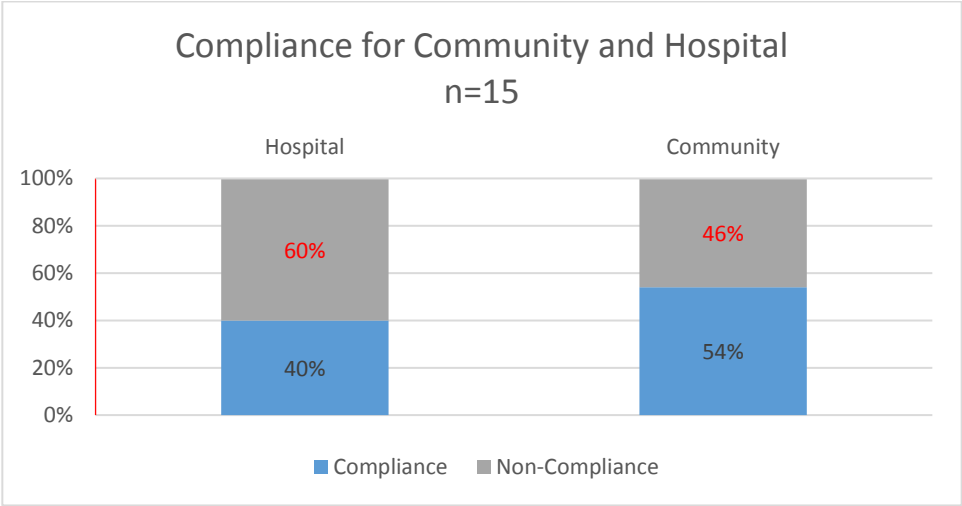
**5.1 Overall compliance with the gap survey tool as self-reported from the participants is 48%.**




**5.2 Hospital versus Community Practice Gap**

When comparing hospital versus community pharmacy compounding environments, we also wanted to know if there is a significant difference in compliance between the two practice environments. Out of the fifteen survey respondents six are hospital and **nine** are community practice-based.

The results from the self-reported gap survey data suggest a slightly higher reported compliance in Community pharmacy practice environments than hospital as shown in the graph below.




## 6.0 New Requirements NAPRA Introduces

**6.1 Competency Assessment Program**

There are a few notable additions that NAPRA introduces with the Model Standards that are not found in USP <797>. The first one being the introduction of the competency assessment programs for the

sterile compounding supervisor along with the third-party evaluation of the supervisor in the NAPRA Model Standards.

*Taken from NAPRA:*

**5.1.2.3 Competency assessment program**

- Sterile Compounding Supervisor shall be evaluated for knowledge and abilities, at the same frequency as compounding personnel by a third party.

**5.1.2.4 Management of the competency assessment program**

- Third Party Evaluator is defined as an evaluator with expertise in sterile compounding, at arm's length from the facility/pharmacy, and free of any real or perceived conflict with the individual being evaluated.

Feedback from the workshop participants indicated that this new addition in the NAPRA model standards would present very few new challenges. Similar responses came up in regards to cost and education/training.

**6.2 Pharmacy Assistants and Compounding**

A second difference with NAPRA and USP 797, is the mention of specific personnel involved in compounding including pharmacy assistants and pharmacy technicians.

*Taken from NAPRA 5.1.1.3*

"A pharmacy assistant with appropriate training, who prepares sterile preparations or performs other technical tasks related to sterile compounding only when assigned to do so by the sterile compounding supervisor and only after completion of a formal delegation of duties from a pharmacist to the pharmacy assistant, in compliance with the requirements of the provincial/territorial authority."

Feedback from survey respondents indicated that any change in the use of non-regulated personnel to compound may present some staffing challenges if not enough pharmacy technicians are graduating or available for employment.

**Recommendation #3**

The College bylaws should reinforce restricted activities as outlined in the Health Professions Act.

**Note:** NAPRA has language in the standards that at first read to some may indicate that pharmacy assistants can compound. In British Columbia, this would not apply as the HPA has listed compounding as a restricted activity to pharmacists and pharmacy technicians.

The NAPRA standards are more in-depth and provide clear must/shall statements and cover aspects such as final verification and cleaning protocols. The two standards (USP <797> and NAPRA) are very similar with the general concepts and intent being similar. USP <797> is currently in a revision cycle. With the updated chapter to be released January 2017, further gaps may be introduced as revisions

occur. The revision cycle for NAPRA updates has not officially been released, and this unknown may lead to concerns from registrants.

**Recommendation #4**

The College should seek formal update/revision cycle information from NAPRA to be shared with registrants.

## 7.0 Barriers Registrants Brought Forward to Implementing NAPRA

### 7.1 Knowledge of Standards

Education on current sterile compounding standards may possibly be a barrier for implementation and adoption of the NAPRA Model Standards. In the survey to frontline pharmacists and pharmacy technicians, we wanted to assess the general awareness of the NAPRA standards, so we asked the question: Are you aware that NAPRA published new Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations in November 2015? Out of 160 respondents 33.8% were not aware of the NAPRA Model Standards. Of the 66.2% of respondents that were aware of the NAPRA Model Standards we learned that respondents are *least likely* to have heard about these new standards from their employer and out of the 31 comments for "other" sources, 30% of the respondents in that category indicated that they learned of the NAPRA Model Standards through College communications.

### 7.2 Cost Constraints

Healthcare dollars are scarce and renovation budgets are planned years in advance. The full cost of implementing sterile compounding standards is not known, as the starting point is different for every facility. The cost of compliance is the top barrier to implementation as reported by 28% of survey respondents.

**Mitigating strategy**

The four-phase, four-year approach to NAPRA adoption and compliance should address most of the cost increases as they will be absorbed incrementally over time. The proposed implementation plan should also include the budget and infrastructure cycles heath authorities work within.

### 7.3 Beyond-Use Dates (BUD)

The BUD in NAPRA is based on the risk that a compounded sterile preparation (CSP) may have been contaminated. Traditionally, before newer standards were published, pharmacy practice was to use drug stability information to determine the expiry date of the CSPs. The introduction of USP <797> changed the way BUDs are applied using drug stability plus sterility to determine the safest BUD. In consultation with the leaders and managers, they revealed that the negative impact could include the following: increase in drug wastage, delivery costs and costs to patients, staffing time, and repetitive strain injuries.

Respondents from the survey indicated that **55.8%** are assigning CSPs a BUD of greater than the 14-day refrigerated maximum. One respondent had the following comment *"Patients will find it next to impossible to access their compounds and the price will be prohibitive."*

**Mitigating strategy:**
Continue to reinforce and inform registrants of the need to change practice when applying BUDs to CSPs.
Note: The requirement of shorter BUDs is not a new concept or a new standard for BC pharmacies. Best evidence is to apply a BUD to a compounded product that takes into consideration the stability and sterility. This is not a deviation from USP <797> and is a patient safety factor.

### 7.4 Change Management

#### 7.4.1 Communication Strategy

Communications are a critical part of the change process. This plan articulates key messages that need to go to various impacted audiences. From the engagement workshop with leaders and feedback from the survey respondents, the change effort required to ensure the standards are adopted in a timely manner is a concern and many respondents cited this as a barrier to implementation.

This change requires multiple stakeholders within the industry to ensure they can meet any new demands, including from within the highest levels of Government and hospital executives to ensure funds are released when hospital pharmacy infrastructure requires updating.

Practice change and behaviour change, both of which are required to ensure our compounding practices are robust and safe, take resources and can be rate-limiting steps. A change effort of this magnitude requires proper planning, a solid methodical approach and leadership who believe this effort is of top importance and will move it forward. Leaders will be required to communicate this change to senior executives and to frontline staff. The College can play a role by developing a communication strategy that reaches stakeholders and frontline staff.

**Recommendation #5**
The College is to develop a communication plan to include messaging that hospital administrators and other leaders can use to help the change effort move forward.

#### 7.4.2 Changing Behaviours

As the old cliché goes "what gets measured gets done". The message is clear: measuring something gives you the information you need in order to make sure you actually achieve what you set out to do. Asking our staff to show up prepared to compound, with no make-up, no nail extensions and in proper attire is one of the lowest cost changes we will be asked to comply with.

Simply asking compounding personnel to make these personal changes may not be robust enough. In fact, results from the gap survey taken revealed we have more work to do.

## 8.0 Risks

There are inherent risks in any change initiative, there are also risks if we decide not to remain status quo. In consulting with leaders and managers of compounding environments, we wanted to know what kinds of risks could surface if NAPRA Model Standards were adopted too quickly and, conversely, too slowly. The results from the participants are listed below.

### 8.1 Risk of Adopting NAPRA too Quickly

1. Facilities will fail
2. Confidence in the College will fall
3. Supply issues
4. Overwhelm frontline staff
5. Loss of economies of scale
6. Patient access to CSPs will be restricted
7. Compounding could be outsourced to less compliant provinces
8. Opportunity to train and gain knowledge may be lost

### 8.2 Risk of Adopting NAPRA too Slowly

1. Risk to public safety
2. Risk to staff
3. Loss of momentum
4. Loss of public respect
5. Standards will continue to change

There are challenges with adopting too fast or too slow. With adopting too quickly, the potential for errors of any kind are present, and this is risky for leadership. It is often less disruptive and less stressful if change occurs slowly; however, the real risk presents itself if adoption occurs too slowly and that is the risk to the public and public respect of the pharmacy profession to provide safe preparations.

## 9.0 Implementation Strategy

During the engagement workshop, participants were asked to provide their ideas on a phased in approach along with suggested timelines for achieving compliance with the phases. The participants were also asked to suggest an all-at-once implementation compliance date. Using the dot voting technique, participants were asked to place their dots on a phased in approach or an all-in-one approach that they believe represented the best option.

*The phased in approached received the majority of the votes along with one particular design of a phased in approach where the main components of compliance were divided into four phases.*

Based on the need to balance implementation and mitigate risks with an approach that is not too fast or too slow, the four-phase model for implementation is a good balanced approach. All of the various models suggested by participants for implementation are in appendix D and the most desirable model presented in table 1.

**Table 1 Most Desirable Option for Compliance**

| Phase | Compliance Component | Date of Expected Phase Compliance |
|---|---|---|
| Phase 1 | Hand Hygiene and Garbing | December 2016 |
| Phase 2 | Cleaning and Disinfecting, | December 2017 |
| | Training and Assessment | |
| | Policies and Procedures | |
| Phase 3 | Quality Assurance and Environmental Monitoring | December 2018 |
| | Media Fill and Fingertip Sampling | |
| Phase 4 | Facilities and BUD | December 2019 +++ |

**Recommendation #6**

**Phased-in Approach**

The implementation of NAPRA Model Standards requires a balanced approach, focused firstly on protection of the public and yet achievable for compounders and organizations. The four-phase approach should be undertaken with a timeline of four years plus a notification period to registrants.

## 10.0 Trends in Compliance

### 10.1 Canadian Compliance

Currently, there is no mechanism to trend compliance with compounding standards in Canada. A national compliance survey tool is not available or developed in Canada, although CSHP is working on a compliance tool that will be based on the newly released CSHP: Guidelines for Pharmacy Compounding (2014). The lack of a national gap tool using the NAPRA Model Standards must and shall statements, makes measuring overall compliance or even site-specific compliance trends nearly impossible.

### 10.2 Past Compounding Trends in Canada

A survey, sent to hospital pharmacies in 2009, was done to compare the extent of compounding compliance during the period from 1993 to 2009. During that time frame, the 1996 CSHP *Guidelines for Preparation of Sterile Products in Pharmacies* had been published for over a decade and USP <797> had been out for five years.

**10.2 United States Compliance Trends**

In the United States, a national compliance study is released each year and participants self-report compliance. This study is based on the shall and should statements found in USP Chapter <797> and results are published each year in their journal published on line on their website at this link: www.pppmag.com This survey may provide some insight into how compliance may look for Canada. While our governance is different, there still may be some insights we can learn from these results.

**US Compliance Results 2015**

www.pppmag.com

TABLE 3

## Overall Compliance Trends in Domain Compliance Scores 2011 vs 2015

| Subject Matter Domains<br>Note: Not all domains or items in each domain pertain to all participants | 2011 | 2015 |
|---|---|---|
| Allergen Extracts as CSPs | 87% | 99% |
| Aseptic Technique | 85% | 90% |
| Bacterial Endotoxin Testing | 47% | 32% |
| Beyond Use Dating | 87% | 89% |
| Compounding Facility Management: Airflows and Pressure Differential Monitoring | 50% | 66% |
| Compounding Facility Management: Cleaning and Disinfecting | 68% | 78% |
| Compounding Facility Management: Equipment Calibration | 73% | 75% |
| Compounding Facility Management: Temperature and Humidity Monitoring | 83% | 86% |
| CSPs for Immediate Use | 74% | 79% |
| Depyrogenation by Dry Heat | 80% | 83% |
| Filter Integrity Test | 16% | 33% |
| Final Release Checks | 88% | 90% |
| General Facility Design | 75% | 76% |
| Gloved Fingertip Sampling | 42% | 62% |
| Handwashing and Garbing | 75% | 82% |
| Hazardous Drug Compounding | 71% | 81% |
| Initial and Ongoing Training and Competency Measurement | 74% | 76% |
| Inventory Storage and Handling/Delivery of CSPs | 93% | 94% |
| Low Risk Level CSPs with 12 Hour or Less BUD | 68% | 74% |
| Personnel Media-Fill Challenging Testing | 81% | 81% |
| Primary/Secondary Engineering Controls | 77% | 84% |
| Quality Management: Environmental Sampling Program | 63% | 72% |
| Quality Management: General | 62% | 67% |
| Quality Management: General Viable Air and Surface Sampling Considerations | 56% | 68% |
| Quality Management: Incubation | 59% | 73% |
| Quality Management: Non-Viable Particle Testing | 90% | 92% |
| Quality Management: Surface Sampling- A personnel metric | 57% | 68% |
| Quality Management: Viable Air Sampling- A facility metric | 58% | 75% |
| Radiopharmaceuticals as CSPs | 52% | 70% |
| Single- and Multiple-Dose Vials | 92% | 94% |
| Steam Sterilization | 87% | 88% |
| Sterility Testing | 54% | 58% |
| Sterilization by Dry Heat | 80% | 94% |
| Sterilization by Filtration | 60% | 68% |
| Sterilization Methods | 88% | 86% |
| **Overall Compliance** | **72%** | **80%** |

**Some noteworthy facts:**

- The US has been enforcing compliance since 2008 in some states
- High-risk compounding practices, such as filter integrity, lag in improvements at only 33% compliance.

We have heard many news stories of improper compounding practices, most notably, the New England Compounding Center (NECC) tragedy of contamination in sterile compounds in the US. Yet, with enforceability and patient safety stories, the data indicates there may still be pockets of change resistance or lack of urgency to comply.

## 11.0 High-Risk Compounding

High-risk compounding as defined by NAPRA is when **any** of the three criteria are in play:

1. Non-sterile ingredients or equipment used before terminal sterilization
2. Non-sterile preparations, containing water, stored for more than 6 hours before terminal sterilization
3. Improper garbing or gloving by compounding personnel

Knowing the risk is inherently higher in high-risk compounding begs the question of whether high-risk compounding practices should be brought to the minimum standard in a speedier timeline. The following question was posed to the workshop participants:

**High-Risk Compounding requires rigorous processes that are validated. For pharmacies that are compounding high-risk compounds or plan to continue, answer the following questions:**

A. **Should these pharmacies be required to fully comply with NAPRA sooner than sites that are not engaged in high-risk compounding?**

B. **If" no" why, if" yes" suggest a date for full compliance for high-risk compounding facilities.**

The participants had limited feedback. The feedback was equally split, half of the comments suggested pharmacies should meet the minimum requirements sooner, and half felt that compliance for consistency not be expedited. One could assume a couple things. The participants are not engaged in high-risk compounding and, therefore, had less of an opinion. Or, perhaps, there is a knowledge gap on what high-risk compounding is. To further understand high-risk compounding and who is engaged in this activity we asked the front-line pharmacists and technicians if their site is engaged in high-risk compounding and **29.5%** of respondents indicated that high-risk compounding occurs in their pharmacy.

**Does your pharmacy prepare high-risk compounding?**

| Response | Chart | Percentage | Count |
|---|---|---|---|
| Yes, we prepare high-risk products. |  | 29.5% | 46 |
| No, we do not prepare high-risk products. |  | 70.5% | 110 |
| | **Total Responses** | | **156** |

The potential for high-risk compounding to have adverse outcomes for our patients is greater due to the complexity and the additional requirement to ***sterilize*** the preparation, whereas the majority of

compounding is around ***maintaining asepsis***; this is the distinct fundamental difference between high-risk sterile compounding and low and medium-risk sterile compounding. Contamination is highly probable if our sterilization processes are inadequate or ineffective.

In my experience, the majority of high-risk preparations that require sterilization are sterilized using a 0.22 micron sterilizing grade filter. In order to confirm the filter performed as required, one must perform a simple *filter integrity test* sometimes known as a *bubble point test*. Looking at the US compliance report shared earlier, it notes only 33% compliance with the filter integrity test. This is alarming and we have to wonder, how are we doing with high-risk compounding in BC?

**Recommendation # 7**

The College should initiate a survey to all compounding facilities who perform high-risk compounding to get a sense of practice and risk and create a list of compounding sites engaged in this activity. A compliance tool for high risk compounding should also be developed.

## 12.0 Conclusion and Implementation Recommendations and Timelines

The adoption of the NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations will take time, money and considerable effort to implement properly and safely. My experience as a process specialist is if you take big initiatives or projects and break them down into attainable chunks of work which can be measured along the way, success of the larger goal will materialize. The phased in model for compliance with the NAPRA Model Standards, which the participants drafted and favored, has been adapted and presented below in the table. The three key sections (5, 6 and 7) in NAPRA have been divided according to the model with proposed timelines.

The adoption of the NAPRA Model Standards by the College of BC Pharmacists, would be in alignment with other provincial regulatory authorities (PRA) such as Alberta and Ontario. There is no reason to exclude any portion of the Model Standards or any reason to adopt partial segments of the chapter. The Model Standards will be in alignment with sterile hazardous and non-sterile compounding model standards which are being released in stages. The Model Standards have gone through extensive pharmacy stakeholder consultation from each PRA and many of the members within the PRA's. Therefore, the recommendation is for BC to adopt the NAPRA Model Standards for non-hazardous sterile compounding as the standard in BC.

## 13.0 Phased in Approach Recommendation and Timelines

| Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations Implementation Plan | | | |
|---|---|---|---|
| **NAPRA ID or page #** | **NAPRA Compliance Area** | **Phase of compliance** | **Proposed compliance date** |
| Step 1 | Define compounding risk level | Phase 1 | November 2017 |
| Step 1 | Complete a gap analysis and prioritize a site plan | Phase 1 | November 2017 |
| 6.3 | Compounded sterile preparation log | Phase 1 | November 2017 |
| 6.4 | Patient file | Phase 1 | November 2017 |
| 6.5 | Conduct of personnel in areas reserved for the compounding of sterile preparations | Phase 1 | November 2017 |
| 6.6 | Aseptic compounding of non-hazardous sterile preparations | Phase 1 | November 2017 |
| 6.7 | Packaging | Phase 1 | November 2017 |
| 6.8 | storage | Phase 1 | November 2017 |
| 6.9 | Transport and delivery of compounded sterile preparations | Phase 1 | November 2017 |
| 6.10 | Recall of sterile products or final compounded sterile preparations | Phase 1 | November 2017 |
| 5.1 | Personnel | Phase 2 | May 2019 |
| 5.2 | Policies and procedures | Phase 2 | May 2019 |

| Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations Implementation Plan | | | |
|---|---|---|---|
| **NAPRA ID or page #** | **NAPRA Compliance Area** | **Phase of compliance** | **Proposed compliance date** |
| 5.4 | General maintenance log | Phase 2 | May 2019 |
| 6.2 | Compounded sterile preparation protocols | Phase 2 | May 2019 |
| 6.11 | Incident and accident management | Phase 3 | May 2020 |
| 6.1 | Beyond-use date and dating methods | Phase 3 | May 2020 |
| 6.12 | Waste management | Phase 3 | May 2020 |
| 7.1 | Program content | Phase 3 | May 2020 |
| 7.2 | Results and action levels | Phase 3 | May 2020 |
| 7.3 | Verification of equipment and facilities | Phase 3 | May 2020 |
| 7.4 | Quality assurance of personnel involved in aseptic compounding | Phase 3 | May 2020 |
| 7.5 | Quality assurance of compounded sterile preparations | Phase 3 | May 2020 |
| 7.6 | Documentation of quality control activities | Phase 3 | May 2020 |
| 5.3 | Facilities and equipment | Phase 4 | May 2021 |

# Appendices

## A. Recommendations for the College

| Recommendation ID | Recommendation(s) |
|---|---|
| 1 | The College should create Bylaws supported by Professional Practice Policies that guide the act of compounding for any pharmacy registrant including the location where sterile compounding is taking place. |
| 2 | Inspector checklists for sterile compounding should include a balance of the many components of sterile compounding including facility design, personnel metrics and quality assurance indicators. |
| 3 | The College bylaws should reinforce restricted activities as outlined in the Health Professions Act.<br><br>Note: NAPRA has language in the standards that at first read to some may indicate that pharmacy assistants can compound. In British Columbia, this would not apply as the HPA has listed compounding as a **restricted activity to pharmacists and pharmacy technicians.** |
| 4 | The College to seek formal update/revision cycle from NAPRA to be shared with registrants. |
| 5 | The College to develop a communication plan to include messaging that hospital administrators and other leaders can use to help the change effort move forward. |
| 6 | Phased in Approach: The implementation of NAPRA Model Standards requires a balanced approach, focused firstly on protection of the public and yet achievable for compounders and organizations. The four-phase approach be undertaken with a timeline of four years plus a notification period to registrants. |
| 7 | The College should initiate a survey to all compounding facilities who perform high-risk compounding to get a sense of practice and risk and create a list of compounding sites engaged in this activity. A compliance tool for high risk compounding should also be developed. |

## B. Survey Questions and Results from Pharmacists and Pharmacy Technicians

Final Results

**I am a...**

| TOTAL RESPONSES | COMPLETED RESPONSES | COMPLETION RATE | COMPLETION TIME |
|---|---|---|---|
| 362 | 362 | 100% | 22:54 |

| Response | Chart | Percentage | Count |
|---|---|---|---|
| Pharmacist |  | 76.8% | 278 |
| Pharmacy Technician | | 23.2% | 84 |
| | | **Total Responses** | **362** |

**1. My pharmacy compounds non-hazardous sterile preparations.**

| Response | Chart | Percentage | Count |
|---|---|---|---|
| Yes |  | 43.6% | 158 |
| No | | 56.4% | 204 |
| | | **Total Responses** | **362** |

**2. Are you aware that NAPRA published new Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations in November 2015?**

| Response | Chart | Percentage | Count |
|---|---|---|---|
| Yes |  | 66.2% | 106 |
| No | | 33.8% | 54 |
| | | **Total Responses** | **160** |

**3. How did you hear about the new NAPRA Model Standards?**

| Response | Chart | Percentage | Count |
|---|---|---|---|
| Employer |  | 29.5% | 31 |
| Colleague | | 34.3% | 36 |
| Other | | 36.2% | 38 |
| | | **Total Responses** | **105** |

**How did you hear about the new NAPRA Model Standards? (Other)**

| # | Response |
|---|---|

| | |
|---|---|
| 1. | PCCA |
| 2. | PCCA |
| 3. | College of pharmacists website |
| 4. | College |
| 5. | compounding companies |
| 6. | email |
| 7. | We are a certified compounding facility that is certified every 6 months. We also heard it from the company certifying us. |
| 8. | PCCA |
| 9. | email from College and Colleagues |
| 10. | CPBC ECTF |
| 11. | hood certification |
| 12. | Reviewing regulatory proposals |
| 13. | internet |
| 14. | Provincial Safe Handling Committee |
| 15. | By following NAPRA, USP regulations |
| 16. | I was aware they were being released in late 2015 |
| 17. | I heard it in one compounding related CE |
| 18. | email blasts |
| 19. | Internet |
| 20. | College committee |
| 21. | PCCA |
| 22. | PCCA compounding course |
| 23. | PTSBC |
| 24. | I work as an instructor |
| 25. | College |
| 26. | conferences |
| 27. | College |
| 28. | College of Pharmacists |
| 29. | college of pharmacists BC |

| | |
|---|---|
| 30. | Aware through activities of work |
| 31. | from PCCA |
| 32. | email from College of Pharmacists of BC |
| 33. | Trade Journal & NAPRA news blast |
| 34. | Colleague and College of Pharmacist committee members |
| 35. | College |
| 36. | College of Pharmacists of BC |
| 37. | College Memo |
| 38. | Representative |

**4. Have you read the new NAPRA Model Standards? Do you use them at your pharmacy?**

| Response | Chart | Percentage | Count |
|---|---|---|---|
| Yes; we use them at my pharmacy. |  | 39.8% | 41 |
| Yes; we don't use them at my pharmacy. |  | 31.1% | 32 |
| No; we use them at my pharmacy. |  | 8.7% | 9 |
| No; we don't use them at my pharmacy. |  | 20.4% | 21 |
| | | **Total Responses** | **103** |

**5. Does your pharmacy follow the beyond-use-dates using the low, medium and high-risk method?**

| Response | Chart | Percentage | Count |
|---|---|---|---|
| Yes, products do not exceed 14 days' fridge dating. |  | 44.2% | 69 |
| No, we do not currently follow beyond-use-dates as outlined. |  | 55.8% | 87 |
| | | **Total Responses** | **156** |

**6. Does your pharmacy prepare high-risk compounding?**

| Response | Chart | Percentage | Count |
|---|---|---|---|
| Yes, we prepare high-risk products. |  | 29.5% | 46 |
| No, we do not prepare high-risk products. |  | 70.5% | 110 |

| | | | |
|---|---|---|---|
| | | **Total Responses** | **156** |

**7. Does your pharmacy provide yearly re-assessments of compounding staff?**

| Response | Chart | Percentage | Count |
|---|---|---|---|
| Yes, compounders are re-assessed at least yearly. |  | 25.0% | 39 |
| No, we have not implemented re-assessments. |  | 75.0% | 117 |
| | | **Total Responses** | **156** |

**8. Does your pharmacy follow robust cleaning procedures?**

| Response | Chart | Percentage | Count |
|---|---|---|---|
| Yes, housekeeping follows this standard. |  | 55.1% | 86 |
| No, housekeeping does not follow this standard. |  | 44.9% | 70 |
| | | **Total Responses** | **156** |

**What barriers, if any, do you anticipate by implementing the NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations? |**

| # | Response |
|---|---|
| 1. | Does the College interpret these standards to mean that Pharmacy Assistants will no longer be permitted to mix? If so, when would the College enforce this requirement?<br><br>We currently do chemo-certification for hazardous drugs. We do not have a process for non-hazardous drugs. Yearly is very difficult to maintain with a larger staff.<br><br>Renovation would be required to meet the standards in this document. What timeframe for compliance would be given?<br><br>Housekeeping standards will be difficult to meet. They do clean daily now, but the walls and ceilings are not done monthly, for example. |
| 2. | Probably the amount of time. Since I work in a hospital we have standards that are set by our health authority. |
| 3. | . |
| 4. | None. |
| 5. | 1) PHARMACARE REIMBURSEMENT. I AM IN FULL AGREEMENT WITH THESE STANDARDS BUT UNLESS PHARMACARE REIMBURSES FOR THE COSTS ASSOCIATED WITH MAINTAINING THESE STANDARDS (IE, GLOVES, GOWNS, STERILITY AND POTENCY TESTING, ENDOTOXIN TESTING, ETC.), IT IS SIMPLY NOT FEASIBLE FOR PHARMACIES TO BILL PHARMACARE FOR REIMBURSEMENT OF THESE COMPOUNDS.<br><br>2) How is the College going to ensure that pharmacies compounding sterile preparations are compliant with the NAPRA guidelines? What sort of training or education programs will College Inspectors undergo so they are equipped with the right tools to inspect sterile compounding pharmacies?<br><br>3) Will the College be accrediting or certifying pharmacies who meet the NAPRA guidelines like in the USA where PCAB accredits compounding pharmacies? |
| 6. | None |
| 7. | Pharmacies with limited space and very little compounding may not follow implemented guidelines |
| 8. | Higher budget required for higher turnover of sterile gloves, bootie-buddy machine, special sprays and wipes for the hood. Training for new employees, current employees will need re-orientation. |
| 9. | No specific barriers have been identified |
| 10. | Nothing to add at the moment |
| 11. | none |
| 12. | Standard training module that can be implemented. |
| 13. | Extra cost for equipment maintenance. |
| 14. | Cost. The margin and volume for sterile compounding in the small community setting does not support some of the major expenditures that are proposed. We offer this as a quick, efficient way for local residents to access treatment, without having to send the Rx to larger centers, and the delays in treatment that will be seen. |
| 15. | cost for training, equipment<br><br>time to implement |

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|---|---|
| | is the system that broken that it needs to be fixed? e.g. has there been compounded medications that have proved hazardous to patients due to improper manufacturing techniques. |
| 16. | Adequate staffing |
| 17. | No barriers |
| 18. | space, financial burdens on retail setting if more equipment needs upgrading, returns may not make it lucrative to compound. |
| 19. | we will no longer sterile compound. Patients will find it next to impossible to access their compounds and the price will be prohibitive.<br><br>imagine a 14-day expiry date on a product. How many times would we expect someone to pay for it? |
| 20. | Buds are too restrictive. Most compounds are singles. Monitoring procedures are too onerous for a community setting |
| 21. | Most store currently "compounding" will no longer be able to provide the service and the public will not understand why, and will go apeshit. |
| 22. | No barriers. I think having more and better standards for non-hazardous compounding is a good thing |
| 23. | None at my pharmacy. Other pharmacies - potentially cost. |
| 24. | Extra work for staff, housekeeping & pharmacy. |
| 25. | staff training, time for record keeping |
| 26. | Not being able to keep up with demand for sterile products because of the requirements (our equipment and budget won't improve in time).<br><br>I foresee patients missing out on valuable products due to regulations and either not receiving therapies entirely or needing to be transferred to higher level of care communities. (Which means increase costs to families and facilities).<br><br>I'm curious to read the stats and data on what has actually harmed patients that we now have to adhere to these new standards.<br><br>Nurses and doctors will continue to prepare sterile products in a non-sterile way, often in environments that are far less controlled and regularly cleaned compared to pharmacy. |
| 27. | Not sure , will haven't review again |
| 28. | I don't see any barriers but educating patient re: shorter beyond use dates raises concern: cost will be number 1. But on the other hand, like our pharmacy we have some of the formulas tested for longer expiry dates and have proper documentation for all BUD's. Hope these exceptions are outlined clearly in the new guidelines. |
| 29. | Too onerous to implement. |
| 30. | 1. Any failure to educate and clearly communicate the new minimum NAPRA standards to ALL personnel involved in the preparation, delivery and administration of sterile products will lead to a deterioration of overall quality and safety: I have seen, first-hand, instances of medium risk sterile products being prepared on a lunch counter by nursing staff who had no patience to wait for pharmacy protocols.<br><br>2. Construction of compliant facilities will present physical and financial challenges in some cases. HVAC for large buildings cannot easily be changed to accommodate the very strict air management requirements in the NAPRA standards. |

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| | 3. Routine facility maintenance, ISO standard testing and training will probably be the most difficult areas to achieve compliance with the NAPRA standard. A significant annual budget is required which is seldom supported by traditional pharmacy budgets or revenue streams. |
| 31. | None, as we are already doing >90% of what is required by NAPRA. With some more investment, we should be at 100% compliance.<br><br>For the safety of patients in BC, the standards need to be implemented ASAP. We have seen too many "fly by night" compounders who think they know what they are doing and are sending out potentially unsafe preparations. As well, they are flouting current expiry and beyond use dates. Others are cutting corners, and undercutting prices to gain market share. This is not in the best interests of patients.<br><br>As well, there are some pharmacies who send one or two staff members to a compounding course and then start compounding, without a clear understanding of what they are doing; as well as the fact that they have not made a proper investment in equipment required. This is not acceptable.<br><br>It has also been brought to our attention that there are certain lower mainland hospital pharmacy departments that are compounding inappropriately, posing a risk to staff, and patients. Their facility/equipment is old, ventilation is inadequate, and proper NAPRA sanitation/cleaning is non-existent. A simple College Audit would identify these deficiencies.<br><br>Thanks for taking on this initiative! |
| 32. | I don't see any for our pharmacy. We are intending to improve our processes, environment until we meet the standards in full. |
| 33. | Time and money |
| 34. | None |
| 35. | following BUD standards will increase workload and no additional funding is available for staffing |
| 36. | None at this time |
| 37. | space<br><br>Time to clean<br><br>Documentation (paperwork burden) |
| 38. | just bringing everyone on board to understand the importance and need for things to be sterile. allot of staff say we have never had a problem before and it is a challenge to change their mind set. always the argument that it is too busy, short staffed so they NEED to cut corners. we are slowly making them understand the importance of proper cleaning of the environment, proper handwashing and garbing of the operator and why the BUD dates have to be shortened.<br><br>we may have never had a problem before but we never tested our products or our staff |
| 39. | Cost of implementing NAPRA standards, both cost in staffing and cost of drugs/shortened expiry<br><br>Development, implementation and consistent adherence of facility/regional P and P to NAPRA standards (i.e.: follow up and/or oversight)<br><br>Possible impact to patient care? Unknown?<br><br>Impact to/on other Pharmacy procedures? |
| 40. | None |
| 41. | The time it will take to do yearly assessments of staff to ensure proper technique. We are professionals and do our jobs professionally. We don't need anyone to come once a year and make sure we are doing our jobs properly! |

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|---|---|
| 42. | n/a |
| 43. | none |
| 44. | workload |
| 45. | Proper technique and formulations require membership with compounding companies. This will increase cost but also guarantee the product produced. There will also be significant expense incurred for compounding equipment and packaging options. The end payer, whether government, insurance companies, or patients must be educated to this fact. |
| 46. | These will conflict with the established USP chapters that govern this type of practice (795, 797, 800). The document allegedly is "final" and yet makes reference to USP chapters that themselves have changed since this NAPRA document began its 4-version journey...only to arrive at something that is now referring to past versions of the USP in specific areas (e.g.: 3 risk categories which are now two per USP 797). The concept of "in-use times" has not been incorporated into the document.<br><br>This is far larger a document than the proposed USP and is going to become confusing when one has to decide, where differences exist between this and USP, which one to follow. You can't call yourself "USP-compliant" in full if you have to compromise that compliance in order to comply with the NAPRA document. And the NAPRA document is not "user friendly" in that it's close to 100 pages long -- how do you find specific references you need in short order, when you already know the references "by heart" per the USP?<br><br>This is re-invention of the wheel. It compromises patient safety, rather than bolsters it. And it contains specific American-type language that resembles the actions of the FDA in the USA to eliminate compounding from pharmacy practice, including "office-use" (by using "patient-specific").<br><br>If it isn't breaking, don't fix it. Require pharmacists to comply with USP requirements; don't invent additional confusing documents, just to have "your name" on them. I understand that Quebec has seen the document and has no intention of adopting something that is going to eliminate "office-use" prescriptions (based on the content of the document not being specifically permissive), as well as "patient-specific" being used which confuses the aspect of "office-use" which, at the time it is dispensed PER A LEGAL PRESCRIPTION, does not have a specific patient name at the pharmacy, but ultimately will be allocated to a patient of the prescriber.<br><br>There ought to be an opportunity to comment as professionals on the CONTENT of the document, rather than have it forced upon us only for acceptance in terms of "time to implement." In deciding on that, one MUST consider the content/requirements in order to respond "yea" or "nay." |
| 47. | We don't compound often. Usually outsourced from compounding pharmacy. |
| 48. | x |
| 49. | 1) There is an increase in staffing resources required to adhere to procedures outlined.<br><br>2) There may be barriers in having non pharmacy staff comply with standards (i.e. housekeeping).<br><br>3) The infrastructure (the existing IV rooms), were not built for these standards. Adapting these standards in the existing environment is challenging. |
| 50. | Unsure |
| 51. | - Cost (supplies, environmental sampling, room renos)<br><br>- Time/people to develop policy and procedures specific to site<br><br>- Time/cost of developing or accessing comprehensive educational materials for staff, and finding good literature or information to base this on<br><br>- Challenge of ensuring external contracted Housekeeping staff follow NAPRA guidelines |

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| 52. | Ensure that everyone is trained accordingly. |
| 53. | 1. Some of the information that is a 'must' is unclear- subject to interpretation<br><br>2. Pharmacy staff is responsible for training housekeeping staff and maintaining employee files- not reasonable<br><br>3. The standards talk about staff that fail a written or practical test, but no information on what/how to test- no standardization; who's to say someone couldn't work at another site and pass then take that pass to their primary site (where they failed) to grieve<br><br>4. Some definitions are missing; other definitions could be clearer<br><br>5. Some information in one section is contradicted in subsequent sections (e.g., 'musts' are contradicted later on in the document<br><br>6. Some of the information is incorrect<br><br>7. Sterile compounding supervisor must perform the final product checks (does not specify 'or delegate') ...not reasonable<br><br>8. Dictates that all received shipments must be stored immediately upon receipt- rarely happens (fridge items yes, not other items)<br><br>9. The sampling says agar plates are a must, but I understand you can use paddles as well...too restrictive in some of the 'how to' sections<br><br>Note: I do NOT find the BUD's too restrictive |
| 54. | The main barrier is coordination across hospital sites |
| 55. | Staffing to accomidate changes to practice, roll out, etc.<br><br>quality testing |
| 56. | cost<br><br>re-training/educating staff<br><br>resistance to change<br><br>waiting for management and higher-ups to direct/implement changes |
| 57. | I have no idea. I haven't read them. |
| 58. | Resistance from management and previously trained personnel.<br><br>Number of re-certifications, updating and re-training and associated costs for taking these actions. |
| 59. | Lack of motivation and time allowed for compounding pharmacy technicians to follow all the guidelines set in the standards. Not enough policing by the College to ensure standards are maintained |
| 60. | ok |
| 61. | Pharmacies that do not wish to expend the monies involved in setting up proper compounding facilities and following strict guidelines that had previously been set out.<br><br>Unfortunately, we already see journals/magazines with pictures of pharmacists/technicians doing performing 'compounds' for a photo op and they are not donning proper PPE! What message does that send out? Even if it is a picture they should still be portraying that they are following guidelines. Saw a photo in a pharmacy journal where the pharmacist is in a lab in what appears to be an outside feather down red coat with a coffee mug beside him. |
| 62. | Expiry dates of fridge items |

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| 63. | I look forward to the NAPRA standards becoming regulation. One of our areas with potential problems are the BUD when preparing admixtures in a hospital based CIVA hub, then transporting to the smaller sites that do not have sterile products facilities. Replacing stock based on a 14 day or lower BUD will have an impact on cost and workload. (I agree with the lower BUD though!)<br><br>Once NAPRA becomes regulation, the pharmacy managers will need to staff this area adequately so that the NAPRA standards can be met. |
| 64. | Not sure currently |
| 65. | Space, old equipment, staffing |
| 66. | My pharmacy must undergo a complete building renovation in order to comply with the regulations. We do so little sterile compounding that this will not be financially justifiable. |
| 67. | Cost to implement.<br><br>Increased workload. |
| 68. | 14 day expiry results in more wastage |
| 69. | None |
| 70. | Some of the physical requirements may propose problems. |
| 71. | I don't disagree with implementing some standards for compounding, and notably sterile compounding. Not sure why we did not adopt USP 795 and 797 standards? Following NAPRA guidelines will change sterile compounding into manufacturing. Financial burden of equipment and ongoing quality assurance programs are significant barriers. I believe that most compounding pharmacies will cease to prepare sterile compounds, thus leaving sterile compounding to only a few - who will in turn become manufacturers for other pharmacies, clinics, etc. The benefits of compounding have always been to be able to customize a medication for a particular patient. The future of the NAPRA paradigm in a community compounding pharmacy setting will prove to be cost prohibitive for patients. |
| 72. | To implement the current standards, our facility would have to undergo extensive renovations. At this moment we are considering the decision between making the necessary changes to meet the standards, or discontinue preparing sterile preparations. |
| 73. | BUD dating too short |
| 74. | BUD of 14 days is a bit strict for outpatient therapy. If we have data to show stability and sterility of a product is beyond 14 days from manufacturer and/or private sterility testing, then I believe this outweighs an overall 14 day stability that is suggested in this NAPRA model. |
| 75. | Time constraints. Hopefully the NAPRA model standards will be clear and concise and applicable to real life situations at different facilities. |
| 76. | Not enough staff or time. |
| 77. | 1. Spacing: We don't have a lot of spaces in the pharmacy for compounding. Sometimes we have to share our working area with front store staff. This can be very troublesome if we have to implement NAPRA standards.<br><br>2. Management: Generally, our pharmacy's business model relies on script counts. The management want you to pump out as many scripts as possible. When you're super busy with dispensing tablets, NAPRA safety standards can be easily ignored.<br><br>3. Staffing: on weekends, our pharmacy only has one pharmacist on duty with no assistant. Sometimes, the pharmacist has to compound while multitasking other pharmacy duties. If she is in a rush to pick up the phone without taking off her gloves which she was using to compounding an HRT cream in the fume hood, it can lead to contamination and safety hazard. |

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| 78. | Wasn't even aware of these standards. Will need to implement training in our pharmacy. So will be a staffing and time issue. |
| 79. | Many:<br>Physical barriers: No USP 797 standards. No properly designated compounding space, just crammed in a filthy corner near a leaky sink.<br>Financial barriers: VGH doesn't have any money to spend on the Pharmacy. We are low priority for the higher-ups. They prefer to focus on pharmacist initiatives more than the day to day nitty gritty things like actually making and dispensing prescriptions to our patients. |
| 80. | We will need more staff to allow for proper time management to implement all of the standards. |
| 81. | None at the moment |
| 82. | poor design of IV room<br>non USP 797 standards<br>not all staff updated on standards |
| 83. | No |
| 84. | Cost |
| 85. | No we do not. |
| 86. | Physical plant |
| 87. | Manager will need to review and remind staff about the standards to make sure everyone is following the procedure. Manager may need a yearly reminder to communicate with staff. |
| 88. | Costs to make preparations will be increased as more rigorous procedures need to be followed. |
| 89. | 1. Pharmacy/sterile room layout. Needs renovations to be closer to 797.<br>2. Money<br>3. Management of hospital<br>4. Lack of knowelagble staff to implement |
| 90. | Costly, time consuming, training, lack of knowledge |
| 91. | Not sure |
| 92. | Consistent training of staff<br>Consistent housekeeping standards for contracted services<br>Capital expenditure for upgrading sterile suites<br>Having adequate testing companies available to perform the required testing |
| 93. | Non |
| 94. | not enough time and not enough staff |
| 95. | I'm not too sure as I have no read the new standards. Noth technicians proper training and I'm sure we will implement any changes that need to happen. |
| 96. | Nor sure |
| 97. | Not sure if our pharmacy would have adequate space to implement the NAPRA model. |

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| 98. | Lack of proper training |
| 99. | does not apply to our pharmacy. We do no compound sterile preparation of any kind |
| 100. | We do not have enough manpower to designate a 30-minute time frame to train or guide an assistant to ensure proper compound procedures and follow the NAPRA Compounding guidelines.<br>In our pharmacy, only some pharmacists and one registered pharmacy tech know how to do the compound properly.<br>The rest has no pharmacy proper training and only to quickly teach when possible which only happened once in a blue moon. This is not ensuring proper training and inefficient.<br>When cutting costs, training time is very limited. It is very difficult to train when no manpower to be at the drop-off Rxs or Pick-up Rxs. Too many interruptions during a quick show on how to compound or a quick monitor if compounds were done according to NAPRA guidelines. |
| 101. | Enough time of pharmacist and staffs |
| 102. | Housekeeping staff is by non-pharmacy technicians and therefore different employer which means they will not invest any more of their time implementing this rule of how and when to clean the iv room. Pharmacy technicians must do their own extra housekeeping. |
| 103. | Pharmacy manager compliance. |
| 104. | not sure |
| 105. | N/A |
| 106. | 2 sites:<br>1 site needs a room for the hood. Hood is in the pharmacy department with no barriers.<br>2 site is almost USP 797 fully compliant. |
| 107. | Time needed to change all the formulas and SOP's. Extra time means extra costs to us and patient, hiring more staff. |
| 108. | Unsure |
| 109. | None at this time |
| 110. | -Time to complete all housekeeping - Pharmacy staff and Housekeeping staff |
| 111. | Staffing, organizational support in the hospital--it would be helpful to continue to get firm reports of what is needed to meet standards so that the room, supplies, staff are available to us to meet the requirements. |
| 112. | $$ for housekeeping staff to clean (as per requirements)<br>Time |
| 113. | cost and time/staffing issues.<br>Waste of drug that we currently have days + expiry now expiring sooner requiring us to compound more often and tighter control will be required from satellite pharmacy's (not very good at reporting) |
| 114. | It appears that time and wages is the biggest barrier. |
| 115. | Costs, space and time to train and implement |
| 116. | time |
| 117. | Require upgrading of existing facility to accommodate complete adherence to NAPRA. |

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| 118. | The only barrier that is foreseen is any colleague not aware of the updates. |
| 119. | upgrade the iv room |
| 120. | There could be possible time constraints in getting product out. Or there could be lack of properly trained staff to be trained in a timely manner. |
| 121. | I see staff and compounding technicians being non-compliant in carrying out the daily cleaning procedures, weekly and monthly, unless it is enforced. I also see them complain about not having enough time allocated to perform all the tasks.<br><br>There are no compliance regulations and guidelines from the College. Every compounding pharmacy does their own thing and are not accountable to any standards and inspections.<br><br>It is imperative to have clear regulations, guidelines and expectations. Most of what is happening is what they learn from attending short training sessions from PCCA or Medisca. And most owners do not invest enough time and resources to achieve a high standard of practice. |
| 122. | housekeeping staff being compliant<br><br>development of procedures |
| 123. | Current Sterile area is nowhere near standards.<br><br>Yearly performance audits are difficult due to resources.<br><br>Surface and finger testing are not currently supported due to cost.<br><br>Robust sterile/ante room cleaning is not supported due to lack of human resources.<br><br>There are many barriers but I would like to see the college adopt strict standards and force the addition of resources. |
| 124. | None |
| 125. | NA |
| 126. | Like of time for training and implementation. Lack of time for proper cleaning |
| 127. | Unknown |
| 128. | Not really sure. We try to implement highest standards possible. I'm not really sure how much the NAPRA model will change that. I think mostly in procedure manuals and that sort of thing. I am not 100% sure of all the new standards. |
| 129. | Awareness, recertification and training of staff. Costs! |
| 130. | management will not implement all procedures |
| 131. | Costly to implement with little return on investment. Will take a long time to recoup the cost of implementation |
| 132. | The only issue that we would face is the holding of an emergency compounded product until the sterility testing results come back. We will be forced to disregard this particular waiting period in order to treat the patient right away. |
| 133. | Nothing really at this time, we are still waiting for management at my workplace to let us know if assistants can still mix hazardous preparations which will probably be in the next model. |
| 134. | not sure as I have not reviewed it yet |
| 135. | Don't think there are any barriers for hospital just better guidelines |
| 136. | narcotics - absence of narcotic safe fridges |

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| 137. | We have tried to implement these standards but many staff/management are unwilling to comply |
| 138. | Allowing extra time for cleaning and upgrading SOPs |
| 139. | Beyond use dating we use is based on formulas from Compounding companies. We also use best clinical judgment based on commercial products, experience, and research. And sterile products are expensive to make, and expensive for the patient. Patient non-compliance would skyrocket if we enforced these guidelines, people couldn't afford it. Most pharmacies wouldn't bother/couldn't afford to do it (most don't anyways) leading to poor access for patients. |
| 140. | Having enough support staff to carry the workload during implementation and after it is adopted. Supervisors need to work the job themselves to see if it is feasible before expecting pharmacy technicians to cram more work into the day. |
| 141. | consistency with cleanliness |
| 142. | the need to renovate the clean room.<br><br>financial investment required to meet the new standard<br><br>resistance to change from compounding personnel<br><br>patient & 3rd party unwillingness to reimburse for increased costs<br><br>a standard implementation date for the standards right across Canada<br><br>The document needs to clarify the wording to allow compounding for office use. Currently it requires a pharmacy-patient-physician relationship to exist which is not strictly possible for office use compounding. Office use compounds are important for naturopaths, veterinarians and physicians and patient need access to these types of meds.<br><br>The College must take the initiative to educate government, patients and 3rd party insurers about the new standards, why they are important and why the cost of compounded injectable has increased.<br><br>The College must advocate on the behalf of compounding pharmacies for adequate reimbursement of compounded injectable by government and insurance companies as it is the College that has set up these new standards |
| 143. | Time restraints to implementation, lack of independent reviewer, lack of internal expertise, cost of new builds or upgrades, staff turnover resulting in lack of ability to maintain sterile preparation services in remote areas, shipping logistics for BUD to remote areas. |
| 144. | Costs will increase for maintaining standards and staff will need to be trained and retrained to maintain standards.<br><br>Additional equipment costs will also be needed |
| 145. | I do not foresee any barriers at this time |
| 146. | There are huge barriers, mostly related to time and money, but some of them are issues of practicality or even patient safety.<br><br>I had not read the NAPRA Model Standards, but on a quick perusal of them (and I only got as far as section 6.9), I had the following concerns:<br><br>- 5.3.2.3 - That the HVAC system must include air conditioning - that is a major facility upgrade, which would be expensive and take a fair bit of time to coordinate, not to mention issues with interruption of the HVAC system (and likely downtime in sterile compounding) while the process is completed.<br><br>- 5.3.2.5 - Activities in the anteroom - it indicates that labeling would happen in the ante-room, but that is not the case in most facilities - there is a potential risk of cross-labeling or mis-labeling that most facilities avoid by labeling items as they are prepared. Not in the PEC LAFW hood, perhaps (and that |

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| | might be worth spelling out in the guidelines), but definitely in the clean room. In addition, it appears to indicate that pass-throughs are strictly from the ante-room into the clean room. I believe this may be contradicted elsewhere, but if it is the case, then most facilities would need to build new pass-through, again, with risks to the cleanliness of the clean room and down time while the process is completed.<br><br>- 5.3.3.2 – Other devices in the clean room – it is my understanding that the Baxa ExactaMix pump is the only one currently licensed for sterile compounding. It might be worth considering how the Baxa system works – in a practical sense – and make sure that the wording of this section (and there are some related sections elsewhere in the Standards) allows for the expected workflow and verification processes. In particular, the Baxa system requires a printer in the vicinity of the hood where the pump is located, because many items (particularly parenteral nutrition solutions) require the "manual additives" section of the Mix-Check report in order to complete the compounding process as well as for documentation of verification. And yet printing in a clean room would generally be inadvisable due to particulate production.<br><br>6.1.2.1 – BUD for single-use vials. The 6-hour expiry is *very* short and the requirement that the vial not leave the ISO 5 PEC means that it cannot be refrigerated (which could be an issue for stability of some drugs). I will leave that decision to the experts, assuming this is based on actual research and not the preferences of manufacturers (who had significant input into USP) for sales and legal protection reasons. However, if this is to be pursued, then this will have **MAJOR** impacts on the cost of health-care delivery in BC. And the government and the taxpayers both need to be made aware in the clearest and obvious ways possible that costs of sterile medication preparation are going to increase significantly. I don't know exact myself, but I hope that part of this process has involved a cost-impact analysis!<br><br>6.1.3 – Table 6 – This table seems to indicate that items prepared for a single patient are lower risk than those prepared for multiple patients. If the other criteria apply, I don't see why this would matter.<br><br>6.1.4 – BUDs for Immediate Use Preparation – this section primarily refers to the activities of *other* health care professionals (primarily nurses, but also many others). Since these guidelines are intended for pharmacists and pharmacies, I don't know how helpful it is to put this here. Will pharmacists be expected to ensure that these things are happening? Have the other health care professionals been consulted on these items? Also, some consideration should be given to how long these "immediate use" preparations are going to be given over. Many Intensive Care nurses, for example, prepare solutions for continuous infusion. While it might be started within an hour of starting compounding, there should probably be some sort of time limit placed on the administration time, because the potentially contaminated product is just sitting there at room temperature for 24 hours, and sometimes 48 hours, or even 72 hours, depending on the facility's policies.<br><br>6.2 – Compounded Sterile Preparation Protocols – This seems to indicate that a pharmacist's signature is required on every protocol. While this might make sense for one-time or custom protocols, and for the initial set-up of a protocol, it doesn't make sense for established protocols in most facilities where Tech-Check-Tech is the norm for sterile compounding. Perhaps this should be modified to include the possibility of having a registered technician's signature in cases where a pharmacist has previously created or verified the protocol.<br><br>6.3 – Lot for each individual patient – This will require significant changes to existing procedures and computer programs in most facilities. If this information could be obtained by cross-reference from other records (something I've done quite often), then is it still required to be part of the patient-specific log? Also, to have to include the "documentation of… any adverse reactions" – is this really the best place for this information? How would it be recorded? Is it feasible to do this? There are many occasions where pharmacies are never notified of such anyway. |
| 147. | Costs, staffing, training |
| 148. | Fiscal approval from organization to get us to standard |

| | |
|---|---|
| 149. | all tools to be cleaned in a timely manner |
| 150. | I feel as though the Air Sampling studies that need to be done every 6 months are excessive. We already get the hoods, equipment, and filters certified every 6 months. We also have an in house quality assurance program where we sample the surfaces in the clean rooms monthly, and look for growth after incubation of agar plates.<br><br>Air sampling is very expensive, and any compounds we do that are covered by pharmacare (such as eye drops, IV bags, or injectables) do not even cover our labor costs to prepare these compounds. We already lose money on labor, it will be very difficult to fit increased testing into our budgets.<br><br>There is also talk that compounding pharmacies may need to send out a percentage of sterile preparations for sterility testing. Sterility testing is very costly, and it would not be viable for our pharmacy. We already do Media Fill Tests for all different types of sterile compounds. Each employee regularly does a media fill test with the same procedure used when making eye preps, injections, IV bags, etc. If the media fill test shows our techniques are sterile, then I feel as though we do not need to send out for testing (as long as we are not creating large batches of medications).<br><br>The above requirements may force us to stop doing sterile compounds entirely. This would be very unfortunate because we are one of the only facilities in the Interior that has the ability to provide patients with these medications. We have patients coming from all over the Okanagan Valley to have us compound sterile eye preps, fertility injections, palliative pain management IV medications, etc. If there is no change in the reimbursement model, and we stop making these medications, it will create an enormous void for the communities in this area. Our pharmacy provides IV bags for hospice patients. We do not have the hospice contract for these homes. We provide the bags as a service to the community. For each bag we are reimbursed the cost of drug, supplies and a 10-minute compounding fee. This fee does not even cover the cost to wash and gown up properly, let alone clean the hood, and prepare the medication. By calling for sterility testing, and extra air sampling, etc. - it will provide barriers which will force us to stop providing these services for the community. |
| 151. | I am all for robust standards and feel there should be some standardization to compounding. My concern is the time and cost associated with the sterile regulations. For a location to put these in place is going to take some time, sufficient time to comply needs to be provided. My concern is more for non-sterile, the rules may be a bit much for some basic compounds. Space will be an issue for more pharmacies to renovate and put in a room. Renovations mean more ridiculous paperwork to the College for approval and diagrams to scale, etc. cleaning is important, the training and evaluation from a third party may be overkill and expensive and where are you going to find a non-biased third party to evaluate? |
| 152. | Please find my comments with respect to NAPRA's Model Standard for Pharmacy Compounding of Non-hazardous Sterile Preparations:<br><br>1. First of all, any general comment about this guideline, especially compared to USP 797, which is the current standards referenced in the provincial legislation;<br><br>The guideline is very straightforward which will make it easy to create or enhance current policies and procedures. It references USP 797 a lot, which is changing and will be modified periodically in the future. How often will the NAPRA guidelines be modified/amended in the future? What if NAPRA doesn't like the changes in 797? Why isn't the College just adopting 797? Why is NAPRA bothering to create their own document when it is essentially the same as 797? What if the pharmacy cannot comply with a certain part of the guideline (i.e. due to physical limitations), but has made an effort to provide an equivalent documented alternative with regard to safety, would the College make an exception?<br><br>2. How would the implementation of this standard impact your practice?<br><br>We currently have the required equipment, maintain a comprehensive policy and procedure manual for compounding sterile products, follow the educational requirements, employee verification and have product quality assurance program. To be compliant with the NAPRA guidelines "to the letter," we |

would have to make a few changes to our procedures and obtain surveillance equipment. We have already made considerable investment in the clean room facility, staff training and quality assurance equipment (i.e. incubator).

3. Any hurdles/issues that you can identified?

Sterile compounding pharmacies provides necessary, and in some cases lifesaving products for many British Columbians. It is essential that the requirements not make it impossible for some pharmacies to continue to provide this service. Our pharmacy has not even begun to recoup the costs of implementation and maintenance of our equipment. The reimbursement by Pharmacare for sterile prescriptions does not cover the true costs of maintaining a sterile program. For example, the reimbursement for CAD pump filling for a palliative patient is $20. I estimate it costs a minimum $40 just to have the sterile assistant prepare, gown up and compound the simplest of sterile compounds. That doesn't even take into account the costs to maintain the sterile room – Hydro, cleaning time and supplies, maintenance, filter replacement, certification etc.

Will the College inspectors be required to take a sterile training course in order to do an inspection of the facility? Will they observe the staff actually compounding? How will the College enforce the implemented guidelines? Will there be a specific "certification" given to a pharmacy that complies so prescribers and the public are aware of which pharmacies to choose?

Beyond Use Dates:

The BUDs in the NAPRA document are unrealistic in community practice. At 3 days, by the time the patient receives a high risk compound, it may be close to or past the BUD. USP 797 now has two categories of sterile preparations making the NAPRA guidelines out of date. It is already difficult to tell physicians that the BUD must be shorter than previously dispensed, because we are trying to follow the USP 797 guidelines for BUD. They question why it has changed and state that other pharmacies' products have a longer BUD. We have lost a considerable amount of business because our competitors offer longer BUDs than stated in USP 797.

Hazardous Drugs:

How does USP 800 play out in all of this? NAPRA already has created the hazardous guidelines so when is that going to be adopted by the College? Are hormones going to be included as hazardous drugs?

Office Use Medications:

The Guidelines as written exclude compounding for "office use".? It is stated on the OCPs website that it is not their intention to eliminate office use compounds. What is the College of Pharmacists of BCs position on this matter?

4. Any suggestions regarding the implementation timeline?

I think the implementation must be done ASAP as the public is at considerable risk with pharmacies providing sterile services without having the required equipment, procedures and quality assurance programs.

Thank you for the opportunity to submit my comments. Please feel free to contact me if you have any questions.

Below are additional comments from the Association of Compounding Pharmacies of Canada (ACPC) I was asked to submit with my comments:

The ACPC welcomes the opportunity to respond and comment on the implementation timeline for NAPRA'S Standards for Pharmacy Compounding of Hazardous (and Non-Hazardous) Sterile Preparations.

It is recognized that the implementation of compounding standards for sterile preparations is necessary to ensure the safe compounding of quality sterile products. Further, it is recognized that proper handling

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| | of hazardous drugs in the sterile room setting, as well as in any environment, is crucial not only for the protection of pharmacy staff but also to prevent cross-contamination and limit exposure of our patients and the environment.<br><br>CONFLICTING GUIDELINES<br><br>Pharmacy compounding is already held to a high standard for patient safety reasons, as well as for consistency of preparations, through pharmacists adhering to the requirements set out in the United States Pharmacopeia (USP 39-NF34). In particular, chapters (non-sterile compounding) and (sterile compounding) address compounding.<br><br>A recent USP call for comments on proposed amendments to USP resulted in a revamping of that chapter, which will be published on November 1, 2016 and go into force on May 1, 2017 (assuming no further amendments are made).<br><br>Similarly, a newly-proposed chapter to the USP has received substantial scrutiny (USP, Hazardous Drugs -- Handling in Healthcare Settings). This chapter will be relevant to all healthcare personnel who "handle HD preparations and all entities that store, prepare, transport, or administer HDs (e.g., pharmacies, hospitals and other healthcare institutions, patient treatment clinics, physicians' practice facilities, or veterinarians' offices)".<br><br>In many instances, the NAPRA guidelines are either in conflict, incomplete or outdated when compared to USP standards. This will create confusion amongst compounders, many of whom are already in compliance with the universally-accepted USP standards and are therefore compounding sterile preparations in a safe, professional manner.<br><br>The NAPRA guidelines may not be implemented by all provinces and territories. This will also add a bevy of issues around entrenching a national standard of practice for compounding sterile preparations. USP is already in place and could easily be adopted nationally.<br><br>OFFICE-USE<br><br>Dispensing for office-use is a vital pharmacy practice in which a pharmacist receives an order from a licensed prescriber for a specified medication, and then dispenses that medication to that prescriber for use in treating their patients. The key component of this practice is the prescriber-pharmacist relationship that exists at the time the order is being placed. Under no circumstances is the pharmacist dispensing medication without that relationship with the prescriber who is directly involved in treating patients.<br><br>Dispensing for office-use is critical to effective patient care in many settings. While emergency-use preparations are most widely recognized, prescribers in many specialties rely on office-use to effectively treat their patients. These environments include:<br><br>• Maternal Fetal Medicine<br><br>• Urology<br><br>• Ophthalmologists and retina specialists<br><br>• Addiction medicine<br><br>• Dermatology<br><br>• Dentistry<br><br>• Autism<br><br>• General practice and pediatrics<br><br>• Ear, nose and throat specialists<br><br>• Pain management |

| | |
|---|---|
| | • Veterinary medicine<br><br>Currently, office-use is allowed in Canada and by the provincial regulatory authorities.<br><br>Significantly, the very terms "patient-specific" and “office-use” are not defined in the NAPRA documents. These critical terms are incorporated into both documents; which pharmacy PRAs are now considering adopting without further modifications. The terms must be defined in the documents in which they are used, as is done with other important terms found within the documents. One such definition suggested is: "patient-specific" shall include "office-use" prescription orders of a practitioner entitled to prescribe in a province/territory of Canada.<br><br>TIMELINE<br><br>Any pharmacy performing sterile compounding should already have SOPs in place (http://www.ocpinfo.com/regulations-standards/policies-guidelines/compounding) as required by the licensing body, along with an internal quality assurance program and follow USP.<br><br>Until pharmacists are able to evaluate and resolve any conflicts between the NAPRA documents and current recognized standards, a timeline for implementation is impossible to calculate. As such, any comment on “timeline” must make reference to what is required to be put into place within that timeline (i.e., contents of proposed standards).<br><br>It is the opinion of the ACPC that changes need to be made to the NAPRA documents to address the issues above and to bring them into compliance with current USP standards. The ACPC also believes that further stakeholder/public feedback is warranted on the content of the documents, given the discrepancies already identified between those documents and the reference documents to which they reference. It is premature at this time to simply look for a timeline to implement the proposed NAPRA standards and the ACPC suggests that input from the broad cross-section of practicing pharmacists with expertise in these areas regarding the content of the documents can only serve to better protect patient and employee safety.<br><br>Erika Lucas, BScPhm<br>Island Pharmacy #10<br>106-284 Helmcken Rd.<br>Victoria, BC<br>V9B 1T2<br>(250) 710-9531 cell<br>erika@islandpharmacy.ca |
| 153. | Funding to meet USP 797 standards.. |
| 154. | The cost of implementing the standards and staff resistance is a barrier.<br><br>The document also needs to clarify the wording in the document, as it currently reflects that compounding for office use medications is not allowed. |

## C. Face-to-Face Engagement Workshop Presentation and Workshop Questions

125 years

### Pharmacy Compounding (Non-hazardous Sterile Preparations) Consultation

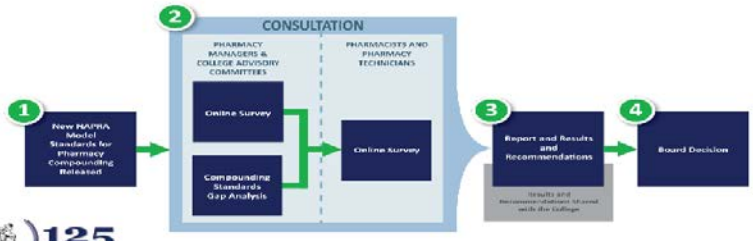
May 25, 2016

### Purpose

With the newly released NAPRA Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations, the College is seeking input from pharmacies and registrants actively engaged with compounding in their practice to help inform the College's approach to implementing NAPRA's new compounding standards.

125 years

### Engagement Process




125 years

## College's Mandate

Our job is to protect public health by licensing and regulating pharmacists and pharmacy technicians and the pharmacies where they practice. We are responsible for making sure every pharmacist and pharmacy technician in BC is fully qualified and able to provide the public with safe and ethical pharmacy care.

125 years

## Dana Lyons – Process Improvement Specialist

**Licensed as a regulated pharmacy technician with the Alberta College of Pharmacists.**

**Expertise in implementation and management of sterile compounding processes and validation specific to USP 797 and CSHP Compounding Guidelines for Pharmacies (2014). Cleanroom management and microbial monitoring in accordance with current cleanroom standards.**

**Expertise in understanding and implementation of USP Chapter 797, Sterile Compounding with a particular interest in large hospital pharmacy distribution setting.**

**Certified Lean Six Sigma Black Belt**
**Certified in Prosci Change Management**

125 years

## Who Eats Here?


125 years

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## Objectives

- Review project phase and outcomes
- Review gap identification data
- Workshop activities
- Wrap up and next steps in engagement process

## Ground Rules

- Start and end promptly
- Everyone participates
- Technology

## Introducing the NAPRA Model Standards into BC Practice

- NAPRA standards (November 2015)
- Consultation with registrants (May 2016)
- Recommendations and report to the Board

## Introductions

1. **Your name**
2. **Workplace**
3. **One interesting thing about you**
4. **One reason you made a choice to be here**

## Recent Misadventures

| | | |
|---|---|---|
| 2012 | California | 9 patients develop fungal endophthalmitis after use of compounded Brilliant Blue-G (BBG) or receiving injections of triamcinolone products from the same compounding pharmacy |
| 2012 | Nationwide (USA) | More than 200 patients contracted fungal meningitis after receiving methylPREDNISolone acetate injection prepared by a compounding pharmacy contaminated with Exserohilum (brown-black mold) and Aspergillus |
| 2013 | Ontario, New Brunswick | 1,202 patients under dosed (1,007 on cyclophosphamide, 191 on gemcitabine, 4 on both – all but 30 being treated for cancer) after contracted compounding pharmacy change |

ISMP Alert

**"When incidents like this occur, we are reminded of the need to remain vigilant to ensure quality throughout every step involved in providing health care services to patients."**

Dr. Jake Thiessen April 9, 2013

Hppt://news.Ontario.ca/mohltc/en/2013/04/dr-jake-thiessen-to-lead-independent-review-of-cancer-drug-system.html Downloaded May 16, 2016

## Part 2 - Workshop

**Instructions:**

1. Each table will pick a scribe and a speaker
2. You will have 14 minutes per question
3. Groups will move to clockwise around the room

## Question 1

If a phased in approach to the NAPRA Model Standards was considered, brainstorm possible/achievable timelines, along with identifying key components from NAPRA Model Standards that would be attached to those timelines.

Groups may choose to build on previous groups work, or start a new timelines with key components.

Note: Be specific with your phases and timelines (for example: a 3 step phased in approach would need three dates and then key NAPRA components which would be attached to each phase)

## Question 2

Considering the media attention sterile compounding has received over the last few years and the pressing need to ensure patient safety answer the following:

A. If the Model Standards were adopted too quickly what consequences might this present? Please list them.

B. Alternatively, if the Model Standards were adopted to slowly what consequences might this present?

C. Once your group has listed the consequences for each question, please suggest two dates for full compliance of the Model Standards and list reasons why these dates seem "reasonable"

## Question 3

Beyond-Use-Dates (BUD) according to risk of microbial contamination outlined in the Model Standards (pg. 36, Table 6 & 7) may present some challenges especially if facility infrastructure is deficient.

A. Please list possible challenges with the immediate (with in 1 year), adoption of the BUD scheme.

B. Identify possible solutions or ideas to mitigate the challenges.


## Questions 4

As part of a full competency assessment, you will be required to involve a third party evaluator for validating the knowledge and abilities of the compounding supervisor. (page 12&14)

Before answering this question take a few minutes to read the requirements for third party evaluator to fully understand the question.

A. What challenges does this present for your workplace – please list them

B. What ideas do you have to overcome this challenge? – please list them


## Question 5

Quality assurance of personnel involved in aseptic compounding (page 60), includes fingertip sampling, and media fill tests as part of initial and ongoing qualification of personnel as mentioned in the following section in NAPRA 5.1.2.2.

Note: This is one of the survey questions in which 89% of respondents were non-compliant.

Prior to answering the question, please take a few minutes to fully read the sections in NAPRA, then as a group answer the follow questions?

A. What concerns or challenges exist with the implementation of this requirement?

B. Brainstorm ideas to overcome the challenges.

## Question 6

**Setting aside the financial impact of implementation of the Model Standards. NAPRA and USP 797 are not leaps and bounds apart, they are similar and we struggled to meet compliance with USP 797. In the inspection reports on average we are 50% compliant.**

A. **What other barriers, to implementation and meeting the standards is occurring? What key components in NAPRA are these barriers related to? (besides money). (i.e. Is it knowledge, training, time etc.).**

## Question 7

**High-Risk Compounding requires rigorous processes that are validated. For pharmacies that are compounding high-risk compounds or plan to continue, answer the following questions:**

A. **Should these pharmacies be required to fully comply with NAPRA sooner than sites that are not engaged in high-risk compounding?**

B. **If "no" why, If "yes" suggest a date for full compliance for high-risk compounding facilities.**

Note: High-risk compounding is when any non-sterile ingredient or container is used in the compounding process. (For example: cocaine eye gtts, alum for irrigation, many others). Discuss within your groups what dangers high risk compounding poses.

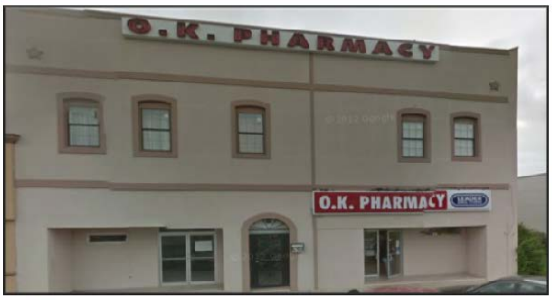
## Question 8

**Training and re-certification activities for compounding and cleaning personnel is rigorous. Review the training and validation requirements (pages 11 – 14) that are required. In your groups answer the following:**

A. **What challenges do the training and assessment present?**

B. **Brainstorm ideas to overcome these challenges.**

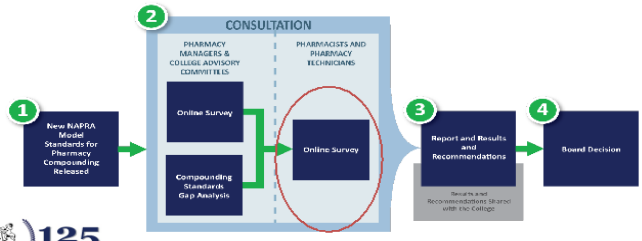
## Who wants to be OK?




125 years

125 years

## Engagement Process Next Steps




125 years

## Thank You!


125 years

**Q1 Phased in Approach Most desirable 26 votes**

| | | |
|---|---|---|
| Phase 1 | Hand hygiene and garbing (6.6,6.5) | Dec 2016 |
| Phase 2 | Cleaning and disinfecting<br>Training and assessment<br>Policies and Procedures | December 2017 |
| Phase 3 | Quality Assurance<br>Environmental monitoring<br>Media fill<br>Fingertip Sampling | December 2018 |
| Phase 4 | Facilities<br>BUD | December 2019 +++ |

**14 votes**

| | | |
|---|---|---|
| Phase 1 | Facility design/layout compliance approved | 18 month |
| Phase 2 | Training/Education, SOP, P&P, Hygiene, Disinfection | 12 – 18 months |

**Two votes**

| | | |
|---|---|---|
| Phase 1 | Training/education for supervisors, trainers and staff<br>PPE, Hand hygiene, garbing, disinfection, training of housekeeping | Dec 2016 |
| Phase 2 | Fingertip testing, media fill testing, surface sampling<br>Practical and theory exam | December 2017 |
| Phase 3 | Facility compliance (renos) | December 2018 |
| | | |

| | | |
|---|---|---|
| Phase 1 | Standards/Training in place | Dec 2017 |
| Phase 2 | QA processes, quality management program, antimicrobial testing etc. | 24 months |
| Phase 2A | Data from testing supports the need for physical upgrades | |

## Question 2

| Too Fast | Too Slow | Target Date |
|---|---|---|
| Facilities will fail | Risk to public | Dec 2018 |
| Lose confidence in College | Risk to staff | Dec 2019 |
| Feel picked on | Lose momentum or respect (process/credibility) | Dec 2020 (6 votes) |
| No opportunity for education/training | Standards could change | Dec 2026 |
| Cost associated with renos/training/education/GFT/QA | 5 years for complex IV products | |
| No time to break people habits/mindset | Prioritize topical vs IV i.e. prioritize based on risk to patients | |
| Supply issues | | |
| Reverting to old practice | | |
| Overwhelm staff | | |
| Pharmacies will close | | |
| Patient access restricted | | |
| Lack of time to be compliant | | |
| Outside BC will undermind local pharmacies selling for lower costs if timelines are different prov to prov. | | |
| Lose economy of scale (share services/lab/QA), shared experiences/knowledge building | | |

**Question 3 BUD**

| Challenges | Solutions | |
|---|---|---|
| Most sites at LMPS would only be able to provide 12 h BUD | Product sterility testing | |
| More frequent and smaller batches adding to scheduling challenges | Outsourcing | |
| More frequent replenishment | Centralized production at compliant facilities | |
| Repetitive strain | Renovate sterile rooms | |
| Increase staffing and set up time | Docking bags MB+ | |
| Increase cost/budget | Robots (<$$ than reno) | |
| Increase delivery costs | Adequate reimbursement incentives for existing compounders to expand services | |
| Significant workflow redesign/optimization | Allow flexibility of BUD if evidence available to support | |
| Increase wastage | Consolidate central or hub processing in centres/sites that are compliant to do batch processes. | |
| Lack of testing facilities | | |
| Delay getting Rx to patient | | |
| Increased patient cots | | |
| Doctor/Patient Expectations for long BUD | | |

**Questions 4 Third Party Evaluator**

| Challenges | Solutions | |
|---|---|---|
| Who would qualify and where would you find them | Private experienced evaluator or College expert inspector | |
| Not in USP 797 | Internal peer expert evaluator | |
| Cost, educating cost to administration | Contract to a service provider | |

**Questions 5 QA of Personnel**

| Challenges | Solutions | |
|---|---|---|
| Time factor – to perform as well as waiting for results | Increase funding | |
| Finding certified labs | Create an implementation plan | |
| Cost of materials | 3rd party outsourcing | |
| Underlying processes need to up to date before starting | List of qualified labs | |
| Extra documentation involved | Group contract pricing | |
| Keeping track of 6 month period for each employee | In house testing (hospital micro labs) | |
| Need remediation plan if positive results | An opportunity for economy of scale and standardization if only a few vendors (labs) are in place | |
| Need for independent assessor or manager or internal fully trained | Education sessions to bring managers/owners up to speed on what the testing means | |

| | | |
|---|---|---|
| Refrigeration and temperature storage of media | Having a defined standard (NAPRA) is already helpful for planning/targets | |
| Staff shortage while waiting for testing | Pass on testing costs to third party payers | |
| Staff intentionally failing so they don't have to work in IV room. | | |
| Knowledge gaps | | |

**Question 6 Other Challenges (other than $)**

| | | |
|---|---|---|
| Wastage of drug (i.e. use of partials) after 6 hours | Solution | |
| BUD | Develop SOPS (massive effort) | |
| Complexity of quality control/sterility | Need time to do it thoroughly | |
| Education for senior hospital leadership | Change management support | |
| Various levels of regulation | Education | |
| Different standards to meet (worksafe BC, Food & Drug Act. Etc.) | | |
| Renovated facilities not to standard | | |
| Qualifications of auditors/decision makers | | |
| Compounding for doctor office use | | |
| Space restrictions | | |
| Resources required | | |
| Time | | |
| Change aversion | | |
| Continuous changes to practice environment | | |
| Values – how to make people care | | |
| Resistances to change | | |
| Old school mindsets | | |
| Change for staff, leadership, head office, Physicians, patients | | |
| Continuously changing regulations | | |
| A college defined standard/legislation will help for long term planning. | | |
| Knowledge of standards is lacking | | |
| Rural vs Urban access to resources (lab, training, expert teachers availability) | | |

**Question 7 High-Risk Compounding**

| Comply sooner than other sites | If no Why | If Yes why |
|---|---|---|
| No all should comply at same time suggestion of 2 – 3 years. All provinces should implement at same time. | Confusion for public | More sever implications with high-risk compounding |
| Yes should comply sooner | No – should be all the same to add consistency | Suggestion of 1 year to meet minimum standard |
| | | May be an opportunity to discontinue legacy an non-standard practices/products |

**Question 8 Training and Assessment**

| Challenges | Solutions | |
|---|---|---|
| Access to training and re-assessment | Realistic/adequate reimbursement by government an insurance companies. | |
| Financial costs | Flexibility to be allowed to adapt rules to fit practice | |
| Certification of staff | 3rd party evaluated provided by College (qualified in sterile compounding) | |
| Time involved, frequency, documentation onerous, cost investment goes up. | Need CPBC support as requirement for licensure | |
| Need for pharmacists or regulated tech to perform certain tasks | Share or co-develop materials e.g. CSHP | |
| Shortage of regulated techs and training schools | FH – LMPS standardized training | |
| Multiple contracted housekeeping services | Centralized training facility | |
| Staff numbers <500 techs | Tech training programs to offer more in-depth sterile compounding as an option. | |
| Collective agreements/unions | | |
| Hard to train staff if they compound infrequently. The cost to train everyone (and turn over training) | | |
| Space to train | | |

College of Pharmacists
of British Columbia

# GAP IDENTIFICATION TOOL

## Adapted from NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations

2016

GAP Identification Tool Instructions

All information gathered through the use of this tool will be confidential. The information will be used for aggregate data collection purposes only.

The name and identification of your facility is not required to complete this gap identification tool.

Please refer to and read the Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations prior to completing this gap identification tool. The questions asked in the document are based on “shall or must” statements in the Model Standards.

Model Standards can be found here:
http://napra.ca/Content_Files/Files/Mdl_Stnds_for_Pharmacy_Compounding_NonHazardous_Sterile_Preparations_Dec2015_FINAL.pdf

Each question has a drop-down list; you must choose one of the available selections.

Please answer all questions in the identification tool.

Note: You may need to consult with your engineering and maintenance department to be able to answer some of the questions related to air changes per hour.

Email completed form to: Legislation at legislation@bcpharmacists.org

| ID | Gap Identification Question(s) | Choose One Response that Accurately Represents Your Facility |
|---|---|---|
| 1 | What is the approximate number of beds of your compounding operation supports (for hospitals only)? | Please Select ONE Option |
| 2 | If you are a Community Pharmacy, how many sterile compounds does your operation prepare on average weekly? | Please Select ONE Option |
| 3 | Do **all** compounding personnel pass an initial gloved finger-tip sample before working in the compounding area? | Please Select ONE Option |
| 4 | Do **all** compounding personnel pass a initial media fill test before working in the compounding area for non-hazardous sterile products? | Please Select ONE Option |
| 5 | **All personnel** (pharmacists, pharmacy technicians and pharmacy assistants) assigned to the compounding of sterile preparations are assessed at least once a year for low or medium risk level; and at least twice a year for high risk level preparations? | Please Select ONE Option |
| 6 | The air supplied to areas used for compounding non-hazardous sterile preparations pass-through a terminally fitted **high-efficiency particulate air (HEPA) filter** to ensure a very high level of cleanliness? | Please Select ONE Option |
| 7 | Particle counts are performed by trained, qualified personnel at least **every 6 months** as | Please Select ONE Option |

| ID | Gap Identification Question(s) | Choose One Response that Accurately Represents Your Facility |
|---|---|---|
| | part of an internal quality control program **for facilities**? (see Appendices 5 and 6) | |
| 8 | Particle counts are performed by trained, qualified personnel at least **every 6 months** as part of an internal quality control program for the **primary engineering control (PEC)**? (see Appendices 5 and 6 in NAPRA) | Please Select ONE Option |
| 9 | Water sources, sinks and drains are **not** located in the clean room? | Please Select ONE Option |
| 10 | Compounding personnel and anyone else who accesses controlled areas wear appropriate protective clothing, as exactly described in **Table 5 (page 33) of the NAPRA Model Standards**? | Please Select ONE Option |
| 11 | **PPE is worn** for the compounding of sterile preparations includes the following: Shoe covers, hair cover, beard cover (if applicable), surgical mask, sterile non-powdered gloves, non-shedding gown (enclosed at neck and sleeves that fit snuggly at the wrist)? | Please Select ONE Option |
| 12 | Cleaning and disinfecting personnel (housekeeping staff) **fully comply** with hand hygiene and garbing procedures before entering sterile compounding areas and performing housekeeping duties? | Please Select ONE Option |
| 13 | **Daily cleaning and disinfecting** occurs for the following surfaces and areas and there is documented proof? (e.g. Counters, Carts, Floors) | Please Select ONE Option |

| ID | Gap Identification Question(s) | Choose One Response that Accurately Represents Your Facility |
|---|---|---|
| 14 | **Monthly cleaning and disinfecting** occurs for the following surfaces and areas and there is documented proof? (Walls, Ceilings, Shelves) | Please Select ONE Option |
| 15 | **Beyond-use dates** are assigned according to stability and the risk level associated with microbial contamination? (Low, Medium and High risk level BUDS) | Please Select ONE Option |
| 16 | **Before entering** the anteroom, personnel always remove personal outer garments (e.g., coat, hat, jacket scarf, sweater, vest, boots and outdoor shoes)? | Please Select ONE Option |
| 17 | **Before entering** the anteroom, personnel always remove jewelry, studs and other accessories from fingers, wrists, forearms, face, tongue, ears and neck (this includes personal electronic devices or accessories, such as cell phone, iPod and earbuds, which are not permitted in the anteroom or clean room)? | Please Select ONE Option |
| 18 | **Before entering** the anteroom, personnel always remove all cosmetics, including makeup, false eyelashes, perfume, hair products such as hairspray, henna tattoos and paper tattoos? | Please Select ONE Option |
| 19 | **Before entering** the anteroom, personnel always remove nail polish and other nail applications? | Please Select ONE Option |
| 20 | Where packaging allows, compounding equipment and products are **disinfected with sterile 70% isopropyl alcohol** just before being introduced into the clean room? | Please Select ONE Option |

| ID | Gap Identification Question(s) | Choose One Response that Accurately Represents Your Facility |
|---|---|---|
| 21 | A biomedical refrigerator or freezer **is used for storing products, ingredients and final compounded sterile preparations** that need to be refrigerated or frozen (see section 5.3.3.2). | Please Select ONE Option |
| 22 | Your pharmacy **has implemented** an environmental sampling plan that measures viable air and surface particles? | Please Select ONE Option |
| 23 | For **each** employee, GFS after the media fill test is completed annually for low- and medium-risk sterile compounding and every 6 months for high-risk sterile compounding and documented proof? | Please Select ONE Option |
| 24 | The cleanroom **meets** ISO 14644-1 for cleanroom particulate airborne cleanliness at the ISO 7 level and there is documentation to support this? | Please Select ONE Option |
| 25 | Sterile Isopropyl Alcohol is used to clean the PEC? | Please Select ONE Option |
| 26 | The anteroom has a **line of demarcation** clearly separating the clean and dirty side? | Please Select ONE Option |
| 27 | Does your pharmacy prepare **high-risk** compounds in batches greater than 25? | Please Select ONE Option |
| 28 | Cardboard **does not** enter the anteroom or cleanroom? | Please Select ONE Option |
| 29 | Alcohol based hand rub (AHBR) **with persistent activity** is used to perform hand antisepsis? | Please Select ONE Option |

| ID | Gap Identification Question(s) | Choose One Response that Accurately Represents Your Facility |
|---|---|---|
| 30 | Bins used to introduce supplies or products into the cleanroom are **always** disinfected prior to use? | Please Select ONE Option |
| 31 | The cleanroom is verified to have a **minimum of 30 air changes per hour** (ACPH)? | Please Select ONE Option |
| 32 | The anteroom is verified to have a **minimum of 20 air changes per hour** (ACPH)? | Please Select ONE Option |
| 33 | The PEC is cleaned and disinfected with clean wipes and germicidal disinfectant detergent, followed by sterile 70% isopropyl alcohol, at the **start and end of the day or shift (minimum twice per day)?** | Please Select ONE Option |

## F. Gap Identification Survey Tool "Collated Results"

| Questionnaire # | Total | NO | Yes | Partially | N/A | no response | blank | Total |
|---|---|---|---|---|---|---|---|---|
| Q1 | 14 | 14% | 29% | 0% | 0% | 0% | 57% | 100% |
| Q2 | 14 | 29% | 0% | 14% | 0% | 0% | 57% | 100% |
| Q3 | 14 | 71% | 14% | 7% | 0% | 0% | 7% | 100% |
| Q4 | 14 | 71% | 7% | 14% | 0% | 0% | 7% | 100% |
| Q5 | 14 | 64% | 14% | 14% | 0% | 0% | 7% | 100% |
| Q6 | 14 | 29% | 64% | 0% | 0% | 0% | 7% | 100% |
| Q7 | 14 | 29% | 50% | 14% | 0% | 0% | 7% | 100% |
| Q8 | 14 | 14% | 71% | 7% | 0% | 0% | 7% | 100% |
| Q9 | 14 | 14% | 79% | 0% | 0% | 0% | 7% | 100% |
| Q10 | 14 | 7% | 57% | 29% | 0% | 0% | 7% | 100% |
| Q11 | 14 | 0% | 93% | 0% | 0% | 0% | 7% | 100% |
| Q12 | 14 | 14% | 50% | 29% | 0% | 0% | 7% | 100% |
| Q13 | 14 | 36% | 36% | 21% | 0% | 0% | 7% | 100% |
| Q14 | 14 | 29% | 36% | 29% | 0% | 0% | 7% | 100% |
| Q15 | 14 | 36% | 21% | 36% | 0% | 0% | 7% | 100% |
| Q16 | 14 | 0% | 64% | 21% | 7% | 0% | 7% | 100% |
| Q17 | 14 | 0% | 50% | 43% | 0% | 0% | 7% | 100% |
| Q18 | 14 | 7% | 36% | 50% | 0% | 0% | 7% | 100% |
| Q19 | 14 | 7% | 71% | 14% | 0% | 0% | 7% | 100% |
| Q20 | 14 | 43% | 43% | 7% | 0% | 0% | 7% | 100% |
| Q21 | 14 | 29% | 43% | 21% | 0% | 0% | 7% | 100% |
| Q22 | 14 | 57% | 21% | 14% | 0% | 0% | 7% | 100% |
| Q23 | 14 | 79% | 7% | 7% | 0% | 0% | 7% | 100% |
| Q24 | 14 | 29% | 43% | 14% | 0% | 7% | 7% | 100% |
| Q25 | 14 | 50% | 36% | 7% | 0% | 0% | 7% | 100% |

| Questionnaire # | Total | NO | Yes | Partially | N/A | no response | blank | Total |
|---|---|---|---|---|---|---|---|---|
| Q26 | 14 | 21% | 43% | 21% | 7% | 0% | 7% | 100% |
| Q27 | 14 | 50% | 7% | 7% | 29% | 0% | 7% | 100% |
| Q28 | 14 | 14% | 71% | 7% | 0% | 0% | 7% | 100% |
| Q29 | 14 | 43% | 43% | 0% | 0% | 7% | 7% | 100% |
| Q30 | 14 | 21% | 64% | 7% | 0% | 0% | 7% | 100% |
| Q31 | 14 | 29% | 50% | 14% | 0% | 0% | 7% | 100% |
| Q32 | 14 | 29% | 43% | 14% | 7% | 0% | 7% | 100% |
| Q33 | 14 | 21% | 36% | 36% | 0% | 0% | 7% | 100% |

Report written by Dana Lyons RPhT

# Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations Engagement Summary and Recommendations

## Consultation and Implementation Approach

This report is part 2 of the consultation reports. Part 1 is a report for Non-Hazardous Sterile Preparations.

This report and recommendations builds on the prior engagement and consultative work done for the implementation of the non-hazardous NAPRA Model Standards. The two reports together, are intended to inform and support implementation for all sterile compounding activities in the province of British Columbia.

Dana Lyons RPhT
January 2017

# Table of Contents

# Executive Summary

In light of the newly released NAPRA Model Standards for Pharmacy Compounding Hazardous Sterile Preparations (NAPRA), and the historically ineffective nature of voluntary guidelines, it was likely that some form of enforceable national sterile compounding standards similar to those in the United States would come into place in Canada. Despite a growing awareness of the importance of good sterile compounding practices, there remains a troubling disconnect between practice guidelines and actual practice. Developing an effective compounding strategy is critical to ensuring patients have access to properly compounded medications, but because each organization's needs differ, a one-size-fits-all solution cannot be applied to every hospital and community practice environment where sterile compounding takes place. The responsibility to plan and become compliant involves facility infrastructure to changing historic personnel practices and cleaning routines.

Building on the prior consultation with registrants and the resulting **seven** recommendations is a proposed plan to adopt NAPRA Model Standards for Pharmacy Compounding of Hazardous Preparations in **four phases**. Each phase has key NAPRA requirements attached to it with specific timelines and aligns with the phased in approach for implementing the sterile non-hazardous NAPRA standards.

To ensure we achieve compliance it is recommended that we measure compliance as we implement the four-phase model with completion of the phases targeted over four years.

Of a pharmacy professional's countless responsibilities, perhaps none is more critical to positive patient outcomes than ensuring patients receive safe medications, compounded according to established standards and this report outlines key steps to achieving this responsibility.

## 1.0 Scope

The scope of this initiative is to review what the current policies, standards and bylaws are that guide hazardous sterile compounding practices in hospital and community pharmacy in the province of British Columbia. This work includes a confirmation of what current state practice is and the potential gaps in practice. This report and its findings builds on the work and engagement done with the non-hazardous NAPRA Model Standards.

## 2.0 Current Bylaws and Practice Guidelines

### 2.1 Community Pharmacy

The policy documents in place to guide sterile compounding practice in the Community Pharmacy setting include:

I. Professional Practice Policy – 64 (Guidelines to Pharmacy Compounding)

The following key statement is found within this policy: ***The Board of the College of Pharmacists of BC adopts the NAPRA Guidelines to Pharmacy Compounding as the Standard of Practice for registrants.***

The NAPRA document referenced in the Professional Practice Policy is based on eight performance indicators.

1. Knowledge and expertise to compound
2. Confirm the need to compound
3. Access to equipment
4. Quality ingredients
5. Labelling
6. Suitable containers
7. Storage
8. Documentation checking, duplicating and tracing.

Within this NAPRA 2006 document, there are three key points specific to sterile compounding practice and they are:

1. Pharmacists engaging in sterile compounding should be knowledgeable and obtain specialized technical training in this area.
2. Carefully established standards for the operation of cleanrooms and the preparation of sterile products should be documented in accordance with a recognized source. (E.g. Canadian Society of Hospital Pharmacists) (CSHP).
3. Sterility testing shall be done according to a clearly defined standard (E.g. United States Pharmacopeia) (USP) and the product assigned an estimated expiry date.

### 2.2 Hospital Pharmacy

**The policy documents that currently guide the compounding practices in hospital pharmacy are:**

I. Professional Practice Policy – 61 (Hospital Pharmacy Published Standards)

II. Professional Practice Policy – 57 (Standards for Pharmacy Assistant Verification of Sterile Products in Hospital Pharmacy Practice)

Within the professional practice policy documents, the following statement can be found: **Sterile Products must be prepared in accordance with the published standards noted below:**

1. CSHP Official Publications – Guidelines for Preparation of Sterile Products in Pharmacies
2. CSHP Official Publications – Handling and Disposal of Hazardous Pharmaceuticals (including cytotoxic drugs)

**Bylaw documents for Hospital Pharmacy include**:

I. Health Professions Act – Bylaws Schedule F (Part 2 – Hospital Pharmacy Standards of Practice)

Within the Health Professions Act – Bylaws Schedule F (Part 2 – Hospital Pharmacy Standards of Practice) under the Drug Distribution section 3 is the following statement:

> **Sterile products must be prepared and distributed in an environment that is in accordance with:**
>
> 1. The CSHP Guidelines for Preparation of Sterile Products in Pharmacies.
> 2. The USP Pharmaceutical Compounding – Sterile Products Guidelines, and
> 3. Such other published standards approved by the Board from time to time

II. WorkSafe BC – Bylaw 34

**CSHP Guidelines**

The CSHP Guidelines for Preparation of Sterile Products in Pharmacies was published in 1996. The scope of this guideline was intended to be used in situations where pharmacies are involved in the preparation of sterile products for patients (e.g., hospitals, community pharmacies, nursing homes, home health care and others). This document was retired in 2014 after the updated CSHP guidelines were published.

**USP Chapter <797> Standards**

The other choice for published guidelines referenced in the bylaws and currently the standard in British Columbia is USP Chapter <797> Pharmaceutical Compounding – Sterile Preparations. Chapter <797> was first published in 2004 and has specific requirements for the following areas:

- Design of the Facility
- Environmental and Engineering Controls
- Environmental Testing
- Personnel Training and Competency Testing
- Standard Operating Procedures and Documentation
- Quality Assurance
- Patient Monitoring and Adverse Events Reporting
- Storage and Dating

## 3.0 Consultation and Engagement

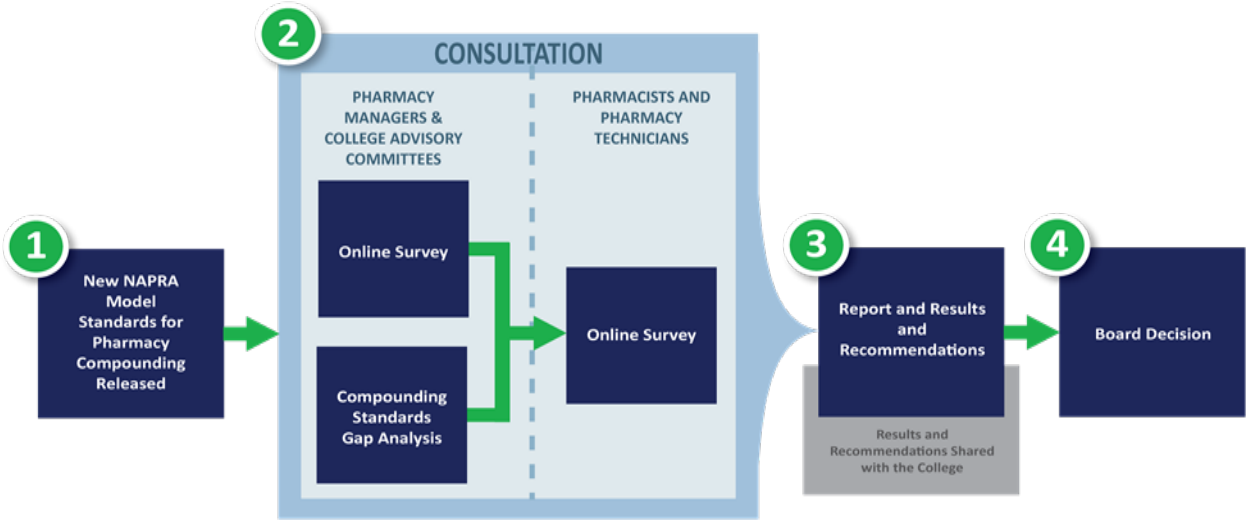
### 3.1 Method

A multi-step consultation process was designed to reach the many stakeholders including, leaders and pharmacy managers, as well as front-line pharmacists and pharmacy technicians all impacted by the changes in sterile compounding standards. Consultation on the hazardous NAPRA Model Standards, builds from the non-hazardous work.

A sixty-question gap tool was designed, and included some repeat questions from the non-hazardous gap tool where the requirement is the same for both hazardous and non-hazardous compliance and included hazardous specific questions as it relates to the "shall" or "must" statements in the NAPRA Model Standards. Participation in this gap tool survey was open to all pharmacists and pharmacy technician registrants in British Columbia.

The results of the survey were used to make recommendations in addition to the 7 recommendations found in the sterile non-hazardous report.

### 3.2 Consultation Process

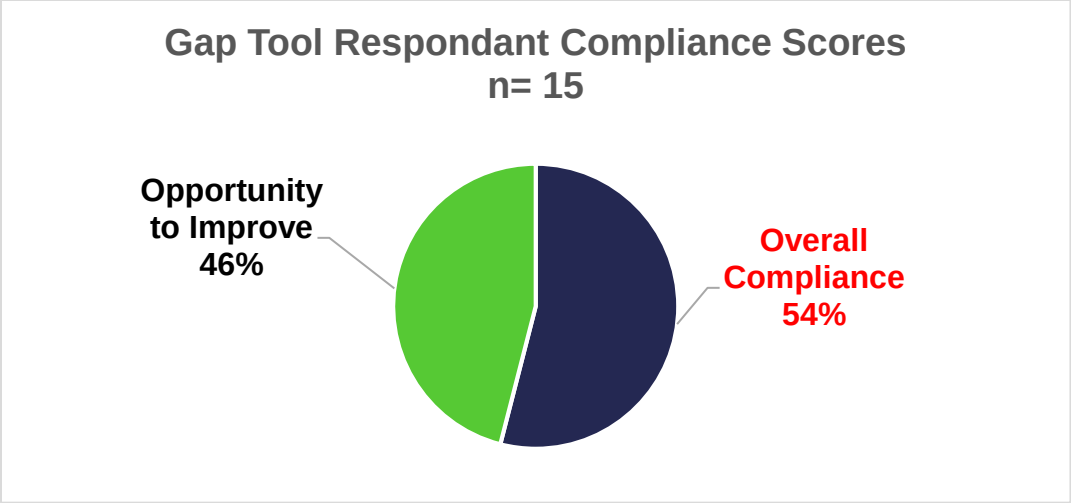



## 4.0 Practice Gap

When looking at practice gaps, we needed to understand what gap we currently have with current standards, and then how does that gap widen with the introduction of new standards. Using the 60-question gap survey results we can start to understand the gap in practice versus NAPRA.

### 4.1 Overall compliance with the gap survey tool as self-reported from the participants is 54%.

A total of 15 respondents submitted the survey which makes the sample size small and results should be interpreted keeping this in mind.




**4.2 Hospital versus Community Practice Gap**

When comparing hospital versus community pharmacy compounding environments, we also wanted to know if there is a significant difference in compliance between the two practice environments. Out of the fifteen survey respondents thirteen are hospital and two are community practice-based.

The low response rate from community practice sites might indicate that hazardous sterile compounding is mainly occurring in a hospital setting. The two community pharmacies self-reported an overall compliance score of 69% and 90%, which is encouraging as these compliance scores fall within the top 5 survey responses.

## 5.0 New Requirements NAPRA Introduces

There are numerous introductions of hazardous drug containment strategies that are over and above what was previously found in USP <797>. The newly published USP <800> chapter was not used for comparison as it was too new to be considered a standard in British Columbia.

## 6.0 Barriers Registrants Brought Forward to Implementing NAPRA

**6.1 Knowledge of Standards**

Education on current sterile compounding standards may possibly be a barrier for implementation and adoption of the NAPRA Model Standards. In the survey to frontline pharmacists and pharmacy technicians, we wanted to assess the general awareness of the NAPRA standards, so we asked the question: **Are you aware that NAPRA published new Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations in September 2016?** Out of 15 respondents 3 **were not** aware of the NAPRA Model Standards prior to the survey and 12 had known this standard was newly released. This is an indicator that pharmacists and pharmacy technicians are understanding that sterile compounding standards are changing in Canada.

The barriers sited from both the hazardous and non-hazardous gap tool surveys are very similar. A complete unedited list of barriers is provided in the appendices. No new barriers came forward and the top barrier remains cost mainly due to infrastructure changes.

**6.2 Cost Constraints**

Healthcare dollars are scarce and renovation budgets are planned years in advance. The full cost of implementing sterile compounding standards is not known, as the starting point is different for every facility and there will likely be additional costs for those facilities where compounding of non-hazardous and hazardous occur. The cost of compliance is a barrier to implementation as reported by survey respondents.

**Mitigating Strategy**

The four-phase, four-year approach to NAPRA adoption and compliance should address most of the cost increases as they will be absorbed incrementally over time. The proposed implementation plan should also include the budget and infrastructure cycles heath authorities work within. The College may need to assess as the implementation rolls out and adjust the compliance dates if availability of infrastructure dollars becomes the rate limiting step.

**6.3 Beyond-Use Dates (BUD)**

The BUD in NAPRA is based on the risk that a compounded sterile preparation (CSP) may have been contaminated. Traditionally, before newer standards were published, common practice was to use drug stability information to determine the expiry date of the CSPs. The introduction of USP <797> changed the way BUDs are applied using drug stability plus sterility to determine the safest BUD. In consultation with the leaders and managers, they revealed that the negative impact could include the following: increase in drug wastage, delivery costs and costs to patients, staffing time, and repetitive strain injuries. *The results from the hazardous gap survey indicates that **73%** of respondents are currently in compliance with BUDs as outlined in NAPRA.*

This is positive news, and the change arounds the BUDS for hazardous drug preparations won't be as onerous as non-hazardous.

**6.4 Changing Behaviours**

As the old cliché goes "what gets measured gets done". The message is clear: measuring something gives you the information you need in order to make sure you actually achieve what you set out to do. Asking our staff to show up prepared to compound, with no make-up, no nail extensions and in proper attire is one of the lowest cost changes we will be asked to comply with.

## 7.0 Implementation Strategy

Based on the need to balance implementation and mitigate risks with an approach that is not too fast or too slow, the four-phase model for implementation is a good balanced approach that can be used for both hazardous and non-hazardous sterile NAPRA Model implementation strategies. All of the various

models of implementation suggested by participants can be found in the *sterile non-hazardous report*, and the most desirable model presented in table 1 below.

**Table 1 Most Desirable Option for Compliance**

| **Phase** | **Compliance Component** | **Date of Expected Phase Compliance** |
|---|---|---|
| Phase 1 | Hand Hygiene and Garbing | Phase 1 |
| Phase 2 | Cleaning and Disinfecting,<br>Training and Assessment<br>Policies and Procedures | Phase 2 |
| Phase 3 | Quality Assurance and Environmental Monitoring<br>Media Fill and Fingertip Sampling | Phase 3 |
| Phase 4 | Facilities and BUD | Phase 4 |

**Recommendation #2**

**Phased-in Approach**

The implementation of NAPRA Model Standards requires a balanced approach, focused firstly on protection of the public and personnel safety, yet achievable for compounders and organizations. The four-phase approach should be undertaken with a timeline of four years plus a notification period to registrants and should include non-hazardous and hazardous sterile compounding. Alternatively, the College could allow timeline extensions or a TBD for major infrastructure based on the need for further renovations when the non-sterile compounding Model Standards are released. (expected to be in 2017)

## 8.0 Conclusion and Implementation Recommendations and Timelines

The adoption of the NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations will take time, money and considerable effort to implement properly and safely. My experience as a process specialist is if you take big initiatives or projects and break them down into attainable chunks of work which can be measured along the way, success of the larger goal will materialize. Nonetheless, the effort required to implement the Model Standards and assess compliance is a large undertaking. The proposed phased in model for compliance with the NAPRA Model Standards, which the participants drafted and favored, has been adapted and presented below in the table. The

three key sections (5, 6 and 7) in NAPRA have been divided according to the model with proposed timelines.

The adoption of the NAPRA Model Standards by the College, would be in alignment with other provincial regulatory authorities (PRA) such as Alberta and Ontario. The Model Standards have gone through extensive pharmacy stakeholder consultation from each Provincial Regulatory Authority and many of the members within the PRA's. Therefore, the recommendation is for BC to adopt the NAPRA Model Standards for Hazardous Sterile Preparations as the standard in British Columbia.

## 9.0 Phased in Approach Recommendation and Timelines

| Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations Implementation Plan | | | |
|---|---|---|---|
| **NAPRA ID** | **NAPRA Compliance Area** | **Phase of compliance** | **Proposed compliance date** |
| Step 1 | **Define compounding risk level** | **Phase 1** | November 2017 |
| Step 1 | **Complete a gap analysis and prioritize a site plan** | **Phase 1** | November 2017 |
| 6.3 | Compounded sterile preparation log | Phase 1 | November 2017 |
| 6.4 | Patient file | Phase 1 | November 2017 |
| 6.5 | Conduct of personnel in areas reserved for the compounding of hazardous sterile preparations | Phase 1 | November 2017 |
| 6.6 | Aseptic compounding of hazardous sterile preparations | Phase 1 | November 2017 |
| 6.7 | Packaging | Phase 1 | November 2017 |
| 6.8 | Receipt and storage of hazardous products | Phase 1 | November 2017 |
| 6.9 | Transport and delivery of hazardous compounded sterile preparations | Phase 1 | November 2017 |
| 6.10 | Recall of hazardous sterile products or final hazardous compounded sterile preparations | Phase 1 | November 2017 |
| 5.1 | Personnel | Phase 2 | May 2019 |
| 5.2 | Policies and procedures | Phase 2 | May 2019 |
| 5.4 | General maintenance log | Phase 2 | May 2019 |
| 6.2 | Compounded sterile preparation protocols | Phase 2 | May 2019 |
| 6.11 | Incident and accident management | Phase 3 | May 2020 |
| 6.1 | Beyond-use date and dating methods | Phase 3 | May 2020 |

| Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations Implementation Plan | | | |
|---|---|---|---|
| **NAPRA ID** | **NAPRA Compliance Area** | **Phase of compliance** | **Proposed compliance date** |
| 6.12 | Hazardous waste management | Phase 3 | May 2020 |
| 7.1 | Program content | Phase 3 | May 2020 |
| 7.2 | Results and action levels | Phase 3 | May 2020 |
| 7.3 | Verification of equipment and facilities | Phase 3 | May 2020 |
| 7.4 | Quality assurance of personnel involved in aseptic compounding | Phase 3 | May 2020 |
| 7.5 | Quality assurance of hazardous compounded sterile preparations | Phase 3 | May 2020 |
| 7.6 | Documentation of quality control activities | Phase 3 | May 2020 |
| 5.3 | Facilities and equipment | Phase 4 | May 2021 |

# Appendices

## A. Recommendations for the College

| Recommendation ID | Recommendation(s) |
|---|---|
| 1 | The College inspect community and hospital sterile compounding practices using the same tools for both settings. The frequency of sterile compounding facility and practice inspections should also be similar. |
| 2 | **Phased-in Approach**<br><br>The implementation of NAPRA Model Standards requires a balanced approach, focused firstly on protection of the public and personnel safety, yet achievable for compounders and organizations. The four-phase approach should be undertaken with a timeline of **four years** plus a notification period to registrants and should include non-hazardous and hazardous sterile compounding as one joint effort. Alternatively, the College could allow timeline extensions or a TBD for major infrastructure based on the need for further renovations when the non-sterile compounding Model Standards are released. (expected to be in 2017) |

College of Pharmacists
of British Columbia

# GAP IDENTIFICATION TOOL

## Adapted from NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations

# 2016

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All information gathered through the use of this tool will be confidential. The information will be used for aggregate data collection purposes only.

The name and identification of your facility is not required to complete this gap identification tool.

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Model Standards can be found here: http://napra.ca/Content_Files/Files/Mdl_Stnds_Pharmacy_Compounding_Hazardous_Sterile_Preparations_Nov2016_Revised.pdf

Each question has a drop-down list; you **must choose one** of the available selections.

Please answer **all** questions in the identification tool.

Note: You may need to consult with your engineering and maintenance department to be able to answer some of the questions related to the facility portion.

Email completed form by December 19th, 2016 to: Legislation at legislation@bcpharmacists.org

Thank you for participating in the survey.

| ID | Gap Identification Question(s) | Choose One Response that Accurately Represents Your Facility |
|---|---|---|
| 1 | Please select if you are a **Community** licensed pharmacy or a **Hospital** licensed pharmacy and if neither apply choose “other”. | Please Select ONE Option |
| 2 | How many **sterile hazardous** compounds does your operation prepare on average weekly? | Please Select ONE Option |
| 3 | Are you aware of the newly released NAPRA Model Standards for Pharmacy Compounding of **Hazardous Sterile** Preparations published September 2016? | Please Select ONE Option |
| 4 | Are you a registered Technician or Pharmacist | Please Select ONE Option |
| 5 | **If you are aware of the new standards**, have you read the Model Standards for Hazardous Sterile Compounding and started implementing them? | Please Select ONE Option |
| 6 | How did you hear about the newly released NAPRA Hazardous Sterile Compounding Standards? | Please Select ONE Option |
| 7 | Do **all** compounding personnel pass an initial gloved finger-tip sample before working in the compounding area? | Please Select ONE Option |
| 8 | Do **all** compounding personnel pass an initial media fill test before working in the compounding area for hazardous sterile products? | Please Select ONE Option |
| 9 | **All personnel** (pharmacists, pharmacy technicians and pharmacy assistants) assigned to the compounding of hazardous sterile preparations are assessed at least once a year for low or medium risk level; and at least twice a year for high risk level preparations? | Please Select ONE Option |

| | | |
|---|---|---|
| 10 | The air supplied to areas used for compounding hazardous sterile preparations pass-through a terminally fitted **high-efficiency particulate air (HEPA) filter** to ensure a very high level of cleanliness? | Please Select ONE Option |
| 11 | Particle counts (non-viable) are performed by trained, qualified personnel at least **every 6 months** as part of an internal quality control program **for facilities**? (see Appendices 5 and 6) | Please Select ONE Option |
| 12 | Particle counts are performed by trained, qualified personnel at least **every 6 months** as part of an internal quality control program for the **primary engineering control (PEC)**? (see Appendices 5 and 6 in NAPRA) | Please Select ONE Option |
| 13 | Water sources, sinks and drains are **not** located in the clean room? | Please Select ONE Option |
| 14 | The initial training and assessment program for compounding personnel includes reading and understanding P&Ps (see appendix 1), theoretical training with assessment (see appendix 3), assessment of aseptic techniques? | Please Select ONE Option |
| 15 | **PPE is worn** for the compounding of hazardous sterile preparations includes the following: Double Shoe covers, hair cover, beard cover (if applicable), N95 or N100 mask, sterile non-powdered gloves, non-shedding gown (enclosed at neck and sleeves that fit snuggly at the wrist, and moisture resistant)? | Please Select ONE Option |
| 16 | **Beyond-use dates** are assigned according to stability and the risk level associated with microbial contamination? (Low, Medium and High risk level BUDS) | Please Select ONE Option |
| 17 | **Before entering** the anteroom, personnel always remove personal outer garments (e.g., coat, hat, | Please Select ONE Option |

| | | |
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| | jacket scarf, sweater, vest, boots and outdoor shoes)? | |
| 18 | **Before entering** the anteroom, personnel always remove jewelry, studs and other accessories from fingers, wrists, forearms, face, tongue, ears and neck (this includes personal electronic devices or accessories, such as cell phone, iPod and earbuds, which are not permitted in the anteroom or clean room)? | Please Select ONE Option |
| 19 | **Before entering** the anteroom, personnel always remove all cosmetics, including makeup, false eyelashes, perfume, hair products such as hairspray, henna tattoos and paper tattoos? | Please Select ONE Option |
| 20 | **Before entering** the anteroom, personnel always remove nail polish and other nail applications? | Please Select ONE Option |
| 21 | Where packaging allows, compounding equipment and products are **disinfected with sterile 70% isopropyl alcohol** just before being introduced into the clean room? | Please Select ONE Option |
| 22 | Your pharmacy **has implemented** an environmental sampling plan that measures viable air and surface particles? | Please Select ONE Option |
| 23 | For **each** employee, a glove finger-tip sample is performed after the media fill test is completed annually for low-risk and medium-risk sterile compounding and every 6 months for high-risk sterile compounding? | Please Select ONE Option |
| 24 | The cleanroom **meets** ISO 14644-1 for cleanroom particulate airborne cleanliness at the ISO 7 level and there is documentation to support this? | Please Select ONE Option |

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| 25 | **<u>Daily</u> cleaning, decontamination and disinfecting** occurs in the C-PEC, counters, carts, floors and frequently touches surfaces in the anteroom and the cleanroom where hazardous drugs are compounded?<br><br>Note: review definitions of cleaning, decontamination and disinfection in NAPRA prior to answering this question. | Please Select ONE Option |
| 26 | Does your pharmacy prepare **high-risk** compounds? **Note:** High-risk is when non-sterile ingredients or supplies are used to create a sterile compound). | Please Select ONE Option |
| 27 | Cardboard **does not** enter the anteroom or cleanroom? | Please Select ONE Option |
| 28 | Alcohol based hand rub (AHBR) **with persistent activity** is used to perform hand antisepsis? | Please Select ONE Option |
| 29 | Bins used to introduce supplies or products into the cleanroom are **always** disinfected prior to use? | Please Select ONE Option |
| 30 | The cleanroom is verified to have a **minimum of 30 air changes per hour** (ACPH) with the air being completely exhausted to the exterior? | Please Select ONE Option |
| 31 | The cleanroom is verified to be kept under **negative** pressure relative to the anteroom. (-2.5 Pa)? | Please Select ONE Option |
| 32 | The anteroom is verified to have a **minimum of 30 air changes per hour** (ACPH)? | Please Select ONE Option |
| 33 | The pharmacy of the health care facility has established a committee comprised of representatives of the employer, representatives of compounding, administration personnel, and representatives of cleaning and disinfecting personnel for the compounding areas and within this team is a **pharmacist or pharmacy** | Please Select ONE Option |

| | | |
|---|---|---|
| | **technician** to support hazardous product management? | |
| 34 | **Cleaning and disinfecting personnel** are provided theoretical training and assessment covering the issues and particularities of cleaning and disinfecting the premises and equipment used for compounding hazardous sterile preparations as outlined in appendix 3? | Please Select ONE Option |
| 35 | The pharmacy has a developed list of hazardous drugs that require special handling precautions. This list is available at the pharmacy and is reviewed at least every 12 months. | Please Select ONE Option |
| 36 | The compounding area consists of an anteroom and a cleanroom. These rooms are each controlled and physically separated by a walls, door and pass-throughs? | Please Select ONE Option |
| 37 | The compounding supervisor is evaluated at the same frequency as compounding personnel, by a third party evaluator? | Please Select ONE Option |
| 38 | The anteroom is separated into **two spaces by a visible demarcation line**. The first space is referred to as “dirty” but chemical free. The second space is referred to as “clean but chemically contaminated”. | Please Select ONE Option |
| 39 | Hazardous products are stored in a properly ventilated room with all air exhausted to the exterior and negative pressure relative to the adjacent rooms with at least **12 air changes per hour**? | Please Select ONE Option |

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|---|---|---|
| 40 | Oncology adjunctive therapies can also be prepared in the BSC's or CACIs, if they are being compounded for the same patient as the hazardous sterile preparation. **These adjunctive therapies are handled and labeled to require hazardous drug precautions?** | Please Select ONE Option |
| 41 | All gloves (sterile and non-sterile) used in the unpacking, cleaning and disinfecting of the cleanroom, disinfecting the C-PEC, compounding, managing a spill and disposing of hazardous products are verified to be compliant with standards **D-6978-05 of ASTM International?** | Please Select ONE Option |
| 42 | When compounding hazardous drugs, both pairs of gloves are discarded and replaced at the earliest of the manufacture's limit for permeation of the gloves, every 30 minutes, or immediately if a tear, puncture or contamination has occurred or is suspected? | Please Select ONE Option |
| 43 | The gown is tested by the manufacturer to be resistant to permeability by hazardous drugs. It closes in the back, and has long sleeves with fitted cuffs at the wrist? | Please Select ONE Option |
| 44 | The gown is discarded and replaced at the earliest of the manufacturers time limit for permeation of the gown or after 2-3 hours of continuous compounding work or after each removal or after a contamination has occurred or is suspected? | Please Select ONE Option |
| 45 | A disposable hair cover is worn during compounding and it is discarded after each removal (not saved for re-use or worn outside of ante-room)? | Please Select ONE Option |
| 46 | **A chemical cartridge respirator with a pre-filter** is worn in the presence of vapours, gas and particles (e.g. dust) or if there has been a spill? (NAPRA page 36) ***Note:** In this case an N95 or | Please Select ONE Option |

| | | |
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| | N100 NIOSH-approved mask offers no protection from vapours, and gases and splashes. | |
| 47 | The mask worn during compounding is changed at the earliest of the following: after 3.5 hours of continuous compounding, after each removal or if contamination is suspected? | Please Select ONE Option |
| 48 | **Goggles and a face shield or full face-piece respirator** is worn when **deactivating, decontaminating and cleaning underneath the work surface of a C-PEC**, when cleaning up a spill, when there is risk of splashes to the face and eyes and when unpacking suspected damaged drugs? ***Note:** In this case an N95 or N100 NIOSH-approved mask offers no protection from vapours, and gases and splashes. | Please Select ONE Option |
| 49 | Compounding personnel wear clean room scrubs, not street clothes? | Please Select ONE Option |
| 50 | Cleaning equipment for cleaning areas used for the compounding of hazardous sterile preparation is specifically designated for this area? | Please Select ONE Option |
| 51 | Housekeeping personnel also don **two pairs of ASTM International gloves**, with the outer gloves being **sterile**? | Please Select ONE Option |
| 52 | **Daily cleaning, decontamination and disinfecting is** occurring for the following areas: C-PEC, counters, carts, floors, and surfaces that are touched frequently such as chairs) in hazardous drug compounding areas? | Please Select ONE Option |

| | | |
|---|---|---|
| 53 | The minimum frequency of surface decontamination, deactivation, and disinfection inside the C-PEC are occurring? (see table 8, in NAPRA) | Please Select ONE Option |
| 54 | The maximum syringe fill limit is **75% or ¾** of the total syringe capacity when withdrawing hazardous drugs? | Please Select ONE Option |
| 55 | The verification of hazardous drug compounding is through direct observation or image capture? | Please Select ONE Option |
| 56 | **Two pairs of ASTM International approved gloves** are donned when **unpacking intact hazardous products** that have been received from the supplier sealed in impervious plastic? | Please Select ONE Option |
| 57 | All PPE worn for hazardous drug handling is discarded in a hazardous waste containor? | Please Select ONE Option |
| 58 | The level of hazardous drug contamination is measured at least every 6 months (wipe sampling program)? | Please Select ONE Option |
| 59 | Compounding personnel wear an N95 respirator when compounding hazardous drugs in a BSC? | Please Select ONE Option |

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| 60 | The NAPRA Model Standards for Pharmacy Compounding of **Hazardous Sterile** Preparations is being adopted as a standard in BC. What barriers to implementation do you anticipate? Please also use the space provided to indicate any other concerns you might face with the NAPRA standards with the understanding that modifications to the standard are unlikely.<br><br>**Please type your responses to this question in the grey text box.** |

Save completed form and email to Legislation at legislation@bcpharmacists.org by December 19, 2016.

## C. Gap Identification Survey Tool "Collated Results"

| Question # | Survey question | % Compliant with each question |
|---|---|---|
| 1 | Please select if you are a **Community** licensed pharmacy or a **Hospital** licensed pharmacy and if neither apply choose "other". | 2 Community<br>13 Hospital |
| 2 | How many **sterile hazardous** compounds does your operation prepare on average weekly? | 1 – 10 preps = 2 respondents<br>11- 50 preps = 6 respondents<br>51 – 200 preps = 5 respondents<br>200> = 2 respondents |
| 3 | Are you aware of the newly released NAPRA Model Standards for Pharmacy Compounding of **Hazardous Sterile** Preparations published September 2016? | 3 no, 11 yes |
| 4 | Are you a registered Technician or Pharmacist | 8 techs & 7 pharmacists |
| 5 | **If you are aware of the new standards**, have you read the Model Standards for Hazardous Sterile Compounding and started implementing them? | 3 – no, 9 yes, 3 planning on it |
| 6 | How did you hear about the newly released NAPRA Hazardous Sterile Compounding Standards? | 3 employer, 5 colleagues, 6 other, 1 unaware |
| 26 | Does your pharmacy prepare **high-risk** compounds? **Note:** High-risk is when non-sterile ingredients or supplies are used to create a sterile compound). | 9 out of 15 respondents prepare HR compounds |
| 7 | Do **all** compounding personnel pass an initial gloved finger-tip sample before working in the compounding area? | 18% |
| 8 | Do **all** compounding personnel pass an initial media fill test before working in the compounding area for hazardous sterile products? | 22% |

| Question # | Survey question | % Compliant with each question |
|---|---|---|
| 9 | **All personnel** (pharmacists, pharmacy technicians and pharmacy assistants) assigned to the compounding of hazardous sterile preparations are assessed at least once a year for low or medium risk level; and at least twice a year for high risk level preparations? | 24% |
| 10 | The air supplied to areas used for compounding hazardous sterile preparations pass-through a terminally fitted **high-efficiency particulate air (HEPA) filter** to ensure a very high level of cleanliness? | 78% |
| 11 | Particle counts (non-viable) are performed by trained, qualified personnel at least **every 6 months** as part of an internal quality control program **for facilities**? (see Appendices 5 and 6) | 73% |
| 12 | Particle counts are performed by trained, qualified personnel at least **every 6 months** as part of an internal quality control program for the **primary engineering control (PEC)**? (see Appendices 5 and 6 in NAPRA) | 76% |
| 13 | Water sources, sinks and drains are **not** located in the clean room? | 60% |
| 14 | The initial training and assessment program for compounding personnel includes reading and understanding P&Ps (see appendix 1), theoretical training with assessment (see appendix 3), assessment of aseptic techniques? | 71% |

| Question # | Survey question | % Compliant with each question |
|---|---|---|
| 15 | **PPE is worn** for the compounding of hazardous sterile preparations includes the following: Double Shoe covers, hair cover, beard cover (if applicable), N95 or N100 mask, sterile non-powdered gloves, non-shedding gown (enclosed at neck and sleeves that fit snuggly at the wrist, and moisture resistant)? | 71% |
| 16 | **Beyond-use dates** are assigned according to stability and the risk level associated with microbial contamination? (Low, Medium and High risk level BUDS) | 73% |
| 17 | **Before entering** the anteroom, personnel always remove personal outer garments (e.g., coat, hat, jacket scarf, sweater, vest, boots and outdoor shoes)? | 73% |
| 18 | **Before entering** the anteroom, personnel always remove jewelry, studs and other accessories from fingers, wrists, forearms, face, tongue, ears and neck (this includes personal electronic devices or accessories, such as cell phone, iPod and earbuds, which are not permitted in the anteroom or clean room)? | 64% |
| 19 | **Before entering** the anteroom, personnel always remove all cosmetics, including makeup, false eyelashes, perfume, hair products such as hairspray, henna tattoos and paper tattoos? | 62% |
| 20 | **Before entering** the anteroom, personnel always remove nail polish and other nail applications? | 76% |
| 21 | Where packaging allows, compounding equipment and products are **disinfected with sterile 70% isopropyl alcohol** just before being introduced into the clean room? | 44% |

| Question # | Survey question | % Compliant with each question |
|---|---|---|
| 22 | Your pharmacy **has implemented** an environmental sampling plan that measures viable air and surface particles? | 29% |
| 23 | For **each** employee, a glove finger-tip sample is performed after the media fill test is completed annually for low-risk and medium-risk sterile compounding and every 6 months for high-risk sterile compounding? | 13% |
| 24 | The cleanroom **meets** ISO 14644-1 for cleanroom particulate airborne cleanliness at the ISO 7 level and there is documentation to support this? | 60% |
| 25 | **Daily cleaning, decontamination and disinfecting** occurs in the C-PEC, counters, carts, floors and frequently touches surfaces in the anteroom and the cleanroom where hazardous drugs are compounded? Note: review definitions of cleaning, decontamination and disinfection in NAPRA prior to answering this question. | 56% |
| 27 | Cardboard **does not** enter the anteroom or cleanroom? | 64% |
| 28 | Alcohol based hand rub (AHBR) **with persistent activity** is used to perform hand antisepsis? | 84% |
| 29 | Bins used to introduce supplies or products into the cleanroom are **always** disinfected prior to use? | 42% |
| 30 | The cleanroom is verified to have a **minimum of 30 air changes per hour** (ACPH) with the air being completely exhausted to the exterior? | 58% |
| 31 | The cleanroom is verified to be kept under **negative** pressure relative to the anteroom. (-2.5 Pa)? | 60% |

| Question # | Survey question | % Compliant with each question |
|---|---|---|
| 32 | The anteroom is verified to have a **minimum of 30 air changes per hour** (ACPH)? | 51% |
| 33 | The pharmacy of the health care facility has established a committee comprised of representatives of the employer, representatives of compounding, administration personnel, and representatives of cleaning and disinfecting personnel for the compounding areas and within this team is a **pharmacist or pharmacy technician** to support hazardous product management? | 20% |
| 34 | **Cleaning and disinfecting personnel** are provided theoretical training and assessment covering the issues and particularities of cleaning and disinfecting the premises and equipment used for compounding hazardous sterile preparations as outlined in appendix 3? | 44% |
| 35 | The pharmacy has a developed list of hazardous drugs that require special handling precautions. This list is available at the pharmacy and is reviewed at least every 12 months. | 44% |
| 36 | The compounding area consists of an anteroom and a cleanroom. These rooms are each controlled and physically separated by a walls, door and pass-throughs? | 71% |
| 37 | The compounding supervisor is evaluated at the same frequency as compounding personnel, by a third-party evaluator? | 20% |

| Question # | Survey question | % Compliant with each question |
|---|---|---|
| 38 | The anteroom is separated into **two spaces by a visible demarcation line**. The first space is referred to as "dirty" but chemical free. The second space is referred to as "clean but chemically contaminated". | 44% |
| 39 | Hazardous products are stored in a properly ventilated room with all air exhausted to the exterior and negative pressure relative to the adjacent rooms with at least **12 air changes per hour**? | 47% |
| 40 | Oncology adjunctive therapies can also be prepared in the BSC's or CACIs, if they are being compounded for the same patient as the hazardous sterile preparation. **These adjunctive therapies are handled and labeled to require hazardous drug precautions?** | 58% |
| 41 | All gloves (sterile and non-sterile) used in the unpacking, cleaning and disinfecting of the cleanroom, disinfecting the C-PEC, compounding, managing a spill and disposing of hazardous products are verified to be compliant with standards **D-6978-05 of ASTM International?** | 67% |
| 42 | When compounding hazardous drugs, both pairs of gloves are discarded and replaced at the earliest of the manufacture's limit for permeation of the gloves, every 30 minutes, or immediately if a tear, puncture or contamination has occurred or is suspected? | 62% |
| 43 | The gown is tested by the manufacturer to be resistant to permeability by hazardous drugs. It closes in the back, and has long sleeves with fitted cuffs at the wrist? | 87% |

| Question # | Survey question | % Compliant with each question |
|---|---|---|
| 44 | The gown is discarded and replaced at the earliest of the manufacturers time limit for permeation of the gown or after 2-3 hours of continuous compounding work or after each removal or after a contamination has occurred or is suspected? | 60% |
| 45 | A disposable hair cover is worn during compounding and it is discarded after each removal (not saved for re-use or worn outside of ante-room)? | 93% |
| 46 | **A chemical cartridge respirator with a pre-filter** is worn in the presence of vapours, gas and particles (e.g. dust) or if there has been a spill? (NAPRA page 36) ***Note:** In this case an N95 or N100 NIOSH-approved mask offers no protection from vapours, and gases and splashes. | 16% |
| 47 | The mask worn during compounding is changed at the earliest of the following: after 3.5 hours of continuous compounding, after each removal or if contamination is suspected? | 69% |
| 48 | **Goggles and a face shield or full face-piece respirator** is worn when **deactivating, decontaminating and cleaning underneath the work surface of a C-PEC**, when cleaning up a spill, when there is risk of splashes to the face and eyes and when unpacking suspected damaged drugs? ***Note:** In this case an N95 or N100 NIOSH-approved mask offers no protection from vapours, and gases and splashes. | 20% |

| Question # | Survey question | % Compliant with each question |
|---|---|---|
| 49 | Compounding personnel wear clean room scrubs, not street clothes? | 80% |
| 50 | Cleaning equipment for cleaning areas used for the compounding of hazardous sterile preparation is specifically designated for this area? | 80% |
| 51 | Housekeeping personnel also don **two pairs of ASTM International gloves**, with the outer gloves being **sterile**? | 20% |
| 52 | **Daily cleaning, decontamination and disinfecting is** occurring for the following areas: C-PEC, counters, carts, floors, and surfaces that are touched frequently such as chairs) in hazardous drug compounding areas? | 56% |
| 53 | The minimum frequency of surface decontamination, deactivation, and disinfection inside the C-PEC are occurring? (see table 8, in NAPRA) | 76% |
| 54 | The maximum syringe fill limit is **75% or ¾** of the total syringe capacity when withdrawing hazardous drugs? | 91% |
| 55 | The verification of hazardous drug compounding is through direct observation or image capture? | 27% |

| Question # | Survey question | % Compliant with each question |
|---|---|---|
| 56 | **Two pairs of ASTM International approved gloves** are donned when **unpacking intact hazardous products** that have been received from the supplier sealed in impervious plastic? | 27% |
| 57 | All PPE worn for hazardous drug handling is discarded in a hazardous waste container? | 82% |
| 58 | The level of hazardous drug contamination is measured at least every 6 months (wipe sampling program)? | 0% |
| 59 | Compounding personnel wear an N95 respirator when compounding hazardous drugs in a BSC? | 47% |
| | | |

## D. Barriers to Implementation (Raw data from respondents)

**Survey question #60 responses**

| **The NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations is being adopted as a standard in BC. What barriers to implementation do you anticipate? Please also use the space provided to indicate any other concerns you might face with the NAPRA standards with the understanding that modifications to the standard are unlikely.** |
|---|
| We do not have a 797 compliant IV room<br>No negative pressure, hazardous medication manufactured in the same room as regular CIVA and no anteroom<br>No ventilated room for storing hazardous products. Currently stored in the compounding room with the BSC<br>We do not have the respirator masks and staff have not been fitted to them<br>BCCA has not been to certify staff since 2014<br>We do not do any fingertip or media fill testing |
| There are a number of concerns with adoption of NAPRA. The staffing level in our facilities are low and the requirement for auditing, training, sampling etc pulls these staff away from their operational duties. |
| Largest barrier would be financial and unless College mandates and provides a timeline for implementation, pharmacy sites will delay as long as possible which is not ideal or best practice. There are also limited training courses on the subject, so properly educating staff by qualified people will be a barrier. |
| Facility does not support implementation of NAPRA standards. New building is being built that will support standards. This will be available in September of 2017. My site has been without a site coordinator since September 2016. As such, there has not been a local supervisor to review the standards and implement changes. In fact, there has not been anyone supervising compounding other than the daily staff doing the work. |

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| We will be challenged to implement the microbial testing of surfaces, media fill testing and gloved -fingertip testing to comply with NAPRA; We do not have the resources to verify HD compounding through direct observation or image capture-this will be a huge challenge to adhere to; The requirement to wear N95/100 NIOSH approved respirator masks when compounding HDs in a BSC (and using CSTD to prepare HDs)is unreasonable; annual HD wipe sampling should be acceptable - not sure why Q58 says every 6 months - NAPRA allows for the frequency of monitoring to be based on the results obtained on previous monitoring; In question 51- I think you mean housekeeping that is working in the cleanroom must wear 2 Pr of sterile chemotherapy approved gloves; |
| Physical and logistical barriers are going to be multitudinous. The fact is that most hospitals in the Lower Mainland simply do not have the space/building requirements to be USP 797 compatible, much less compatible with the new NAPRA Hazardous Compounding standards. Funding is a huge issue and it is the frequently cited excuse by VCH and FH upper management for why we do not have adequate Sterile Compounding areas. |
| |
| At VGH Pharmacy, the hand wash sink is still directly next to the LFH's and BSC's, inside the 'sterile' room. We have no anteroom or buffer room. Management does not mandate Fingertip testing. The IV Supervisor has not been evaluated in many years, and regular check ins for Sterile Compounding staff are nonexistent. |
| |
| Serious steps should be taken to impress the need for these standards to Upper Management in the Health Authorities, and throughout LMPS. Beyond self-driven standards for excellence, Technicians are having to work in very substandard compounding rooms that are not, by definition, sterile in any way. |
| We do not currently do GFS or Media-fill tests- although it is something I know we need to start doing sooner rather than later. I do not know what is involved in setting up this type of program and therefore do not know how long it would take to get going on it. |
| Because we outsource our housekeeping services, we do not have control over their training and competency assessments. I do not know that we will ever be able to annually assess our housekeeping staff (as they are not 'our' housekeeping staff) |
| I believe our center complies with the requirements of annual testing by an 'independent' person, however, this is not defined so I am not sure. Also, I do not know if it can be considered 'independent' when the pharmacy manager dictates what the staff are tested on. More clarity here would be helpful. |
| Our 'independent' evaluator currently does not comply with all the requirements mentioned in that section as they do not do annual competencies themselves. |
| In section 5.1.2.3 NAPRA talks about 'Failures' of compounding personnel, however, in Section 7.2, the Results and Action Levels do not talk about 'failures'. What is a 'failure'? More clarity here would be helpful. |

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| The BUD of vials- wherein we can only reuse a vial that stays in an ISO Class 5 environment…I understand this requirement, however, ISMP would argue that having a cabinet full of vials is not safe. I don't know what to do with this one, however, as we use 'single-use' vials for up to 6 hours…and we remove them from out cabinet. This is another area we are NOT compliant |
| Implementing a camera checking system will take resources that my organization is currently looking at. We are not willing to have a person dedicated in the cleanroom to checking every preparation 'in real time' but we are willing to use a camera system. Hopefully we will be able to implement the camera checking by the time NAPRA is enforced. This checking process is WAY overdue for high-alert drugs. |
| We do not currently record the lot/expiry date of the IV solution bags and non-hazardous drugs used to compound patient-specific preparations…we do record the lot/expiry of each hazardous drug used. |
| Using a sporicidal to wipe items going into the cleanroom- I do not see the value in using a sporicidal for the sake of using a sporicidal. Because most (all?) sporicidal have an extended contact time to actually kill any spores, it would take an incredibly LONG time to introduce items into the cleanroom. I do not see us ever being compliant with this…we can use a sporicidal, but what is the point if we are not using it correctly? |
| Section 6.6.6.1- Role of personnel in verification- it is the supervisor's responsibility to verify all compounded hazardous drugs. This is not reasonable. We have alternate staff checking final products and therefore will not ever comply with this section of the standards. |
| Same section, it is the person that compounds the preparation's responsibility to store the final product where applicable- this also does not happen. For us, it is the person performing the final product check that ensures proper storage for products that are not immediately dispensed to nursing staff or the patient…it is not reasonable for the compounding staff to leave the cleanroom to store final products. We will never comply with this section of the standards. |
| When dispensing a final product for same-day use (e.g., within 1-2 hours' maximum), we do not put a BUD on the product UNLESS the product is time sensitive (e.g., must be adminstered within 30 minutes of first puncture of the vial stopper) |
| The layout of the existing pharmacy would need to be completely re-done including the ventilation system and temperature control and negative pressure. New fridges would need to be purchased. More staff would need to be hired. |
| 1) Storage of hazardous products in a negative pressure room with at least 12 air exchange per hour - this will be especially difficult for any products that require refrigeration as our cleanroom and anteroom do not have enough space for a refrigerator. That means we have to construct a special room just to store the product, a challenge in an already built pharmacy. |

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| 2) Implementing a wipe sampling program every 6 months as that will add significant cost to send the samples for analysis. |
| It is unlikely that facility can be re-modeled to meet the standards in a short-time frame. If the standards were to be enforced by the College, then I foresee that many facilities will step away from compounding hazardous sterile products, resulting in lessened access for patients. |
| cost |
| dependent on upper management to implement |
| would require major renovations to anteroom/cleanroom |
| would increase preparation time = patients would need to wait longer for medication |
| A major concern that I have and one that will be a barrier for implementing NAPRA standards, is the physical layout and inadequate space of the area where the BSCs are located. Specifically, for my Kootenay Boundary Regional Hospital site [Trail, BC], the non-hazardous hood is located in a small room, with no anteroom, and no air exchange system. This "clean" room is accessed from the main pharmacy where there is heavy traffic. In addition, the staff are required to wash hands at the opposite end of the Pharmacy, prior to entering the clean room and donning PPE. Coupled to that is the very small and inadequate size of the overall Pharmacy Department. A sustainability plan for KBRH site has been drafted but is contingent on financial support from the Ministry. Based on competing priorities for very lean capital funding, the likelihood of this sustainability project moving forward is slim. Further to this issue our hazardous room, which does have an anteroom and an air exchange system, has one disadvantage of inappropriate access. The anteroom opens up to a public hallway. Due to major space constraints, we had no other options when planning the construction of this space and we tried to make due with limited opportunities. I do have a compounding facility in my Nelson Pharmacy that possible could meet the NAPRA standards, however it would be very impractical and result in significant time delays if I manufactured all sterile products at that facility and then had to transfer them to Trail. It takes over an hour to travel between sites and coupled with poor driving conditions, limited transportation options and poor stability of some manufactured products it would make this opportunity impossible. |
| aspects of NAPRA that are misaligned/"exceed" requirements of USP 800, NIOSH recommendations, provincial or health authority hazardous drugs handling policies |
| e.g. requirement for image capture or direct observation for compounding verification, requirement to wear N95 mask for hazardous compounding<br>- cost of implementation<br>- change saturation of staff e.g. layering on top of medication reconciliation, Clinical Systems Transformation project |

Barriers: some barriers I anticipate include

1. BUD: this will change our practice and will need Pyxis/Omni cell capacity as well as time to manufacture more frequently

2. ceiling tiles used in my clean rooms are not sealed

We are having some air pressure issues in regards to the Pa of our ante room

4. We do not have fingertip sampling or media fill test set up

5. need to know if a fridge holding hazardous drugs is meant to be in the negative pressure clean room?

6. My site has difficulty maintaining regular/trained housekeeping staff to ensure proper procedures are known and followed

7. A working group for my health authority is working on a hazardous drug policy: having the knowledge from this group will help us move forward with proper receiving/storage and a complete list of hazardous drugs to follow

8. having someone verify that our products (egg. gown/gloves) are certified/tested for mixing/handling hazardous products

## Other Jurisdictions that have Adopted the Released NAPRA Model Standards

Below is a summary of the regulatory authorities that have adopted the released NAPRA Model Standards and their implementation schedules, if applicable. Please note, that Alberta, Ontario and Manitoba have adopted the Model Standards through multi-year implementation phases.

### Alberta

- Adopted Hazardous Sterile Model Standards: June 2016
- Adopted Non Hazardous Sterile Model Standards: December 2016
- Implementation (same for both):
    - Phase 1 by July 1, 2018
    - Phase 2 by January 1, 2019
    - Phase 3 has not yet been approved by Council
- Implementation phase details are below:

| Phase 1<br>(July 1, 2018) | Phase 2<br>(January 1, 2019) | Phase 3<br>(timing not yet approved) |
|---|---|---|
| • Review NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations<br>• Identify risk level (complexity, volume) of compounded sterile preparations<br>• Perform a gap analysis by comparing the Model Standards with current pharmacy sterile compounding procedures and facilities<br>• Prioritize the gap analysis and develop an action plan for compliance with the Model Standards<br>• Initiate a quality assurance program<br>• Verification of equipment, including PEC<br>- Verification of controlled areas (clean room and anteroom)<br>- Development of a written sampling plan for controlled areas according to specifications of a recognized standard, such as CETA | • Meet or exceed core requirements for a sterile compounding service<br>- Personnel – both compounding personnel and cleaning personnel<br>- Policies and procedures<br>• Meet or exceed production preparation requirements<br>- Compliance with beyond use dating and dating methods – including consideration of the requirements surrounding sterility and endotoxin testing<br>- Compounded sterile preparation protocols<br>- Compounded sterile preparation log<br>- Patient file<br>- Conduct of personnel in areas reserved for the compounding of sterile preparations<br>- Aseptic compounding of non-hazardous sterile preparations – including but not limited to hand and forearm hygiene and garbing, cleaning and disinfection<br>- Packaging<br>- Storage | • Meet or exceed core requirements for a sterile compounding services<br>- Facilities and equipment |

| | | |
|---|---|---|
| applications guide CAG-002, CAG-003, or CAG-008 | - Transport and delivery<br>• Complete quality assurance program<br>- Verification of equipment and facilities – certification and written sampling plan (Implementation Framework, step one)<br>- Results and action levels<br>- Quality assurance of personnel involved in aseptic compounding – Gloved fingertip sampling, media fill test<br>- Quality assurance of compounded sterile preparations<br>- Documentation of quality control activities | |

## Ontario

- Adopted Hazardous Sterile Model Standards: September 2016
- Adopted Non Hazardous Sterile Model Standards: September 2016
- Implementation (both): Everything by January 1, 2019

## Nova Scotia

- Adopted both Hazardous Sterile and Non-Hazardous Sterile: November 2016
- No implementation schedule except for the following:
  - Standards 5.3 – Facilities and Equipment and 7.0 Quality Assurance Program: should a pharmacy identify that they are deficient in meeting this standard (either through a self-administered or external audit), the pharmacy should be provided with *6 months* [emphasis added] to address the deficiency because of the time to implement the changes.

## Newfoundland and Labrador

- Adopted Hazardous Sterile Model Standards: February 2017
- Adopted Non Hazardous Sterile Model Standards: February 2016
- No implementation schedule.

## Manitoba

- Adopted both Hazardous Sterile and Non-Hazardous Sterile: February 2017
- Implementation (both):
  - Phase 1 by June 1, 2018
  - Phase 2 by June 1, 2019
  - Phase 3 by January 1, 2021
- Implementation phase details are below:

| Phase 1<br>(June 2018) | Phase 2<br>(June 2019) | Phase 3<br>(January 2021) |
|---|---|---|
| • 5.1 Develop and implement a training and assessment program for staff involved in non-hazardous sterile compounding.<br>• 5.2 Develop and implement documented policies and procedures for non-hazardous sterile compounding<br>• 6.2, 6.3, and 6.4 Develop and implement protocols and preparation logs for compounded sterile preparations.<br>• 6.7, 6.8, 6.9, 6.12 Develop and implement protocols for non-hazardous medication packaging, storage, transport, waste management, and delivery procedures.<br>• 6.10, 6.11 Develop recall procedures (traceability), and incident/accident management procedures.<br>• 7. Develop and implement a quality assurance program for non-hazardous sterile compounding. | • 6.5, 6.6 Educate and validate all staff involved in non-hazardous sterile compounding (includes conduct of personnel in areas reserved for compounding, handwashing, garbing, aseptic compounding techniques, cleaning and disinfecting, verification, and labelling). | • 6.1 Establish documented beyond-use dates and dating methods.<br>• 5.3 Facilities and Equipment |

College of Pharmacists of British Columbia

# c) HPA – Filing (Fees)

College of Pharmacists of British Columbia

# HPA Fee Changes

- At the February 2017 Board meeting, the Board approved fee increases as part of the College's 2017/2018 budget.
- To make these fee changes take effect, amendments to the *Health Professions Act* (HPA) Bylaws Schedule D – Fee Schedule are required.
- These HPA fee changes are not required to be publicly posted.
- Once approved by the Board, the bylaws will be sent to the Ministry of Health for filing.

College of Pharmacists of British Columbia

# HPA Fee Changes – Filing with MoH

**MOTION:**

RESOLVED THAT, in accordance with the authority established in section 19(1) of the *Health Professions Act*, and subject to filing with the Minister as required by section 19(3) of the *Health Professions Act*, the board amend the bylaws of the College of Pharmacists of British Columbia, as set out in the schedule attached to this resolution.

College of Pharmacists of British Columbia

# BOARD MEETING
# April 21, 2017

## 4c. Legislation Review Committee
## i) HPA Bylaw Changes – Fee Changes

## DECISION REQUIRED

### Recommended Board Motion:

*Approve the following resolution:*

*RESOLVED THAT, in accordance with the authority established in section 19(1) of the Health Professions Act, and subject to filing with the Minister as required by section 19(3) of the Health Professions Act, the board amend the bylaws of the College of Pharmacists of British Columbia, as set out in the schedule attached to this resolution.*

### Purpose

To approve amendments to the *Health Professions Act* (HPA) Bylaws Schedule D – Fee Schedule in accordance with the College's 2017/2018 budget, as set out in the attached schedule to the resolution (Appendix 1).

### Background

The Board may make bylaws as per section 19(1)(p) of the HPA to establish fees payable to the College by registrants. These fees must be consistent with the duties and objectives of the College. Section 19(2.1) of the HPA also provides authority to the Board to establish forms and further allows for the Registrar to establish these forms.

Section 19(6.2) of the HPA exempts the establishment of HPA fees (amongst other bylaw making authorities) from the 90 day public posting period. Accordingly, once approved by the Board, these bylaws are to be sent to the Ministry of Health for filing.

This package includes proposed bylaw amendments to actualize HPA fee increases previously approved as part of the College's 2017/2018 budget. At their February 2017 meeting, the Board approved the 2017/2018 budget, which included fee increases in order to meet the needs of

the College. See Appendix 2 for the February 2017 Board briefing note outlining both discussion and details of the budget.

The College seeks to have the majority of these HPA fee changes take effect for the January 1 – December 31, 2018 pay period. Student fee changes would be on a different timing schedule: those changes would be effective for the September 2017 to August 2018 pay period, to be consistent with the school calendar.

In addition to the amended fee schedule, revised forms have also been approved by the Registrar. College staff recommend that these forms also be sent to the Ministry of Health for filing.

## Next Steps

Upon approval by the Board, the amended fee schedule and forms will be sent to the Ministry of Health for filing. As noted above, the College is seeking that the majority of the increased HPA fees are made effective for the January 2018-December 2018 pay period. The proposed student fee increases would take effect for the September 2017-August 2018 pay period, in line with the school calendar.

## Recommendation

The Legislation Review Committee recommends that the Board approve the HPA Bylaws Schedule D – Fee Schedule for filing with the Ministry of Health, as circulated.

| **Appendix** | |
|---|---|
| 1 | Schedule to the Resolution (track changes) |
| 2 | February 2017 Board Briefing Note – Budget 2017-18 |

**College of Pharmacists of B.C.**

**FEE SCHEDULE**

**HPA Bylaw "Schedule D"**

## REGISTRATION FEES

| | | | |
|---|---|---|---|
| **Pharmacist** | | | |
| Application for Pre-registration | Valid for up to three years. | ~~$ 315.00~~ | $ 399.00 |
| Application for Re-instatement | Valid for up to three years. | ~~$ 315.00~~ | $ 399.00 |
| Full Pharmacist - registration | For a term of one year. | ~~$ 580.00~~ | $ 699.00 |
| Full Pharmacist - registration renewal | For a term of one year. | ~~$ 580.00~~ | $ 699.00 |
| Non-practising Pharmacist - registration | For a term of one year. | ~~$ 580.00~~ | $ 699.00 |
| Non-practising Pharmacist - registration renewal | For a term of one year. | ~~$ 580.00~~ | $ 699.00 |
| Limited Pharmacist - registration | For a term of one year. Maximum three one-year terms. | $ 580.00 | |
| Limited Pharmacist - renewal | Maximum two one-year renewal terms | $ 580.00 | |
| Temporary Pharmacist | Valid for up to 90 days; during an emergency situation only. | $ 0.00 | |
| Late registration renewal fee (≤90 days from renewal date). | | ~~$ 100.00~~ | $ 125.00 |
| **Student Pharmacist** | | | |
| New Student Pharmacist (UBC) | Valid for one year. | ~~$ 0.00~~ | $ 100.00 |
| New Student Pharmacist (Non UBC) | Valid for one year. | ~~$ 0.00~~ | $ 100.00 |
| Registration Renewal (UBC) | Valid for one year. | $ 0.00 | |
| Application for Re-instatement (UBC) | For re-instatment after 90 days of registration expiry; valid for one year. | $ 0.00 | |
| **Pharmacy Technician** | | | |
| Application for Pre-registration | Valid for up to three years. | ~~$ 210.00~~ | $ 266.00 |
| Application for Re-instatement | Valid for up to three years. | ~~$ 210.00~~ | $ 266.00 |
| Pharmacy Technician - registration | For a term of one year. | ~~$ 386.00~~ | $ 465.00 |
| Pharmacy Technician - registration renewal | For a term of one year. | ~~$ 386.00~~ | $ 465.00 |
| Non-practising Pharmacy Technician - registration | For a term of one year. | ~~$ 386.00~~ | $ 465.00 |
| Non-practising Pharmacy Technician - registration renewal | For a term of one year. | ~~$ 386.00~~ | $ 465.00 |
| Temporary Pharmacy Technician | Valid for up to 90 days; during an emergency situation only. | $ 0.00 | |
| Late registration renewal fee (≤90 days from renewal date). | | ~~$ 100.00~~ | $ 125.00 |
| Structured Practical Training Program | Valid for 6 months from application date. | ~~$ 341.25~~ | $ 375.00 |

## CERTIFICATION FOR INJECTION DRUG ADMINISTRATION

| | | |
|---|---|---|
| Application for certification | $ 100.00 | |

## ADMINISTRATION FEES

| | | | |
|---|---|---|---|
| Replacement of registration certificate | | ~~$ 100.00~~ | $ 125.00 |
| Certificate of standing | | ~~$ 100.00~~ | $ 125.00 |
| Processing of non-sufficient funds (NSF) cheque | | ~~$ 100.00~~ | $ 125.00 |
| Criminal Record Check (CRC) | See Criminal Record Check Fee Regulation BCReg238/2002 as amended | - | |
| Jurisprudence Examination (JE) | | ~~$ 190.00~~ | $ 249.00 |
| Pharmacy Practice Manual (available free on website) | | ~~$ 250.00~~ | $ 275.00 |

***NOTES:***

*1) Fees are non-refundable.*

*2) All fees except Criminal Record Check are subject to GST.*

*3) Annual registration renewal notices are sent at least thirty (30) days prior to expiry date.*

*4) Completion of registration forms may be required for items with $0.00 fee amounts.*

College of Pharmacists of British Columbia

# BOARD MEETING
# February 17, 2017

## 5. Audit & Finance Committee – Draft 2017/18 Budget
## Addendum to the original Briefing Note – added February 16, 2017

## DECISION REQUIRED

### Recommended Board Motion:

*Approve the 2017/18 budget Plan C with revenue totaling $8,262, 070 and expenditures totaling $9,594,567, and the accompanying list of fees, as attached in the appendix to this motion.*

### Synopsis

The Audit and Finance Committee met on February 16th to review the budget options. After careful review and discussion a third option was requested and prepared. The Audit and Finance Committee is recommending the new Plan C Budget.

### Plan C Budget – Total Revenues - $8,262,070

Plan C's budget has only a slight change from Plan B's revenue – increasing the Pharmacy licence fee to $2,250 in 2017-18. All other aspects remain the same as in Plan B.

| | Base | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Year 6 |
|---|---|---|---|---|---|---|---|
| | 2016-17 | 2017-18 | 2018-19 | 2019-20 | 2020-21 | 2021-22 | 2022-23 |
| Pharmacy | $2,001 | $2,250 | $2,275 | $2,315 | $2,315 | $2,315 | $2,315 |
| Pharmacist | $580 | $699 | $799 | $824 | $824 | $824 | $824 |
| Ph. Tech. | $386 | $465 | $532 | $549 | $549 | $549 | $549 |

### Recommendation

The Audit and Finance Committee recommends that the Board approve the Plan C budget for the following reasons:

- The fee increases are spread out over the next few years bringing the College's reserves back to the targeted balance within the next six years.
- By modifying the initial Pharmacy licence fee, the closing balance of the reserves does not drop quite as low as Plan B and there is a possibility of returning to fully funded reserves a year earlier.

| **Appendix** | |
|---|---|
| 1 | Budget Plan C package |
| 2 | Multi Year Fee Table for Comparison |

College of Pharmacists of British Columbia

# c) PODSA – Public Posting (Fees and Forms)

College of Pharmacists of British Columbia

# PODSA Fee and Form Changes

- At the February 2017 Board meeting, the Board approved fee increases as part of the College's 2017/2018 budget.
- To make these fee changes take effect, amendments to the *Pharmacy Operations and Drug Scheduling Act* (PODSA) Bylaws Schedule A – Fee Schedule are required.
- Once approved by the Board, the bylaws and forms will be posted on the College website for a legislated 90 day public posting period.

College of Pharmacists of British Columbia

# PODSA Fee and Form Changes

**MOTION:**

Approve the proposed draft Pharmacy Operations and Drug Scheduling Act Bylaws Schedule A – Fee Schedule and related forms for public posting, as circulated.

College of Pharmacists of British Columbia

# BOARD MEETING
# April 21, 2017

## 4c. Legislation Review Committee
## ii) PODSA Bylaw Changes – Fee Changes

## DECISION REQUIRED

### Recommended Board Motion:

*Approve the following resolution:*

*RESOLVED THAT, in accordance with the authority established in section 21(8) of the Pharmacy Operations and Drug Scheduling Act, the board approve the proposed draft bylaws of the College of Pharmacists of British Columbia, and related forms for public posting, as circulated.*

### Purpose

To approve amendments to the *Pharmacy Operations and Drug Scheduling Act* (PODSA) Bylaws Schedule A – Fee Schedule and related forms in accordance with the College's 2017/2018 budget, as circulated (Appendix 1).

### Background

The Board may make bylaws as per section 21(1)(d) of PODSA to determine requirements for the licensing and operation of a pharmacy – including fees and forms. Unlike the *Health Professions Act* (HPA), PODSA does not exempt particular bylaws (e.g. fee schedules) from the 90 day public posting period requirement. Additionally, in contrast to the HPA, PODSA does not authorize the Registrar to establish forms.

This package includes proposed bylaw amendments to actualize PODSA fee increases previously approved as part of the College's 2017/2018 budget. At their February 2017 meeting, the Board approved the 2017/2018 budget which included fee increases in order to meet the needs of the College. See Appendix 2 for the February 2017 Board briefing note outlining both discussion and details of the budget.

The related form changes (Appendix 3) recommended under PODSA are:

- Form 1A – 'Application for New Pharmacy - Community'
- Form 1B – 'Application for New Pharmacy – Hospital'
- Form 1C – 'Application for New Pharmacy – Education Site'
- Form 1D – 'Application for Change of Ownership'
- Form 2 – 'Application for Telepharmacy Services'
- Form 3 – 'Application for Hospital Satellite'
- Form 4 – 'Community Pharmacy Licence Renewal Notice'
- Form 5 – 'Hospital Pharmacy Licence Renewal Notice'
- Form 6 – 'Education Site Licence Renewal'

## Next Steps

Once the 90 public posting period is completed, both the bylaws and forms will be brought to the Board at their September 2017 meeting for filing approval. As noted above, these fee increases are to take effect for the February 2018 – January 2019 pay period.

## Recommendation

The Legislation Review Committee recommends that the Board approve the PODSA Bylaws Schedule A – Fee Schedule and related forms for public posting as circulated.

| **Appendix** | |
|---|---|
| 1 | Amended Fee Schedule (track changes) |
| 2 | February 2017 Board Briefing Note – Budget 2017-18 |
| 3 | Forms (track changes) |

**College of Pharmacists of B.C.**

**FEE SCHEDULE**

**PODSA Bylaw "Schedule A"**

## PHARMACY

### LICENSURE FEES

| | | | |
|---|---|---|---|
| Community Pharmacy | Annual license fee. | ~~$ 2,001.00~~ | $ 2,250.00 |
| Hospital Pharmacy | Annual license fee. | ~~$ 2,001.00~~ | $ 2,250.00 |
| Pharmacy Education Site | Annual license fee. | ~~$ 315.00~~ | $ 550.00 |
| Telepharmacy Service | Annual fee for each site receiving service, to be charged to Pharmacy providing service. | ~~$ 210.00~~ | $ 300.00 |
| Hospital Pharmacy Satellite | Annual fee for each satellite site, to be charged to Hospital Pharmacy. | ~~$ 210.00~~ | $ 300.00 |
| Application for New Pharmacy Licensure | Application valid for up to three years. Includes change of ownership. | ~~$ 525.00~~ | $ 550.00 |

### INSPECTION FEE

| | | |
|---|---|---|
| Follow-up site review(s) | Where 3 or more site reviews are required to address deficiencies. From visit 3 onwards, this fee applies for each additional visit. | $ 1,000.00 |

***NOTES:***

*1) Fees are non-refundable.*

*2) Fees are subject to GST.*

*3) Annual renewal notices of pharmacy licensure are sent at least thirty (30) days prior to the expiry date.*

College of Pharmacists of British Columbia

# BOARD MEETING
# February 17, 2017

## 5. Audit & Finance Committee – Draft 2017/18 Budget
## Addendum to the original Briefing Note – added February 16, 2017

## DECISION REQUIRED

### Recommended Board Motion:

*Approve the 2017/18 budget Plan C with revenue totaling $8,262, 070 and expenditures totaling $9,594,567, and the accompanying list of fees, as attached in the appendix to this motion.*

### Synopsis

The Audit and Finance Committee met on February 16th to review the budget options. After careful review and discussion a third option was requested and prepared. The Audit and Finance Committee is recommending the new Plan C Budget.

### Plan C Budget – Total Revenues - $8,262,070

Plan C's budget has only a slight change from Plan B's revenue – increasing the Pharmacy licence fee to $2,250 in 2017-18. All other aspects remain the same as in Plan B.

| | Base | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Year 6 |
|---|---|---|---|---|---|---|---|
| | 2016-17 | 2017-18 | 2018-19 | 2019-20 | 2020-21 | 2021-22 | 2022-23 |
| Pharmacy | $2,001 | $2,250 | $2,275 | $2,315 | $2,315 | $2,315 | $2,315 |
| Pharmacist | $580 | $699 | $799 | $824 | $824 | $824 | $824 |
| Ph. Tech. | $386 | $465 | $532 | $549 | $549 | $549 | $549 |

### Recommendation

The Audit and Finance Committee recommends that the Board approve the Plan C budget for the following reasons:

- The fee increases are spread out over the next few years bringing the College's reserves back to the targeted balance within the next six years.
- By modifying the initial Pharmacy licence fee, the closing balance of the reserves does not drop quite as low as Plan B and there is a possibility of returning to fully funded reserves a year earlier.

| **Appendix** | |
|---|---|
| 1 | Budget Plan C package |
| 2 | Multi Year Fee Table for Comparison |

College of Pharmacists of British Columbia

# APPLICATION FOR NEW PHARMACY

Community

## APPLICANT INFORMATION

☐ Corporation ☐ Sole proprietor / Partnership

Cert. of Incorporation # _____ Incorporation Date _____

Company name _____

Address _____ Tel _____

_____ Fax _____

_____ _____ Email _____

*Postal code*

| *Director ** | *Pharmacist* | *Director ** | *Pharmacist* |
|---|---|---|---|
| _____ | ☐ | _____ | ☐ |
| _____ | ☐ | _____ | ☐ |

* Majority must be BC registered pharmacists

## PROPOSED PHARMACY INFORMATION

Operating name _____

Address _____ Tel _____

_____ Fax _____

_____ _____ Manager _____

*Postal code*

Contact + _____

Opening date _____ Tel + _____

Software Vendor _____ Fax + _____

+ *Only if manager not available before opening*

*I attest that:*

☐ The Pharmacy is in compliance with the Health Professions Act, the Pharmacy Operations and Drug Scheduling Act, the Pharmacists Regulation and the Bylaws of the College of Pharmacists of British Columbia made pursuant to these Acts.

☐ I have read and understood the Pharmacy Licensure in British Columbia – Information Guide and Resources package.

☐ I will maintain a valid business licence for the duration of the pharmacy licence.

_____ _____

Name (please print) Signature

_____ _____

Position Date

The College collects the personal information on this application form to process the application and administer the College's related activities. The collection is authorized by the *Pharmacy Operations and Drug Scheduling Act*, *Health Professions Act*, and *Freedom of Information and Protection of Privacy Act*. Should you have any questions about the collection, please contact the College's Privacy Officer at 604-733-2440 or 1-800-663-1940 or privacy@bcpharmacists.org

College of Pharmacists of British Columbia

# APPLICATION FOR NEW PHARMACY

Community

**Application must be received by the College Office <u>at least 10 weeks</u> prior to the proposed opening date.**

**The following must be submitted together with this application:**

- ☐ Diagram detailing the layout (see diagram requirement checklist below)
- ☐ Copy of the Certificate of Incorporation
- ☐ Copy of the certified Incorporation Application
- ☐ Copy of the certified Notice of Articles

**The following must be submitted at least 2 weeks prior to opening:**

- ☐ Acknowledgement of Completion of Confidentiality Form
- ☐ Copy of valid business licence

**The following information must be included on the diagram:**

***scale: ¼ inch = 1 foot***

- ☐ Dispensary area size - minimum 15 $m^2$ (160 sq ft)
- ☐ Dispensary area counters - minimum 3 $m^2$ (30 sq ft)
- ☐ Storeroom space - minimum 4 $m^2$ (40 sq ft) of shelf space
- ☐ Description of the front counter and shelf height
- ☐ Location of the double stainless steel sink
- ☐ Location of the refrigerator
- ☐ Location and type of consultation area (semi-private or private)
- ☐ Drug storage cabinet and/or safe
- ☐ Type of security system
- ☐ Location of Professional Service Area or Schedule 2 items, if applicable
- ☐ Location of Professional Product Area or Schedule 3 items - visible and up to 7.6 m (25 ft) from dispensary, if applicable
- ☐ Location of "Medication Information" sign, if applicable

**The following information must be provided:**

- ☐ Description of how the professional service area is made visually distinctive or indicate location of Pharmacy signs:

  _____

  _____

- ☐ Description of the method used to make the dispensary inaccessible to the public

  _____

College of Pharmacists of British Columbia

# APPLICATION FOR NEW PHARMACY

Community

## PAYMENT OPTION

Pharmacy Name _____

☐ Cheque/Money order *(payable to College of Pharmacists of BC)* ☐ VISA ☐ MasterCard

Card # _____ Exp _____ /_____

Cardholder name _____

Cardholder signature _____

| | |
|---|---|
| Application fee | $~~525.00~~ 550.00 |
| Initial licence fee | ~~2001.00~~ 2250.00 |
| GST | ~~126.30~~ 140.00 |
| **Total** | **$~~2652.30~~ 2940.00** |
| | GST # R106953920 |

**For office use ONLY**

iMIS ID: _____ Finance stamp:

Lic initials: _____

Date to Finance: _____

College of Pharmacists of British Columbia

# APPLICATION FOR NEW PHARMACY

Hospital

## APPLICANT INFORMATION

- Corporation

Cert. of Incorporation # _____ Incorporation Date _____

Hospital name _____

Address _____ Tel _____

_____ Fax _____

_____ _____ Email _____

*Postal code*

| *Director ** | *Pharmacist* | *Director ** | *Pharmacist* |
|---|---|---|---|
| _____ | ▪ | _____ | ▪ |
| _____ | ▪ | _____ | ▪ |

* Majority must be BC registered pharmacists

## PROPOSED PHARMACY INFORMATION

Operating name _____

Address _____ Tel _____

_____ Fax _____

_____ _____ Manager _____

*Postal code*

Contact + _____

Opening date _____ Tel + _____

Software Vendor _____ Fax + _____

+ *Only if manager not available before opening*

*I attest that:*

- The Pharmacy is in compliance with the Health Professions Act, the Pharmacy Operations and Drug Scheduling Act, the Pharmacists Regulation and the Bylaws of the College of Pharmacists of British Columbia made pursuant to these Acts.
- I have read and understood the Pharmacy Licensure in British Columbia – Information Guide and Resources package.

_____ _____

Name (please print) Signature

_____ _____

Position Date

The College collects the personal information on this application form to process the application and administer the College's related activities. The collection is authorized by the *Pharmacy Operations and Drug Scheduling Act*, *Health Professions Act*, and *Freedom of Information and Protection of Privacy Act*. Should you have any questions about the collection, please contact the College's Privacy Officer at 604-733-2440 or 1-800-663-1940 or privacy@bcpharmacists.org

College of Pharmacists of British Columbia

# APPLICATION FOR NEW PHARMACY

Hospital

**Application must be received by the College Office <u>at least 8 weeks</u> prior to the proposed opening date.**

**The following must be submitted together with this application:**

- ☐ Diagram detailing the layout (see diagram requirement checklist below)
- ☐ Copy of the Certificate of Incorporation
- ☐ Copy of the certified Incorporation Application
- ☐ Copy of the certified Notice of Articles

**The following must be submitted at least 2 weeks prior to opening:**

- ☐ Acknowledgement of Completion of Confidentiality Form

**The following information must be included on the diagram:**

***scale: ¼ inch = 1 foot***

- ☐ Dispensary area size - minimum 15 $m^2$ (160 sq ft)
- ☐ Dispensary area counters - minimum 3 $m^2$ (30 sq ft)
- ☐ Storeroom space - minimum 4 $m^2$ (40 sq ft) of shelf space
- ☐ Description of the front counter and shelf height
- ☐ Location of the double stainless steel sink
- ☐ Location of the refrigerator
- ☐ Location and type of consultation area (semi-private or private)
- ☐ Drug storage cabinet and/or safe
- ☐ Type of security system
- ☐ Location of Professional Service Area or Schedule 2 items, if applicable
- ☐ Location of Professional Product Area or Schedule 3 items - visible and up to 7.6 m (25 ft) from dispensary, if applicable
- ☐ Location of "Medication Information" sign, if applicable

**The following information must be provided:**

- ☐ Description of how the professional service area is made visually distinctive or indicate location of Pharmacy signs:

  _____

  _____

- ☐ Description of the method used to make the dispensary inaccessible to the public

  _____

College of Pharmacists of British Columbia

# APPLICATION FOR NEW PHARMACY

Hospital

## PAYMENT OPTION

Pharmacy Name _____

☐ Cheque/Money order *(payable to College of Pharmacists of BC)* ☐ VISA ☐ MasterCard

Card # _____ Exp _____ /_____

Cardholder name _____

Cardholder signature _____

| | |
|---|---|
| Application fee | $~~525.00~~ 550.00 |
| Initial licence fee | ~~2001.00~~ 2250.00 |
| GST | ~~126.30~~ 140.00 |
| **Total** | **$~~2652.30~~ 2940.00** |

GST # R106953920

**For office use ONLY**

iMIS ID: _____ Finance stamp:

Lic initials: _____

Date to Finance: _____

# APPLICATION FOR NEW PHARMACY
Education Site

## APPLICANT INFORMATION

☐ Corporation ☐ Sole proprietor/Partnership Cert. of Incorporation # _____

Company name _____ Incorporation date _____

Address _____ Tel _____

_____ Fax _____

_____ Email _____

_____ _____
*Postal Code*

## PROPOSED PHARMACY INFORMATION

Institution name _____ Tel _____

Address _____ Fax _____

_____ Manager _____

_____ _____ Contact* _____
*Postal Code*

Opening date _____ Tel _____

Fax _____

*If manager is not available before opening

## ~~PAYMENT OPTION~~

~~☐ Cheque/Money order *(payable to College of Pharmacists of BC)*~~ ~~☐ VISA~~ ~~☐ MasterCard~~

~~Card #~~ _____ ~~Exp ____/____~~

~~Cardholder name~~ _____

~~Cardholder signature~~ _____

| | |
|---|---|
| ~~Initial licence fee~~ | ~~315.00~~ |
| ~~GST~~ | ~~15.75~~ |
| ~~**Total**~~ | ~~**$330.75**~~ |

~~GST # R106953920~~

I attest that:

- ☐ The Pharmacy is in compliance with the Health Professions Act, the Pharmacy Operations and Drug Scheduling Act, the Pharmacists Regulation and the Bylaws of the College of Pharmacists of British Columbia made pursuant to these Acts.
- ☐ I have read and understood the Pharmacy Licensure in British Columbia – Information Guide and Resources package.

_____ _____
Name (please print) Signature

_____ _____
Position Date

The College collects the personal information on this application form to process the application and administer the College's related activities. The collection is authorized by the *Pharmacy Operations and Drug Scheduling Act*, *Health Professions Act*, and *Freedom of Information and Protection of Privacy Act*. Should you have any questions about the collection, please contact the College's Privacy Officer at 604-733-2440 or 1-800-663-1940 or privacy@bcpharmacists.org

# APPLICATION FOR NEW PHARMACY
Education Site

## PAYMENT OPTION

Pharmacy Name _____

☐ Cheque/Money order *(payable to College of Pharmacists of BC)* ☐ VISA ☐ MasterCard

Card # _____ Exp _____ /_____

Cardholder name _____

Cardholder signature _____

| | |
|---|---|
| Initial licence fee | ~~315.00~~ 550.00 |
| GST | ~~15.75~~ 27.50 |
| **Total** | **~~$330.75~~ 577.50** |

GST # R106953920

**For office use ONLY**

iMIS ID: _____ Finance stamp:

Lic initials: _____

Date to Finance: _____

College of Pharmacists of British Columbia

**Form 1D**



# APPLICATION FOR CHANGE OF OWNERSHIP

## CURRENT PHARMACY INFORMATION

PharmaCare code _____

Operating name _____

Owner _____

Manager _____

Address _____ Tel _____

_____ Fax _____

_____ _____ Email _____

*Postal code*

## PROPOSED PHARMACY INFORMATION

Operating name _____

Manager _____ Tel _____

Effective Date _____ Fax _____

Software Vendor _____ Email _____

☐ Corporation ☐ Sole proprietor / Partnership

Cert. of Incorporation # _____ Incorporation Date _____

Company name _____

Tel _____

Fax _____

Email _____

| *Director ** | *Pharmacist* | *Director ** | *Pharmacist* |
|---|---|---|---|
| _____ | ☐ | _____ | ☐ |
| _____ | ☐ | _____ | ☐ |

* Majority must be BC registered pharmacists

*I attest that:*

☐ The Pharmacy is in compliance with the Health Professions Act, the Pharmacy Operations and Drug Scheduling Act, the Pharmacists Regulation and the Bylaws of the College of Pharmacists of British Columbia made pursuant to these Acts.

☐ I have read and understood the Pharmacy Licensure in British Columbia – Information Guide and Resources package.

☐ I will maintain a valid business licence for the duration of the pharmacy licence.

_____ _____

Name (please print) Signature

_____ _____

Position Date

The College collects the personal information on this application form to process the application and administer the College's related activities. The collection is authorized by the *Pharmacy Operations and Drug Scheduling Act*, *Health Professions Act*, and *Freedom of Information and Protection of Privacy Act*. Should you have any questions about the collection, please contact the College's Privacy Officer at 604-733-2440 or 1-800-663-1940 or privacy@bcpharmacists.org

College of Pharmacists of British Columbia

# APPLICATION FOR CHANGE OF OWNERSHIP

**Application must be received by the College Office <u>at least 10 weeks</u> prior to the proposed opening date.**

**The following must be submitted together with this application:**

- ☐ Diagram detailing the layout (see diagram requirement checklist below)
- ☐ Copy of the Certificate of Incorporation
- ☐ Copy of the certified Incorporation Application
- ☐ Copy of the certified Notice of Articles

**The following must be submitted at least 2 weeks prior to opening:**

- ☐ Acknowledgement of Completion of Confidentiality Form
- ☐ Copy of valid business licence

## DIAGRAM REQUIREMENT CHECKLIST

**The following information must be included on the diagram:**

***scale: ¼ inch = 1 foot***

- ☐ Dispensary area size - minimum 15 $m^2$ (160 sq ft)
- ☐ Dispensary area counters - minimum 3 $m^2$ (30 sq ft)
- ☐ Storeroom space - minimum 4 $m^2$ (40 sq ft) of shelf space
- ☐ Description of the front counter and shelf height
- ☐ Location of the double stainless steel sink
- ☐ Location of the refrigerator
- ☐ Location and type of consultation area (semi-private or private)
- ☐ Drug storage cabinet and/or safe
- ☐ Type of security system
- ☐ Location of Professional Service Area or Schedule 2 items, if applicable
- ☐ Location of Professional Product Area or Schedule 3 items - visible and up to 7.6 m (25 ft) from dispensary, if applicable
- ☐ Location of "Medication Information" sign, if applicable

**The following information must be provided:**

- ☐ Description of how the professional service area is made visually distinctive or indicate location of Pharmacy signs:

  _____

  _____

- ☐ Description of the method used to make the dispensary inaccessible to the public

  _____

College of Pharmacists of British Columbia



# APPLICATION FOR CHANGE OF OWNERSHIP

## PAYMENT OPTION

Pharmacy Name _____

☐ Cheque/Money order *(payable to College of Pharmacists of BC)* ☐ VISA ☐ MasterCard

Card # _____ Exp _____ /_____

Cardholder name _____

Cardholder signature _____

| | |
|---|---|
| Application fee | $~~525.00~~ 550.00 |
| Licence fee | ~~2001.00~~ 2250.00 |
| GST | ~~126.30~~ 140.00 |
| **Total** | **$~~2652.30~~ 2940.00** |
| | GST # R106953920 |

**For office use ONLY**

iMIS ID: _____ Finance stamp:

Lic initials: _____

Date to Finance: _____

# APPLICATION FOR TELEPHARMACY SERVICES

## APPLICANT INFORMATION

Company name _____

Central pharmacy _____

Address _____ Tel _____

_____ Fax _____

_____ _____ Email _____

*Postal Code*

## PROPOSED REMOTE SITE

Operating name _____ Tel _____

Address _____ Fax _____

_____ Email _____

_____ _____

*Postal Code*

Hours of operation for Telepharmacy _____

_____

## ~~PAYMENT OPTION~~

~~☐ Cheque/Money order *(payable to College of Pharmacists of BC)*~~ ~~☐ VISA~~ ~~☐ MasterCard~~

~~Card #~~ _____ ~~Exp ____ / ____~~

~~Cardholder name~~ _____

~~Cardholder signature~~ _____

| | |
|---|---|
| ~~Initial licence fee~~ | ~~210.00~~ |
| ~~GST~~ | ~~10.50~~ |
| ~~**Total**~~ | ~~**$220.50**~~ |

~~GST # R106953920~~

I attest that:

- ~~☐~~ The Pharmacy is in compliance with the Health Professions Act, the Pharmacy Operations and Drug Scheduling Act, the Pharmacists Regulation and the Bylaws of the College of Pharmacists of British Columbia made pursuant to these Acts.
- ~~☐~~ I have read and understood the Pharmacy Licensure in British Columbia – Information Guide and Resources package.

_____ Name (please print)

_____ Signature

_____ Position

_____ Date

The College collects the personal information on this application form to process the application and administer the College's related activities. The collection is authorized by the *Pharmacy Operations and Drug Scheduling Act*, *Health Professions Act*, and *Freedom of Information and Protection of Privacy Act*. Should you have any questions about the collection, please contact the College's Privacy Officer at 604-733-2440 or 1-800-663-1940 or privacy@bcpharmacists.org

# APPLICATION FOR TELEPHARMACY SERVICES

## APPLICATION REQUIREMENT CHECKLIST

**Application must be received by the College Office <u>at least 60 days</u> prior to the planned operation of the pharmacy.**

**Application must be approved PRIOR to commencement of telepharmacy services.**

**The following must be submitted together with this application:**

- Diagram detailing the layout of the telepharmacy services at the remote site
- Copy of the final Policy and Procedure Manual which outlines specific telepharmacy operations (see template on College website at www.bcpharmacists.org)

PharmaNet connection for both sites? ☐ Yes ☐ No

# APPLICATION FOR TELEPHARMACY SERVICES

## PAYMENT OPTION

Pharmacy Name _____

☐ Cheque/Money order *(payable to College of Pharmacists of BC)* ☐ VISA ☐ MasterCard

Card # _____ Exp _____ /_____

Cardholder name _____

Cardholder signature _____

| | |
|---|---|
| Initial Licence fee | ~~210.00~~ 300.00 |
| GST | ~~10.50~~ 15.00 |
| **Total** | **~~$220.50~~ 315.00** |
| | GST # R106953920 |

**For office use ONLY**

iMIS ID: _____ Finance stamp:

Lic initials: _____

Date to Finance: _____

# APPLICANT FOR HOSPITAL SATELLITE

## APPLICANT INFORMATION

Company name _____

Central pharmacy _____

Pharmacy manager _____

Address _____ Tel _____

_____ Fax _____

_____ _____ Email _____

*Postal Code*

## PROPOSED REMOTE SITE

Remote site address, including name of pharmacy _____ Tel _____

_____ Fax _____

_____ Email _____

_____ _____

*Postal Code*

Hours of operation for Satellite _____

_____

## ~~PAYMENT OPTION~~

~~☐ Cheque/Money order *(payable to College of Pharmacists of BC)*~~ ~~☐ VISA~~ ~~☐ MasterCard~~

~~Card #~~ _____ ~~Exp ____ / ____~~

~~Cardholder name~~ _____

~~Cardholder signature~~ _____

| | |
|---|---|
| ~~Initial licence fee~~ | ~~210.00~~ |
| ~~GST~~ | ~~10.50~~ |
| ~~**Total**~~ | ~~**$220.50**~~ |

~~GST # R106953920~~

I attest that:

- ☐ The Pharmacy is in compliance with the Health Professions Act, the Pharmacy Operations and Drug Scheduling Act, the Pharmacists Regulation and the Bylaws of the College of Pharmacists of British Columbia made pursuant to these Acts.
- ☐ I have read and understood the Pharmacy Licensure in British Columbia – Information Guide and Resources package.

_____ _____

Name (please print) Signature

_____ _____

Position Date

The College collects the personal information on this application form to process the application and administer the College's related activities. The collection is authorized by the *Pharmacy Operations and Drug Scheduling Act*, *Health Professions Act*, and *Freedom of Information and Protection of Privacy Act*. Should you have any questions about the collection, please contact the College's Privacy Officer at 604-733-2440 or 1-800-663-1940 or privacy@bcpharmacists.org

# APPLICATION FOR HOSPITAL SATELLITE

## APPLICATION REQUIREMENT CHECKLIST

**Application must be received by the College Office <u>at least 60 days</u> prior to the planned operation of the hospital satellite.**

**Application must be approved PRIOR to commencement of hospital satellite service.**

**The following must be submitted together with this application:**

- Diagram detailing the layout of the telepharmacy services at the remote site
- Copy of the final Policy and Procedure Manual which outlines specific telepharmacy operations (see template on College website at www.bcpharmacists.org)

PharmaNet connection for both sites? ☐ Yes ☐ No

# APPLICATION FOR HOSPITAL SATELLITE

## PAYMENT OPTION

Pharmacy Name _____

☐ Cheque/Money order *(payable to College of Pharmacists of BC)* ☐ VISA ☐ MasterCard

Card # _____ Exp _____ /_____

Cardholder name _____

Cardholder signature _____

| | |
|---|---|
| Initial Licence fee | ~~210.00~~ 300.00 |
| GST | ~~10.50~~ 15.00 |
| **Total** | **~~$220.50~~ 315.00** |
| | GST # R106953920 |

**For office use ONLY**

iMIS ID: _____ Finance stamp:

Lic initials: _____

Date to Finance: _____

College of Pharmacists of British Columbia

FORM 4
*Page 1*

# COMMUNITY PHARMACY LICENCE RENEWAL NOTICE

| | |
|---|---|
| *ID #* | |
| *Pharmacare #* | |
| *Current licence expires* | |

## PHARMACY

Pharmacy Manager
Pharmacy
Address
City, Prov Postal Code

Tel: *
Fax: *
Email: *

* *required information - please provide update*

## OWNER

**Name of Owner**
(Corporation or Sole Proprietor)

**Corporate Director(s)**

*Has there been a change of directors? If yes, a copy of Notice of Articles / Notice of Directors must be provided.*

## STAFF REGISTRANTS

**Confirm if the following are still employed at this pharmacy by checking one of the checkboxes**

| Current employee? | | Name | Reg # | Status | Renewed To |
|---|---|---|---|---|---|
| ☐ Yes | ☐ No | | | | |
| ☐ Yes | ☐ No | | | | |

**Add registrants not listed above in the following table. Attach additional sheet if necessary**

| Name | Reg # | Full time | Part time | Casual |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

☐ I attest that:

- The Pharmacy is in compliance with the Health Professions Act (HPA), the Pharmacy Operations and Drug Scheduling Act (PODSA), the Regulation and the Bylaws of the College of Pharmacists of British Columbia made pursuant to these Acts.
- I understand my obligations as described in Part I of the PODSA bylaws: "Responsibilities of the Pharmacy Managers, Owners and Directors."

☐ I attach a copy of the pharmacy's valid business licence.

_____ Date

_____ Pharmacy Manager

The College collects the personal information on this application form to process the application and administer the College's related activities. The collection is authorized by the *Pharmacy Operations and Drug Scheduling Act*, *Health Professions Act*, and *Freedom of Information and Protection of Privacy Act*. Should you have any questions about the collection, please contact the College's Privacy Officer at 604-733-2440 or 1-800-663-1940 or privacy@bcpharmacists.org

over >>>

# COMMUNITY PHARMACY LICENCE RENEWAL NOTICE

College of Pharmacists of British Columbia

| | |
|---|---|
| *ID #* | |
| *Pharmacare #* | |
| *Current licence expires* | |

## PAYMENT OPTION

Pharmacy Name _____

☐ Cheque/Money order *(payable to College of Pharmacists of BC)* ☐ VISA ☐ MasterCard

Card # _____ Exp _____ /_____

Cardholder name _____

Cardholder signature _____

| | |
|---|---|
| Licence fee | ~~2001.00~~ 2250.00 |
| GST | ~~100.05~~ 112.50 |
| **Total** | **$~~2101.05~~ 2362.50** |

GST # R106953920

**For office use ONLY**

iMIS ID: _____ Finance stamp:

Lic initials: _____

Date to Finance: _____

College of Pharmacists of British Columbia

FORM 5
*Page 1*

# HOSPITAL PHARMACY LICENCE RENEWAL NOTICE

| | |
|---|---|
| *ID #* | |
| *Pharmacare #* | |
| *Current licence expires* | |

## PHARMACY

Pharmacy Manager
Pharmacy
Address
City, Prov Postal Code

Tel: *
Fax: *
Email: *

* *required information - please provide update*

## HEALTH AUTHORITY

**Name of Health Authority**

## STAFF REGISTRANTS

| Name | Reg# | Status | Renewed To | Name | Reg# | Status | Renewed To |
|---|---|---|---|---|---|---|---|

**Add registrants not listed above in the following table. Attach additional sheet if necessary**

| Name | Reg # | Full time | Part time | Casual |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

☐ I attest that:

- The Pharmacy is in compliance with the Health Professions Act (HPA), the Pharmacy Operations and Drug Scheduling Act (PODSA), the Regulation and the Bylaws of the College of Pharmacists of British Columbia made pursuant to these Acts.
- I understand my obligations as described in Part I of the PODSA bylaws: "Responsibilities of the Pharmacy Managers, Owners and Directors."

_____ Date

_____ Pharmacy Manager

The College collects the personal information on this application form to process the application and administer the College's related activities. The collection is authorized by the *Pharmacy Operations and Drug Scheduling Act*, *Health Professions Act*, and *Freedom of Information and Protection of Privacy Act*. Should you have any questions about the collection, please contact the College's Privacy Officer at 604-733-2440 or 1-800-663-1940 or privacy@bcpharmacists.org

over >>>

# HOSPITAL PHARMACY LICENCE RENEWAL NOTICE

College of Pharmacists of British Columbia

| | |
|---|---|
| *ID #* | |
| *Pharmacare #* | |
| *Current licence expires* | |

## PAYMENT OPTION

Pharmacy Name _____

☐ Cheque/Money order *(payable to College of Pharmacists of BC)* ☐ VISA ☐ MasterCard

Card # _____ Exp ____ /____

Cardholder name _____

Cardholder signature _____

| | |
|---|---|
| Licence fee | ~~2001.00~~ 2250.00 |
| GST | ~~100.05~~ 112.50 |
| **Total** | **$~~2101.05~~ 2362.50** |

GST # R106953920

**For office use ONLY**

iMIS ID: Finance stamp:

Lic initials:

Date to Finance:

# EDUCATION SITE LICENCE RENEWAL

Date

**Pharmacy Manager**
Pharmacy
Address
City, Prov  Postal Code

Dear Pharmacy Manager,

**Education Site Licensure Expiry:**

Enclosed please find your Education Site Licence Renew… …s of information are mandatory. Terms of an Education … …found in the Bylaws of the Pharmacy Operations and Drug S… …ion 5.

Pages 1 and 2 must be completed, sig… …ent on or before your licence expiry date.

If you have any questi… …el free to contact:

Rene…

…g or (604) 733-2440

Delete this page

Registrar

FORM 6

# EDUCATION SITE LICENCE RENEWAL NOTICE

| | |
|---|---|
| *ID #* | |
| *Pharmacare #* | |
| *Current licence expires* | |

## PHARMACY

Pharmacy Manager
Pharmacy
Address
City, Prov Postal Code

Tel: *
Fax: *
Email: *

* *required information - please provide update*

## SITE OWNER

**Name of Site Owner**

## ~~PAYMENT ADVICE~~

| | FEE | GST | TOTAL |
|---|---|---|---|
| ~~**Pharmacy Licence fee**~~ | ~~$315.00~~ | ~~+ $15.75 =~~ | ~~**$330.75**~~ |

~~**$330.75**~~

~~**Payment option**~~

~~**Total payment $**~~

☐ ~~Cheque/Money order~~ ~~*(payable to College of Pharmacists of BC)*~~

☐ ~~VISA~~ ☐ ~~MasterCard~~

~~Card #~~ _____ ~~Exp~~ ____/____

~~Cardholder~~ _____

~~Cardholder signature~~ _____

~~GST # R106953920~~

~~**Please return this notice with payment**~~

over >>>

H0034-10212009

# EDUCATION SITE LICENCE RENEWAL NOTICE

| | |
|---|---|
| *ID #* | |
| *Pharmacare #* | |
| *Current licence expires* | |

## STAFF ~~PHARMACISTS~~ REGISTRANTS

| Name | Reg # | Status | Renewed To | Name | Reg # | Status | Renewed ToBB |
|---|---|---|---|---|---|---|---|
| | | | | | | | |

**Add ~~Pharmacists~~ registrants not listed above in the following table. Attach additional sheet if necessary**

| Name | Reg # | Full time | Part time | Casual |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

☐ I attest that:

- The Pharmacy is in compliance with the Health Professions Act (HPA), the Pharmacy Operations and Drug Scheduling Act (PODSA), the Regulation and the Bylaws of the College of Pharmacists of British Columbia made pursuant to these Acts.
- I understand my obligations as described in Part I of the PODSA bylaws: "Responsibilities of the Pharmacy Managers, Owners and Directors."

_____ _____

Date Pharmacy Manager

The College collects the personal information on this application form to process the application and administer the College's related activities. The collection is authorized by the *Pharmacy Operations and Drug Scheduling Act*, *Health Professions Act*, and *Freedom of Information and Protection of Privacy Act*. Should you have any questions about the collection, please contact the College's Privacy Officer at 604-733-2440 or 1-800-663-1940 or privacy@bcpharmacists.org

# EDUCATION SITE LICENCE RENEWAL NOTICE

| | |
|---|---|
| *ID #* | |
| *Pharmacare #* | |
| *Current licence expires* | |

## PAYMENT OPTION

Pharmacy Name _____

☐ Cheque/Money order *(payable to College of Pharmacists of BC)* ☐ VISA ☐ MasterCard

Card # _____ Exp ____ /____

Cardholder name _____

Cardholder signature _____

| | |
|---|---|
| Licence fee | ~~315.00~~ 550.00 |
| GST | ~~15.75~~ 27.50 |
| **Total** | **~~$330.75~~ 577.50** |

GST # R106953920

**For office use ONLY**

iMIS ID: _____ Finance stamp:

Lic initials: _____

Date to Finance: _____

College of Pharmacists of British Columbia

# d) PODSA Bylaws – Public Posting (Telepharmacy)

College of Pharmacists of British Columbia

# Background

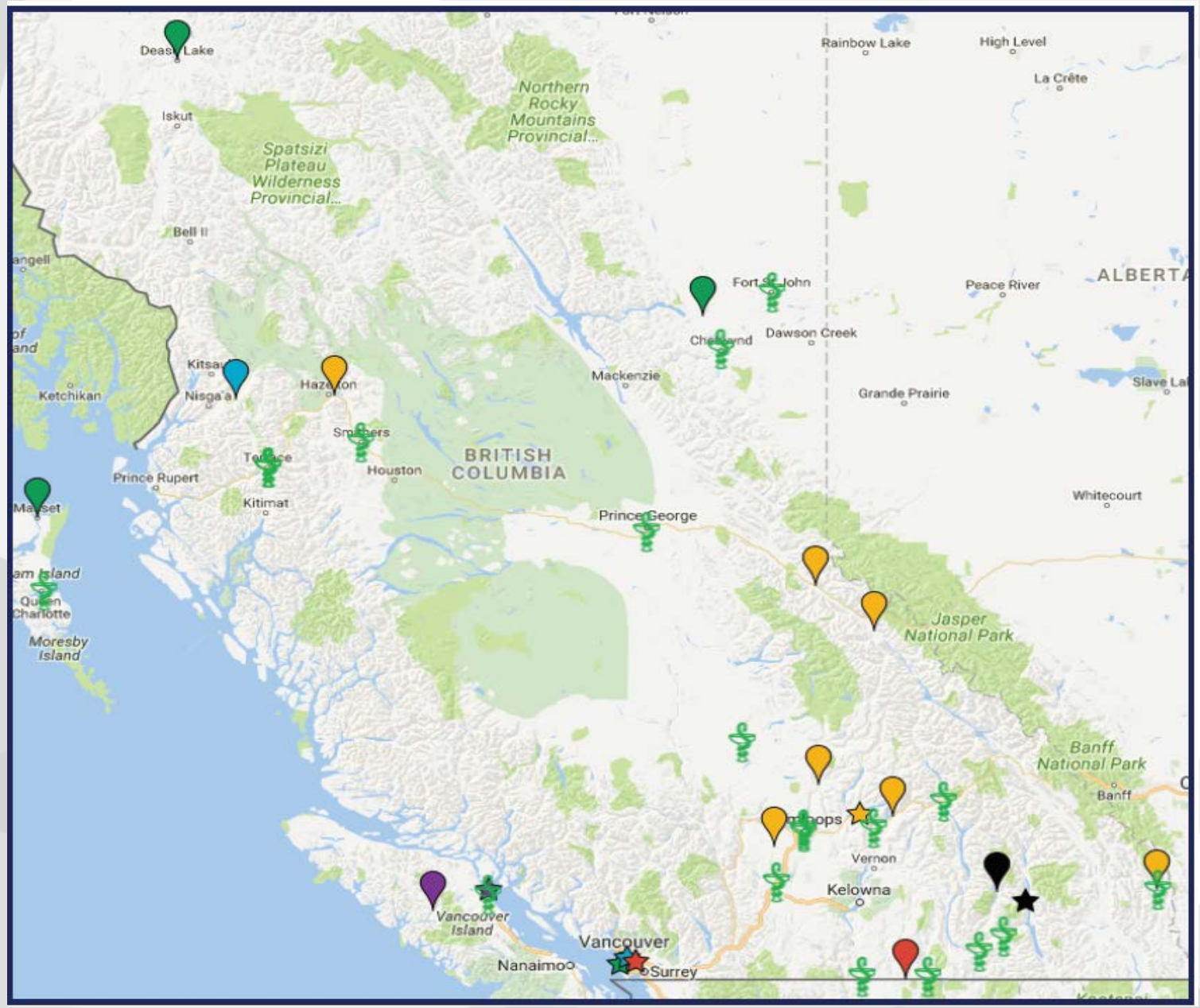
- Telepharmacy is the delivery of traditional pharmacy services via telecommunications to patients in locations where they may not have local access to a pharmacist.
- Similar to telemedicine, telepharmacy is designed to provide access to pharmacy services in rural and remote communities by allowing pharmacies to operate, without requiring a pharmacist to be physically present.

College of Pharmacists of British Columbia

# Background

- The PODSA – Bylaws states that telepharmacy is the process by which a central pharmacy site operates one or more remote sites, all of which are connected to the central pharmacy site via computer, video and audio link.
- Community telepharmacies have been in BC for approximately 10 years.

College of Pharmacists of British Columbia




- Central Site
- Telepharmacy Site
- Nearest Community Pharmacy

College of Pharmacists of British Columbia

# Staffing of Telepharmacy Remote Sites

- Previous to the regulation of pharmacy technicians in BC, telepharmacy remote sites could be staffed by pharmacy assistants.
- Currently, the PODSA-Bylaws require that pharmacy technicians staff telepharmacy remote sites; however, they have continued to be staffed by pharmacy assistants.
- The College originally set a deadline of January 1, 2016, for telepharmacy operators to meet this requirement, which was extended to December 2016.
- Telepharmacy operators have consistently raised concerns that they cannot meet the pharmacy technician staffing requirement.

College of Pharmacists of British Columbia

# Review of Telepharmacies

- The College has conducted multiple reviews of telepharmacies since 2014:
  - Review of sites done in September 2014.
  - External consultants hired in 2016 to develop recommendation for these sites.
  - All telepharmacy central and remotes sites reviewed in 2016. Follow-up visits were also completed for some sites.

College of Pharmacists of British Columbia

# Proposed Telepharmacy Amendments

- Amendments to the PODSA-Bylaws and a new Telepharmacy Standard of Practice have been developed.
- These amendments apply to community telepharmacies only. Hospital telepharmacies will be captured under the existing definition of a hospital satellite:

  > *"…a physically separate area on or outside the hospital premises used for the provision of pharmacy services which is dependent upon support and administrative services from the hospital pharmacy."*

- Hospital pharmacy satellites are required to follow the Hospital Pharmacy Standards of Practice under the *Health Professions Act* (HPA)-Bylaws.

College of Pharmacists of British Columbia

# Key PODSA-Bylaw Amendments

- **Created a distinct telepharmacy license type:** Telepharmacies are currently authorized as services, not as licenses. As pharmacy services are being provided in telepharmacies, it is appropriate that they be licensed sites.
- **Amended definitions of "central pharmacy site" and "telepharmacy":** "central pharmacy" means a community pharmacy that holds one or more telepharmacy licences; and "telepharmacy" means a pharmacy located in a rural and remote community that is licenced to provide pharmacy services.
- **Defined "rural and remote community" for telepharmacy:** Currently, that term is not defined. The proposed definition is consistent with the Rural Practice Subsidiary Agreement.
- **Defined "direct supervision" for telepharmacy:** Currently, that term is not defined. Created a definition focused on the real time audio and visual observation by a pharmacist, and not focused on the technology to be used (since technology changes rapidly).
- **Clearer restrictions on telepharmacy locations:** Telepharmacies will only be permitted in:
  - A rural and remote community where there is no existing community pharmacy or telepharmacy; and
  - Where the next telepharmacy or community pharmacy is at least 25km away.

College of Pharmacists of British Columbia

# Key PODSA-Bylaw Amendments (continued)

- **Enhanced requirements on telepharmacy identification:**
  - The telepharmacy name must include the word “telepharmacy”
  - Telepharmacy name must be on advertising, signage, etc.
  - Prescriptions and labels must identify the prescription as having been dispensed at the telepharmacy.
- **Increased audits and inspections:** Increased requirement from three to four audits per year (consistent with PPP-65 “Narcotic Counts and Reconciliation”).

College of Pharmacists of British Columbia

# Key PODSA-Bylaw Amendments (continued)

- New pharmacy security requirements now apply to telepharmacies.
- Existing physical requirements for a community pharmacy premise now apply to telepharmacies.
- The requirement for pharmacy technician staff has been maintained, with exceptions.
- Associated fee and form changes have also been made.

College of Pharmacists of British Columbia

# Telepharmacy Standards of Practice

- Telepharmacy Standards of Practice have been developed to address this unique practice environment.
- Telepharmacies must follow the Community Pharmacy and the Telepharmacy Standards of Practice.
- The new Telepharmacy Standards of Practice focuses on the following areas:
  - **Direct Supervision:** The supervising pharmacist must be able to directly supervise staff at the telepharmacy, and be available for patient consultation. The pharmacist does not need to directly supervise a pharmacy technician, when they are practicing within their scope.
  - **Receipt of Prescriptions and Transfer of Prescription Information:** Provides clarity on designating medication for pick-up at the telepharmacy, and requires stamping prescriptions at the telepharmacy with the telepharmacy name and date. These requirements will help to better distinguish prescriptions of the central pharmacy and those of the telepharmacy.

College of Pharmacists of British Columbia

# Telepharmacy Standards of Practice (continued)

- **Prescription Processing and Product Preparation:** Requires a secure connection between the telepharmacy and central pharmacy to transfer prescription and confidential health information. Additionally, prescription processing must occur at the central pharmacy, except when a pharmacist is physically present and is practicing at the telepharmacy.
- **Patient Counselling:** Clarifies that patient counselling by the supervising pharmacist must occur over real time video/audio link, unless a full pharmacist is physical present and on duty at the telepharmacy.
- **Documentation:** Requires that all prescriptions, patient records, invoices, etc., be stored at the central pharmacy.

College of Pharmacists of British Columbia

# Grandfathering Provisions

- Bylaw drafting was done with a view not to adversely affect the level of pharmacy services currently in place.
- Grandfathering provisions were added for existing sites.
- To balance the need for pharmacy services with the College's aim of public protection, additional requirements were added to grandfathered sites.
- Grandfathered sites would **need to meet all new requirements**, with the following exceptions:
  - Existing sites would not have to meet two pharmacy premise requirements (i.e., the dispensary area being at least 160 square feet, and having a dispensing counter with at least 30 square feet of clear working space) until such time as they renovate their premises.
  - Four existing sites would be permitted to have both a telepharmacy and community pharmacy license. These sites would be able to switch, at times, from a traditional community pharmacy to a telepharmacy (e.g., switch into "telepharmacy mode"). All other telepharmacies must only hold one license type.
  - All existing sites would be permitted to staff telepharmacies with pharmacy assistants instead of pharmacy technicians.

College of Pharmacists of British Columbia

# Grandfathering Provisions (continued)

**Additional Requirements for 'Grandfathered' Telepharmacies:**

- Required to perform monthly narcotic counts, signed by the supervising pharmacist, and provided immediately to the College, upon request.
- Direct supervision requirement for the telepharmacy is greater when staffed by a pharmacy assistant. Pharmacy technicians do not need to be supervised when practicing within their scope.

College of Pharmacists of British Columbia

# Section 56 Exemption

- Federal legislation may prohibit narcotics and controlled drugs from being available in telepharmacies without a pharmacist physically present.
- The College is currently seeking a section 56 exemption from Health Canada, and meetings have been positive.
- These exceptions are for provisions within the *Controlled Drugs and Substances Act*, and the regulations under that Act.
- Telepharmacies will not be able to dispense narcotics and controlled drugs, without the section 56 exception in place.

College of Pharmacists of British Columbia

# Questions

College of Pharmacists of British Columbia

# PODSA Bylaws – Public Posting (Telepharmacy)

**MOTION:**

Approve the following resolution to publicly post the draft telepharmacy bylaws:

*RESOLVED THAT, in accordance with the authority established in section 21(8) of the Pharmacy Operations and Drug Scheduling Act, the board approve the proposed draft bylaws of the College of Pharmacists of British Columbia regarding telepharmacies, and related schedules and forms for public posting, as circulated.*

College of Pharmacists of British Columbia

# BOARD MEETING
# April 21, 2017

## 4d. PODSA Bylaws – Public Posting (Telepharmacy)

## DECISION REQUIRED

**Recommended Board Motion:**

*Approve the following resolution:*

*RESOLVED THAT, in accordance with the authority established in section 21(8) of the Pharmacy Operations and Drug Scheduling Act, the board approve the proposed draft bylaws of the College of Pharmacists of British Columbia regarding telepharmacies, and related schedules and forms for public posting, as circulated.*

**Purpose**
To seek approval from the Board to publicly post bylaw amendments regarding telepharmacies, as circulated, for a period of ninety days.

**Background**
Telepharmacy is the delivery of traditional pharmacy services, including the dispensing of medications and providing patient counselling, via telecommunications to patients in locations where they may not have local access to a pharmacist. Similar to telemedicine, telepharmacy is designed to provide access to pharmacy services in rural and remote communities by allowing pharmacies to operate, without requiring a pharmacist to be physically present.

**Community Telepharmacies in BC**
The first community telepharmacies were established ten years ago, in 2007, as a pilot project. That model continued, and most of the current community telepharmacies were established in 2009.

Specific requirements for telepharmacy operations can be found primarily in section 16 of the *Pharmacy Operations and Drug Scheduling Act* ("PODSA") – Bylaws. The PODSA – Bylaws, states that telepharmacy is the process by which a central pharmacy site operates one or more remote sites, all of which are connected to the central pharmacy site via computer, video and audio link. A telepharmacy remote site, is a pharmacy providing pharmacy services,

a) without a full pharmacist present,
b) in a rural or remote community, and
c) under the supervision and direction of a full pharmacist at a central pharmacy site.

Currently, there are six central community pharmacy sites and 12 community telepharmacy remote sites[1]. Four of these central pharmacy sites only have one telepharmacy remote site connected to them. However, there are two larger telepharmacy groupings: one central site has three remote sites connected to it; and, the other central pharmacy site has five remote sites connected to it.

Appendix 1 maps the existing central sites and pharmacy remote sites in the province, as well as the closest community pharmacy to the remote site.

**Bylaw Requirement to Staff Telepharmacies with Pharmacy Technicians**

According to PODSA – Bylaws s. 16 (8) (b), if a pharmacy technician is not on duty at the telepharmacy remote site, the telepharmacy remote site must not remain open and prescriptions must not be dispensed. This bylaw section was amended in 2010; however, the date to restrict the title of "pharmacy technician" was effective on January 1, 2011. Previous to that date, pharmacy assistants were permitted to staff telepharmacy remote sites.

On June 8, 2015, College staff reminded current telepharmacy operators, of the PODSA-Bylaw requirement that telepharmacy remote sites be staffed by pharmacy technicians, as pharmacy assistants were staffing these sites. In addition, it noted that all remote sites will need to adhere to the staffing requirement by January 1, 2016. This timing aligned with the Pharmacy Technician transition period to have all current pharmacy assistants meet the requirements for a pharmacy technician by December 31, 2015. As telepharmacy operators indicated that they could not meet this deadline, an extension was provided to December 31, 2016.

**College Review of Telepharmacies**

The College conducted multiple reviews of telepharmacies since 2014, following a concern raised by the Board about the quality of pharmaceutical care being provided at these sites. College staff conducted a review of sites in September 2014, and an update on the status of telepharmacies was presented at the Board's September 2015 meeting. That presentation focused on the use of unregulated staff in remote sites.

In 2016, the College hired external consultants to conduct research, review options and develop recommendations for these sites. Later that year, the College also conducted in-person reviews of all telepharmacy central sites and remote sites across the province. These site reviews were conducted simultaneously at the central and remote sites, and follow-up site visits were also completed at some sites.

**Discussion**

Informed by research and analysis conducted on telepharmacies and the recent reviews of these sites across the province, College staff have developed draft amendments to the PODSA-Bylaws

[1] Please note that one central site, Lancaster Prescriptions #2, recently closed as a central site. It was linked to one remote site (Boundary Pharmacy), which is currently seeking to secure another central site.

with respect to telepharmacies. Additionally, a new Standard of Practice for telepharmacies has been developed.

**Proposed PODSA Bylaw Amendments**

The proposed bylaws regarding telepharmacy significantly amend the current requirements. It is important to note that these provisions apply only to community telepharmacies.

Hospital telepharmacies will be captured under the following current definition of hospital pharmacy satellite in the PODSA-Bylaws: "*hospital pharmacy satellite" means a physically separate area on or outside the hospital premises used for the provision of pharmacy services which is dependent upon support and administrative services from the hospital pharmacy.* Hospital pharmacy satellites are required to follow the Hospital Pharmacy Standards of Practice under the *Health Professions Act* (HPA)-Bylaws.

An overview of the key changes to the PODSA-Bylaws and Standards of Practice with respect to telepharmacies is outlined in Appendix 2 and 3. A 'track changes' version of the PODSA Bylaws, indicating all proposed amendments, is attached in Appendix 4.

**Grandfathering Provisions**

The proposed telepharmacy bylaw amendments have been drafted with a view not to adversely affect the level of pharmacy services currently in place in BC rural and remote communities. Grandfathering provisions have been added to help preserve the current level of pharmacy services, and additional requirements were added to grandfathered sites, to balance the need for pharmacy services with the College's aim of public protection. Grandfathered sites would need to meet all new requirements, with the particular exceptions, as noted below:

- Existing sites would not have to meet two pharmacy premise requirements (i.e., the dispensary area being at least 160 square feet, and having a dispensing counter with at least 30 square feet of clear working space) until such time as they renovate their premises.
- Four existing sites would be permitted to have a license as a telepharmacy and community pharmacy. These sites would be able to switch from a traditional community pharmacy to a telepharmacy, at times (e.g., switch into "telepharmacy mode"). However, all other telepharmacies must only hold one license type (i.e., a community pharmacy or telepharmacy license).
- All existing sites would be permitted to staff telepharmacies with pharmacy assistants instead of pharmacy technicians, but will be required to meet additional requirements (please see "Public Safety Concerns in Telepharmacies" for more information).

**Public Safety Concerns in Telepharmacies**

Concerns regarding public protection served as the impetus for the requirement for technician staffing at telepharmacy remote sites. Public safety concerns are raised by having unregulated pharmacy personal, such as pharmacy assistants, with access to Schedule I, II and III medications, and in particular controlled drug substances, and to confidential patient personal health

information. Since pharmacy assistants are not registrants, the College does not maintain a register of who they are, their qualifications or employment patterns. Further, the College does not have the legislative authority to require that Criminal Records Checks be conducted on them or to hold them accountable for their actions.

The proposed bylaws regarding telepharmacy require a pharmacy technician to staff the telepharmacy site. Existing sites will be 'grandfathered' to continue to allow a pharmacy assistant staffing model. To address concerns regarding unregulated staffing of these pharmacies, the bylaws have been strengthened with new requirements that aim to increase the security of drugs and confidential health information, and include additional requirements for 'grandfathered' sites.

New requirements for all telepharmacies to enhance public protection:

- The proposed amendments change telepharmacy from a service to a distinct license type. Potential telepharmacy operators will be required to provide fulsome information about the proposed telepharmacy during the application process, and will be expected to meet licensure requirements. Currently, quite limited information is requested for community pharmacy operators requesting to operate a telepharmacy service[2].
- Requiring that the new pharmacy security provisions apply to telepharmacies. These pharmacy security provisions are outlined in s.11.1 of the PODSA-Bylaws, and include requirements for security cameras, motion sensors, and time-delay safes, etc. When the telepharmacy is not being directly supervised by a pharmacist and the premise is accessible to non-registrants (e.g., in locations where the pharmacy is not 100% of the premise), monitored alarms will be required in the dispensary and physical barriers[3] will be required around Schedule I and II drugs, controlled drug substances and confidential health information.
- Increased number of inspections and audits from three to four times per year. This is consistent with Professional Practice Policy-65: Narcotic Counts and Reconciliations. In addition, these inspections and audits must occur at intervals of not less than two months, to avoid inspections and audits only being done at certain times of the year (e.g., all four inspections being done in the summer months).
- The draft Telepharmacy Standards of Practice requires that all prescription processing[4] be completed at the central pharmacy, unless a pharmacist is physically present and on duty at the telepharmacy. This will require the pharmacist to be involved with the processing of all prescriptions received at the telepharmacy, as well as being involved in all aspects of the prescription processing where a pharmacist is required.
- To ensure that the full pharmacist has access to, and oversight of, all patient records and related documentation, the draft Telepharmacy Standards of Practice requires that all

[2] http://library.bcpharmacists.org/7_Forms/7-3_Pharmacy/9040-App_Telepharmacy_Services.pdf
[3] Please note that the physical barriers requirement is subject to a three-year transition period.
[4] Prescription processing includes, entering the prescription information on the pharmacy's local computer system, transmitting the prescription to PharmaNet, reviewing the patient medication history to determining the appropriateness of the therapy, checking for drug interaction, allergies, and conducting the final check of the product to ensure correctness, etc.

original and stamped prescriptions, patient records, invoices and documentation in respect of prescriptions, be stored at the central pharmacy, not at the telepharmacy.
- The draft Telepharmacy Standards of Practice requires that the pharmacist at the central pharmacy must be able to directly supervise the telepharmacy, even if the staff person at the telepharmacy has not requested this supervision.

Additional requirements for 'grandfathered' telepharmacies with pharmacy assistants, include:
- In addition to the above-noted increased number of inspections and audits, 'grandfathered' telepharmacies will be required to perform monthly narcotic counts, signed by the supervising pharmacist, and provided immediately to the College, upon request.
- The requirement of direct supervision of the telepharmacy with a pharmacy assistant is to be greater than when staffed by a technician. When practicing within their scope of practice within a telepharmacy, pharmacy technicians do not need to be supervised by a pharmacist. However, assistants will be required to be supervised when performing any technical pharmacy activities.

**Section 56 Exemption**

The *Controlled Drugs and Substances Act* (CDSA) provides a framework for the control of import, export, production, distribution and use of substances that can alter mental processes and that may produce harm to health and to society when distributed or used without supervision. Section 56 of that Act states that the Minister can exempt a person, class or persons, or any controlled substance from the application of any of the provisions of the Act or the regulations, if necessary for a medical or scientific purpose or otherwise in the public interest.

College staff have had multiple meetings with Health Canada staff regarding a potential s.56 exemption for telepharmacies. These meetings have been quite positive and productive. Without an s.56 exemption, federal legislation prohibits narcotics and controlled drugs from being available in telepharmacies without a pharmacist physically present. As such, telepharmacies will only be permitted to dispense narcotics and controlled drugs, if an s.56 exemption is secured. College staff expect to have more information on the potential timing of such an exemption in the coming months. Additionally, existing telepharmacy operators have been informed of the need for an s.56 exemption.

**Consultation**

College staff held a consultation with existing telepharmacy operators and Ministry of Health staff on March 22, 2017. Overall, stakeholders expressed agreement with the proposal. Two main concerns were raised: (1) the proposed requirement to have the term 'telepharmacy' on telepharmacy signage, as it would require operators to obtain new signage and may discourage patients from seeking pharmacy care at a telepharmacy; and (2) requiring direct supervision via video link to occur when a full pharmacist is working on-site at a telepharmacy.

In looking further into the concerns noted above, staff recommend that the telepharmacy signage requirement remain. It is important that patients and the public understand the difference between

a telepharmacy and community pharmacy, and can make an informed decision when seeking healthcare services from a telepharmacy. With respect to the second concern, it has been clarified that there is no requirement for video or audio link to the central site, when a full pharmacist is working on-site at a telepharmacy.

**Associated Fee and Form Amendments**
The proposed bylaw package includes related schedule and form updates. The key fee change included in Form 2 and 12 is requiring the same fee amount for telepharmacy license applications and renewals, as required by community and hospital pharmacies. This is to reflect the fact that telepharmacies are a license type, and provide pharmacy services to the public.

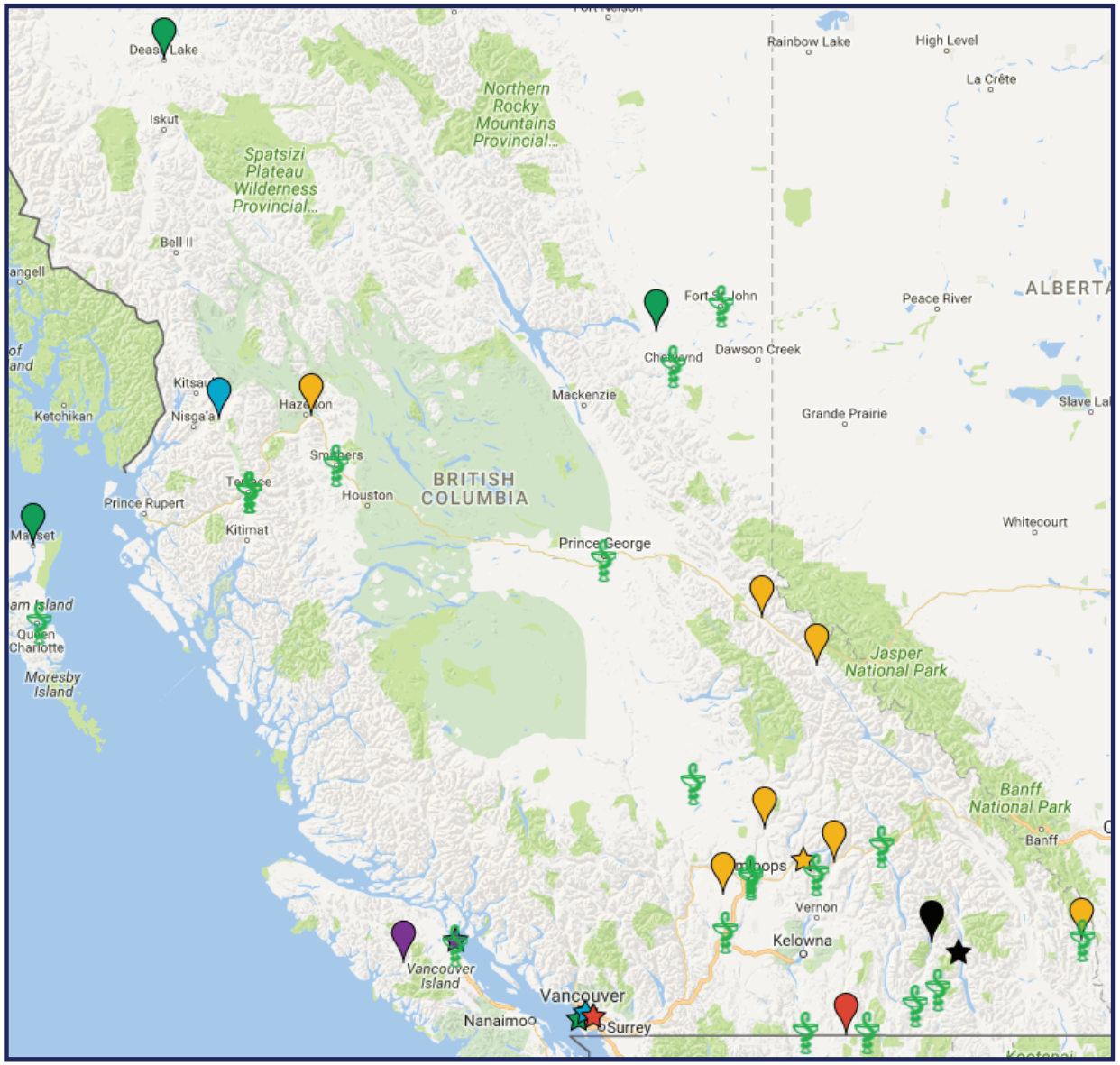
**Recommendation**
That the Board approve the proposed bylaws for public posting, as presented.

| **Appendix** | |
|---|---|
| 1 | Map of Telepharmacies in BC |
| 2 | Overview of PODSA-Bylaw and Standard of Practice Amendments |
| 3 | PODSA Bylaws (proposed amendments in track changes) |
| 4 | Telepharmacy Standards of Practice |
| 5 | Schedule A, C, E, F, G |
| 6 | Forms 2, 11, 12 |

# Map of Telepharmacies in British Columbia

**Legend**

- Pharmasave Health Centre #022 - YVR (Central Site)
- Pharmasave Health Centre #074 - Telepharmacy Dease Lake (Remote Site)
- Pharmasave Health Centre #075 - Telepharmacy Hudson's Hope (Remote Site)
- Pharmasave Health Centre #076 - Telepharmacy Haida Gwaii (Masset) (Remote Site)
- Pharmasave Health Centre #077 (Commercial Ave- Vancouver) (Central Site)
- Nisga'a Valley Pharmasave - Telepharmacy (New Aiyansh Pharmasave (Nass Valley) (Remote Site)
- Peoples Drug Mart #139 (Quathiaski Cove) (Central Site)
- Peoples Pharmacy #239 (Gold River) (Remote Site)
- Munro's Sorrento Prescription (Sorrento) (Central Site)
- Eagle Valley IDA Pharmacy (Sicamous) (Remote Site)
- Barriere IDA Pharmacy (Barriere) (Remote Site)
- Valemount IDA Pharmacy (Valemount) (Remote Site)
- Robson Valley IDA Pharmacy (McBride) (Remote Site)
- Logan Lake IDA Pharmacy (Logan Lake) (Remote Site)
- New Hazelton IDA Pharmacy (New Hazelton) (Remote Site)
- Elkford IDA Pharmacy (Elkford) (Remote Site)
- Lancaster Prescriptions #2 (Burnaby) (Central Site)
- Boundary Pharmacy (Midway) (Remote Site)
- Kaslo Community Pharmacy (Central Site)
- New Denver Community Pharmacy (Remote Site)




- Central Site
- Telepharmacy Site
- Nearest Community Pharmacy

College of Pharmacists of British Columbia

## Proposed Amendments Regarding Telepharmacies

**PODSA-Bylaws:**

The proposed amendments regarding telepharmacies involve PODSA-Bylaw changes as well as a new Standard of Practice. Highlights of key proposed telepharmacy amendments to the PODSA-Bylaws, are outlined in the chart below:

| Category | Brief Description | Rationale |
|---|---|---|
| **Definitions** | • Added a definition of direct supervision of a telepharmacy site: *"direct supervision" means real-time audio and visual observation by a full pharmacist of pharmacy services performed at a telepharmacy consistent with a pharmacy manager's responsibilities as set out in subsection 3(2);* | • The act of direct supervision is defined, but not the technology to be used.<br>• As technology advances very quickly, this definition will be relevant despite technology changes.<br>• Provides linkage to the pharmacy manager's responsibilities (e.g., to actively participate in the day-to-day management of the pharmacy, etc.). |
| | • Amended the definition of a central pharmacy site to: *"central pharmacy" means a community pharmacy that holds one or more telepharmacy licences;* | • Clarifies that the central pharmacy is the pharmacy that holds the telepharmacy license. |
| | • Amended the definition of telepharmacy to: *"telepharmacy" means a pharmacy located in a rural and remote community that is licenced to provide pharmacy services.* | • The term telepharmacy is now what was previously called the "remote site."<br>• Clarifies that telepharmacies are now licensed sites. |
| | • Added a definition of rural and remote community: *"rural and remote community" means a community that, as of April 1, 2016, has been given an A, B, C or D designation under the Rural Practice Subsidiary Agreement* (RSA) *between the Government of BC, Doctors of BC, and the Medical Services Commission;* | • The current PODSA-Bylaws requires telepharmacies to be located in a rural and remote community; however that term is not defined.<br>• The RSA[1] provides premiums to physicians working in rural and remote communities. It uses a criteria-based evaluation to determine the level of isolation of a community. That criteria includes:<br>- Number of Designated Specialties within 70 km;<br>- Number of General Practitioners within 35 km;<br>- Community size; |

[1] http://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/physician-compensation/rural-practice-programs/rural-practice-subsidiary-agreement

| Category | Brief Description | Rationale |
|---|---|---|
| | | - Distance from major medical community; and<br>- Degree of Latitude.<br>• This definition of rural and remote included in the PODSA-Bylaws, refers to the current RSA list of designated isolated communities[2]. |
| **Telepharmacy License** | • Creating a distinct telepharmacy license type. | • Telepharmacies are currently authorized as telepharmacy services, not as a distinct license type.<br>• Some telepharmacy sites are at times, staffed by a pharmacist who is practicing pharmacy. In addition, drugs are being stored and sold, and confidential health information is being stored in these premises. As such, it is appropriate for these premises to be licensed as pharmacies.<br>• Community pharmacies would no longer be able to switch from a traditional community pharmacy to a telepharmacy (e.g., switch into "telepharmacy mode"). Instead, sites must select which license type to apply for (i.e., community pharmacy or telepharmacy).<br>• The central pharmacy holds the telepharmacy license, linking both pharmacies during the licensure process.<br>• The central pharmacy and telepharmacy are to have the same owner, as shared ownership provides consistency for the development and application of policies and procedures. |
| **Telepharmacy Location Restrictions** | • Telepharmacies will only be permitted in the following locations:<br>- In a rural and remote community where there is no existing community pharmacy or telepharmacy; and | • Consistent with the concept that a telepharmacy enhances access to pharmacy services, in locations where such services are difficult to access.<br>• Consistent with eligibility criteria for Pharmacare's Rural Incentive Program[3], which includes: the applicant pharmacy is the only pharmacy in the |

[2] http://www2.gov.bc.ca/assets/gov/health/practitioner-pro/rsa_community.pdf
[3] http://www2.gov.bc.ca/assets/gov/health/forms/5384fil.pdf

| Category | Brief Description | Rationale |
|---|---|---|
| | - Where the next telepharmacy or community pharmacy is at least 25km away. | community, and the nearest pharmacy is at least 25km away. |
| **Telepharmacy Identification** | The following provisions were added:<br>• The proposed business name of the telepharmacy must include the word "telepharmacy."<br>• Managers and owners must use the telepharmacy operating name on advertising, signage, etc.<br>• Prescriptions and labels relating to prescriptions dispensed at a telepharmacy must identify the prescription as having been dispensed at that telepharmacy. | • Helps ensure that patients and the public can clearly distinguish between a community pharmacy and telepharmacy.<br>• The prescription and labelling requirement helps to identify when and where a prescription is being dispensed, for accountability and transparency purposes. |
| **Audits and Inspections** | • Currently, the pharmacy manager must inspect and audit a telepharmacy three times a year.<br>• The amendments increase this requirement to four times per year, and require that records of the audit be provided to the College immediately, upon request.<br>• 'Grandfathered' telepharmacies with an assistant staffing model will be required to also conduct monthly narcotic counts. | • Enhances oversight of the telepharmacy by the pharmacist at the central site.<br>• Increasing the audits and inspections to four times per year aligns with the number of narcotic counts required in *Professional Practice Policy* (PPP) *65 – Narcotic Counts and Reconciliation*.<br>• Requires an additional layer of oversight over 'grandfathered' telepharmacies. |

Other key amendments include, requiring that provisions regarding the physical requirements of community pharmacy premises (section 11 of the PODSA-Bylaws) and pharmacy security requirements (s.11.1 of the PODSA-Bylaws) apply to telepharmacies. Additionally, the pharmacy technician requirement has been maintained in the bylaws, with specific exceptions (see section on "Grandfathering Provisions" in the April 2017 Board briefing note).

**Telepharmacy Standards of Practice:**

Telepharmacy Standards of Practice have been developed to address the practice environment of telepharmacies. An amendment to the HPA-Bylaws will be required to implement these new Standards.

It is proposed that telepharmacies be required to follow the Community Pharmacy Standards of Practice and the Telepharmacy Practice of Standards. The draft Telepharmacy Standards of Practice focused on five key areas:

1. **Direct Supervision:** The supervising pharmacist must be able to directly supervise staff at the telepharmacy, and be available for patient consultation. However, the pharmacist does not need to directly supervise a pharmacy technician, when they are practicing within their scope. Additionally, the supervising pharmacist must be able to directly supervise staff at the telepharmacy, independent of any action or request made by telepharmacy staff.
2. **Receipt of Prescriptions and Transfer of Prescription Information:** A prescription provided at the central pharmacy can be designated for pick-up at the associated telepharmacy, and a prescription submitted to the telepharmacy must be stamped with the date and telepharmacy name. This will distinguish between prescriptions submitted to the central pharmacy and the telepharmacy.
3. **Prescription Processing and Product Preparation:** A secure connection between the telepharmacy and central pharmacy must be maintained to transfer prescription and other confidential health information. Prescription processing is to occur at the central site, except when a pharmacist is practicing at the telepharmacy. The prescription processing requirement is an added 'check and balance' to ensure that the supervising pharmacist is involved in the assessment of every prescription, and that they review the PharmaNet profile.
4. **Patient Counselling:** Clarifies that patient counselling by the supervising pharmacist must occur over real time video/audio link, unless a full pharmacist is physically present and on duty at the telepharmacy.
5. **Documentation:** Requires that all prescriptions, patient records, invoices, etc., be stored at the central pharmacy. Any of these documents in the telepharmacy must be transferred to the central pharmacy on a quarterly basis. This will ensure that documentation is kept at one site, to better ensure that the pharmacist has immediate access to all pharmacy records.

# *Pharmacy Operations and Drug Scheduling Act* - BYLAWS

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Schedule “A” – Fee Schedule

Schedule “C” – Community Pharmacy and Telepharmacy Diagram and Photo/Videos

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Schedule “F” – Telepharmacy/Community Licenced Sites

Schedule “G” – Telepharmacy Staff Exempted Sites

## FORMS

1. New Pharmacy Licence Application
2. Telepharmacy Licence ~~Services~~ Application
3. Hospital Pharmacy Satellite Application
4. Community Pharmacy Licence Renewal Notice
5. Hospital Pharmacy Licence Renewal Notice
6. Education Site License Renewal Notice

11. Telepharmacy Pre-Opening Inspection Report
12. Telepharmacy Licence Renewal

## Definitions

1. In these bylaws:

**"*Act*"** means the *Pharmacy Operations and Drug Scheduling Act*;

**"central pharmacy ~~site~~"** means a community pharmacy ~~authorized under Part IV to provide telepharmacy services~~that holds one or more telepharmacy licences;

**"community pharmacy"** means a pharmacy licensed to sell or dispense drugs to the public, but does not include a telepharmacy;

**"*Community Pharmacy Standards of Practice*"** means the standards, limits and conditions for practice established under section 19 (1) (k) of the *Health Professions Act* respecting community pharmacies;

**"controlled drug substance"** means a drug which includes a substance listed in the Schedules to the *Controlled Drugs and Substances Act* (Canada) or Part G of the Food and Drug Regulations (Canada);

**"controlled prescription program"** means a program approved by the board, to prevent prescription forgery and reduce inappropriate prescribing of drugs;

**"direct supervision"** means real time audio and visual observation by a full pharmacist of pharmacy services performed at a telepharmacy consistent with a pharmacy manager's responsibilities as set out in subsection 3(2);

**"dispensary"** means the area of a community pharmacy or a telepharmacy that contains Schedule I and II drugs;

**"drug"** has the same meaning as in section 1 of the *Pharmacy Operations and Drug Scheduling Act*;

**"health authority"** means

(a) a regional health board designated under the *Health Authorities Act*, or
(b) the Provincial Health Services Authority, or
(c) First Nations Health Authority;

**"hospital"** has the same meaning as in section 1 of the *Hospital Act*;

**"hospital pharmacy"** means a pharmacy licensed to operate in or for a hospital;

**"hospital pharmacy satellite"** means a physically separate area on or outside the hospital premises used for the provision of pharmacy services which is dependent upon support and administrative services from the hospital pharmacy;

***"Hospital Pharmacy Standards of Practice"*** means the standards, limits and conditions for practice established under section 19 (1) (k) of the *Health Professions Act* respecting hospital pharmacies;

**"incentive"** has the same meaning as in Part 1 of Schedule F of the bylaws of the college under the *Health Professions Act;*

**"outsource prescription processing"** means to request another community pharmacy to prepare or process a prescription drug order;

**"patient's representative"** has the same meaning as in section 64 of the bylaws of the college under the *Health Professions Act*;

**"personal health information"** has the same meaning as in section 25.8 of the *Health Protection Act*;

**"pharmacy education site"** means a pharmacy

(a) that has Schedule I, II and III drugs, but no controlled drug substances,
(b) that is licensed solely for the purpose of pharmacy education, and
(c) from which pharmacy services are not provided to any person;

**"pharmacy security"** means

(a) measures to prevent unauthorized access and loss of Schedule I, IA, II and III drugs, and controlled drug substances;,
(b) measures providing for periodic and post-incident review of pharmacy security;,
(c) measures to protect against unauthorized access, collection, use, disclosure or disposal of personal health information;

**"pharmacy services"** has the same meaning as in section 1 of the bylaws of the college under the *Health Professions Act*;

**"pharmacy technician"** has the same meaning as in section 1 of the bylaws of the college under the *Health Professions Act*;

**"prescription drug"** means a drug referred to in a prescription;

**"professional products area"** means the area of a community pharmacy that contains Schedule III drugs;

**"professional service area"** means the area of a community pharmacy that contains Schedule II drugs;

***"Residential Care Facilities and Homes Standards of Practice"*** means the standards, limits and conditions for practice established under section 19 (1) (k) of the *Health Professions Act* respecting residential care facilities and homes;

**"rural and remote community"** means a community that, as of April 1, 2016, has been given an A, B, C or D designation under the Rural Practice Subsidiary Agreement between the Government of BC, Doctors of BC, and the Medical Services Commission;

**"Schedule I, Schedule IA, Schedule II, or Schedule III"**, as the case may be, refers to the drugs listed in Schedule I, IA, II or III of the Drug Schedules Regulation;

**"support person"** has the same meaning as in the Act except that it does not include a pharmacy technician~~.~~;

**"telepharmacy"** means ~~the process by which~~ a ~~central~~ pharmacy located in a rural and remote community that is licenced to provide pharmacy services~~site operates one or more telepharmacy remote sites, all of which are connected to the central pharmacy site via computer, video and audio link~~;

**"*Telepharmacy Standards of Practice*"** means the standards, limits and conditions for practice established under subsection 19(1)(k) of the Health Professions Act respecting the operation of telepharmacies.

~~**"telepharmacy services"** means prescription processing or other pharmacy services, provided by or through telepharmacy;~~

~~**"telepharmacy remote site"** means a pharmacy providing pharmacy services to the public, or in or for a hospital,~~

~~(a) without a full pharmacist present,~~
~~(b) in a rural or remote community, and~~
~~(c) under the supervision and direction of a full pharmacist at a central pharmacy site;~~

## PART I - All Pharmacies

### Application of Part

2. This part applies to all pharmacies except pharmacy education sites.

### Responsibilities of Pharmacy Managers, Owners and Directors

3. (1) A full pharmacist may not act as manager of more than one pharmacy location, unless the pharmacy of which the full pharmacist is manager includes

(a) a telepharmacy ~~remote site~~,

(b) a hospital pharmacy,

(c) a hospital pharmacy satellite, or

(d) a pharmacy education site.

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

(a) actively participate in the day-to-day management of the pharmacy;

(b) confirm that the staff members who represent themselves as registrants are registrants;

(c) notify the registrar in writing of the appointments and resignations of registrants as they occur;

(d) cooperate with inspectors acting under section 17 of the *Act* or sections 28 or 29 of the *Health Professions Act*;

(e) ensure that

(i) registrant and support persons staff levels are sufficient to ensure that workload volumes and patient care requirements are met at all times in accordance with the bylaws, Code of Ethics and standards of practice,

(ii) meeting quotas, targets or similar measures do not compromise patient safety or compliance with the bylaws, Code of Ethics or standards of practice;

(f) ensure that new information directed to the pharmacy pertaining to drugs, devices and drug diversion is immediately accessible to registrants and support persons;

(g) establish policies and procedures to specify the duties to be performed by registrants and support persons;

(h) establish procedures for

(i) inventory management,

(ii) product selection, and

(iii) proper destruction of unusable drugs and devices;

(i) ensure that all records related to the purchase and receipt of controlled drug substances are signed by a full pharmacist;

(j) ensure appropriate security and storage of all Schedule I, II, and III drugs and controlled drug substances for all aspects of pharmacy practice including operation of the pharmacy without a registrant present;

(k) ensure there is a written drug recall procedure in place for pharmacy inventory;

(l) ensure that all steps in the drug recall procedure are documented, if the procedure is initiated;

(m) ensure that each individual working in the pharmacy wears a badge that clearly identifies the individual's registrant class or other status;

(n) notify the registrar as soon as possible in the event that he or she will be absent from the pharmacy for more than eight weeks;

(o) notify the registrar in writing within 48 hours of ceasing to be the pharmacy's manager;

(p) ensure the correct and consistent use of the community pharmacy operating name as it appears on the community pharmacy licence for all pharmacy identification on or in labels, directory listings, signage, packaging, advertising and stationery;

(p.1) if the pharmacy is a central pharmacy, ensure the correct and consistent use of each telepharmacy operating name as it appears on the telepharmacy licence for all pharmacy identification on or in labels, directory listings, signage, packaging, advertising and stationery associated with that telepharmacy;

(q) establish and maintain policies and procedures respecting pharmacy security;

(r) ensure that pharmacy staff are trained in policies and procedures regarding pharmacy security;

(s) notify the registrar of any incident of loss of narcotic and controlled drug substances within 24 hours;

(t) in the event of a pharmacy closure or relocation~~,~~

(i) notify the registrar in writing at least thirty days before the effective date of a proposed closure or relocation, unless the registrar determines there are extenuating circumstances,

(ii) provide for the safe transfer and appropriate storage of all Schedule I, II, and III drugs and controlled drug substances,

(iii) advise the registrar in writing of the disposition of all drugs and prescription records at the time of a closure,

(iv) provide the registrar with a copy of the return invoice and any other documentation sent to Health Canada in respect of the destruction of all controlled drug substances,

(v) arrange for the safe transfer and continuing availability of the prescription records at another pharmacy, or an off-site storage facility that is bonded and secure, and

(vi) remove all signs and advertisements from the closed pharmacy premises;

(u) ensure sample drugs are dispensed in accordance with the requirements in the Drug Schedules Regulation;

(v) advise the registrar if the pharmacy is providing pharmacy services over the internet, and provide to the registrar the internet address of every website operated or used by the pharmacy;

(w) ensure the pharmacy contains the reference material and equipment approved by the board from time to time;

(x) require all registrants, owners, managers, directors, pharmaceutical representatives, support persons and computer software programmers or technicians who will access the in-pharmacy computer system to sign an undertaking in a form approved by the registrar to maintain the confidentiality of patient personal health information;

(y) retain the undertakings referred to in paragraph (x) in the pharmacy for 3 years after employment or any contract for services has ended;

(z) be informed of the emergency preparedness plan in the area of the pharmacy that he or she manages and be aware of his or her responsibilities in conjunction with that plan;

(aa) ensure that no incentive is provided to a patient or patient's representative for the purpose of inducing the patient or patient's representative to

(a) deliver a prescription to a particular registrant or pharmacy for dispensing of a drug or device specified in the prescription, or

(b) obtain any other pharmacy service from a particular registrant or pharmacy~~.~~, and

(bb) notify the registrar of persistent non-compliance by owners and directors with their obligations under the bylaws~~;~~.

(3) Subsection (2)(p) does not apply to a hospital pharmacy, hospital pharmacy satellite or a pharmacy education site.

(4) Owners and directors must comply with subsection (2) (d), (e), (j), (p), (p.1), (q), (t), (v), (w), (x) and (aa).

(5) An owner or director must appoint a manager whenever necessary, and notify the registrar in writing of the appointment and any resignation of a manager.

(6) Owners and directors must ensure that the requirements to obtain a pharmacy licence under the *Act* are met at all times.

(7) For the purpose of subsection (2)(t), a pharmacy closure includes a suspension of the pharmacy licence for a period greater than 30 days, unless otherwise directed by the registrar.

3.1 Subsection (2)(aa) does not prevent a manager or director, or an owner from

(a) providing free or discounted parking to patients or patient's representatives,

(b) providing free or discounted delivery services to patients or patient's representatives, or

(c) accepting payment for a drug or device by a credit or debit card that is linked to an incentive.

3.2 Subsection (2)(aa) does not apply in respect of a Schedule III drug or an unscheduled drug, unless the drug has been prescribed by a practitioner.

**Sale and Disposal of Drugs**

4. (1) Schedule I, II, and III drugs and controlled drug substances must only be sold or dispensed from a pharmacy.

(2) A registrant must not sell or dispense a quantity of drug that will not be used completely prior to the manufacturer's expiry date, if used according to the directions on the label.

(3) If the manufacturer's expiry date states the month and year but not the date, the expiry date is the last day of the month indicated.

(4) Every registrant practising in a pharmacy is responsible for the protection from loss, theft or unlawful sale or dispensing of all Schedule I, II, and III drugs and controlled drug substances in or from the pharmacy.

(5) A registrant must not sell, dispense, dispose of or transfer a Schedule I drug except

(a) on the prescription or order of a practitioner,

(b) for an inventory transfer to a pharmacy by order of a registrant in accordance with the policy approved by the board,

(c) by return to the manufacturer or wholesaler of the drug, or

(d) by destruction, in accordance with the policy approved by the board.

(6) Drugs included in the controlled prescription program must not be sold or dispensed unless

(a) the registrant has received the prescription on the prescription form approved by both the board and the College of Physicians and Surgeons of British Columbia, and

(b) the prescription form is signed by the patient or the patient's representative upon receipt of the dispensed drug.

(7) A new prescription from a practitioner is required each time a drug is dispensed, except for

(a) a part-fill,

(b) a prescription authorizing repeats,

(c) a full pharmacist-initiated renewal or adaptation, or

(d) an emergency supply for continuity of care.

(8) Subsection (6) does not apply to prescriptions written for

(a) residents of a facility or home subject to the requirements of the *Residential Care Facilities and Homes Standards of Practice*, or

(b) patients admitted to a hospital.

**Drug Procurement/Inventory Management**

5. (1) A full pharmacist may authorize the purchase of Schedule I, II, or III drugs or controlled drug substances only from

(a) a wholesaler or manufacturer licensed to operate in Canada, or

(b) another pharmacy in accordance with the policy approved by the board.

(2) A registrant must record a transfer of drugs that occurs for any reason other than for the purpose of dispensing in accordance with a practitioner's prescription.

(3) All drug shipments must be delivered unopened to the pharmacy or a secure storage area.

(4) Non-usable and expired drugs must be stored in a separate area of the pharmacy or a secure storage area until final disposal.

(5) A full pharmacist must not purchase Schedule I, II and III drugs and controlled drug substances unless they are for sale or dispensing in or from a pharmacy.

**Interchangeable Drugs**

6. When acting under section 25.91 of the *Health Professions Act,* a full pharmacist must determine interchangeability of drugs by reference to Health Canada's Declaration of Equivalence, indicated by the identification of a Canadian Reference Product in a Notice of Compliance for a generic drug.

**Returned Drugs**

7. No registrant may accept for return to stock or reuse any drug previously dispensed except in accordance with section 11(3) of the *Residential Care Facilities and Homes Standards of Practice* or section 5(2) of the *Hospital Pharmacy Standards of Practice.*

**Records**

8. (1) All prescriptions, patient records, invoices and documentation in respect of the purchase, receipt or transfer of Schedule I, II and III drugs and controlled drug

substances must be retained for a period of not less than three years from the date

(a) a drug referred to in a prescription was last dispensed, or

(b) an invoice was received for pharmacy stock.

(2) Registrants, support persons, managers, directors, and owners must not, for commercial purposes, disclose or permit the disclosure of information or an abstract of information obtained from a prescription or patient record which would permit the identity of the patient or practitioner to be determined.

(3) Despite subsection (1), a registrant must not destroy prescriptions, patient records, invoices or documentation until the completion of any audit or investigation currently underway for which the registrant has received notice.

**Pharmacy Licences**

9. (1) The registrar may issue a licence for any of the following:

(a) a community pharmacy~~;~~,

(b) a hospital pharmacy~~;~~,

(c) a pharmacy education site, or

(d) a telepharmacy.

(2) An applicant for a pharmacy licence other than a telepharmacy licence must submit the following to the registrar:

(a) a completed application in Form 1~~;~~,

(b) a diagram to scale of ½ inch equals 1 foot scale including the measurements, preparation, dispensing, consulting, storage, professional service area, professional products area, entrances and packaging areas of the pharmacy~~;~~,

(c) the applicable fee set out in Schedule "A"~~;~~, and

(d) for a community pharmacy, proof in a form satisfactory to the registrar that the jurisdiction ~~municipality~~ in which the pharmacy is located has issued a business licence for the pharmacy to the pharmacy's owner or manager.

(2.1) An owner of a community pharmacy may apply for a new telepharmacy licence by submitting to the registrar:

(a) a completed application in Form 2,

(b) the applicable fee specified in Schedule "A",

(c) a diagram professionally drawn to a scale of ¼ inch equals 1 foot, including the measurements and entrances of the telepharmacy, and confirming that the telepharmacy meets the requirements listed in Schedules C and E,

(d) photographs or video in Form 11 of the requirements listed in Schedules C and E, and

(e) if applicable, a copy of the telepharmacy's business licence issued by the jurisdiction in which the telepharmacy is located.

(3) The registrar may renew a pharmacy licence other than a telepharmacy licence upon receipt of the following:

(a) a completed notice in Form 4, 5 or 6, as applicable, signed by the manager~~;~~, and

(b) the applicable fee set out in Schedule "A".

(3.1) The registrar may renew a telepharmacy licence upon receipt of the following:

(a) an application in Form 12,

(b) the fee set out in Schedule "A", and

(c) if applicable, a copy of the telepharmacy's business licence issued by the jurisdiction in which the telepharmacy is located.

(4) A pharmacy's manager must submit to the registrar, in writing, any proposed pharmacy design changes or structural renovations together with a new pharmacy diagram for approval before the commencement of construction or other related activities.

(5) If a pharmacy will be closed temporarily for up to 14 consecutive days, the pharmacy's manager must

(a) obtain the approval of the registrar,

(b) notify patients and the public of the closure at least 30 days prior to the start of the closure, and

(c) make arrangements for emergency access to the pharmacy's hard copy patient records.

(6) A pharmacy located in a hospital which dispenses drugs to staff, out-patients or the public and which is not owned or operated by a health authority, must be licenced as a community pharmacy.

(7) Subsections (4) to (6) do not apply to a pharmacy education site.

## PART II – Community Pharmacies

**Community Pharmacy Manager – Quality Management**

10. (1) A community pharmacy's manager must develop, document and implement an ongoing quality management program that

(a) maintains and enforces policies and procedures to comply with all legislation applicable to the operation of a community pharmacy,

(b) monitors staff performance, equipment, facilities and adherence to the *Community Pharmacy Standards of Practice*, and

(c) includes a process for reporting, documenting and following up on known, alleged and suspected errors, incidents and discrepancies.

(2) If a community pharmacy is a central pharmacy, the quality management program in subsection (1) must include all telepharmacies associated with the central pharmacy and must comply with the *Telepharmacy Standards of Practice*.

**Community Pharmacy and Telepharmacy Premises**

11. (1) In locations where a community pharmacy or telepharmacy does not comprise 100 per cent of the total area of the premises, the community pharmacy~~'s~~ manager or the central pharmacy manager in the case of a telepharmacy, must ensure that

(a) the professional products area extends not more than 25 feet from the perimeter of the dispensary and is visually distinctive from the remaining areas of the premises by signage, and

(b) a sign reading "Medication Information" is clearly displayed to identify a consultation area or counter at which a member of the public can obtain a full pharmacist's advice.

(2) Subject to subsection (3), ~~T~~the dispensary area of a community pharmacy or a telepharmacy must

(a) be at least 160 square feet,

(b) be inaccessible to the public by means of gates or doors across all entrances,

(c) include a dispensing counter with at least 30 square feet of clear working space, in addition to service counters,

(d) contain adequate shelf and storage space,

(e) contain a double stainless steel sink with hot and cold running water, and

(f) contain an adequate stock of drugs to provide full dispensing services.

(3) A telepharmacy that was authorized by the registrar to provide pharmacy services as a telepharmacy remote site as of January 1, 2017 is exempt from the requirements in subsections (2)(a) and (c) until such time as it commences a renovation of all or part of the premises.

(~~3~~4) In all new and renovated community pharmacies or telepharmacies, an appropriate area must be provided for patient consultation that

(a) ensures privacy and is conducive to confidential communication, and

(b) includes, but is not limited to, one of the following:

(i) a private consultation room~~;~~, or

(ii) a semiprivate area with suitable barriers.

(4~~5~~) All new and renovated community pharmacies and telepharmacies must have a separate and distinct area consisting of at least 40 square feet reserved as secure storage space.

**Community Pharmacy and Telepharmacy Security**

11.1 (1) A community pharmacy or telepharmacy must:

(a) ~~K~~keep Schedule IA drugs in a locked metal safe that is secured in place and equipped with a time delay lock set at a minimum of five minutes~~;~~,

(b) ~~i~~install and maintain a security camera system that:

(i) has date/time stamp images that are archived and available for no less than 30 days, and

(ii) is checked daily for proper operation~~;~~, and

(c) ~~i~~install and maintain motion sensors in the dispensary~~;~~.

(2) When no full pharmacist is present and the premise is accessible to non-registrants,

(a) the dispensary area ~~of a community pharmacy~~ must be secured by a monitored alarm, and

(b) Subject to subsection (2.1), schedule I and II drugs, controlled drug substances and personal health information, are secured by physical barriers~~;~~.

(2.1) A community pharmacy or telepharmacy that exists on the date this provision comes into force and is not renovated during the period must comply with section 11.1(2)(b) no later than three years after the date that provision comes into force~~;~~.

(2.2) For the purposes of subsection (2), a full pharmacist is deemed to be present at a telepharmacy when he or she is engaged in direct supervision of the telepharmacy.

(3) Subject to subsection (5), a community pharmacy and a telepharmacy must clearly display at all external entrances that identify the premises as a pharmacy, and at the dispensary counter signage provided by the College;

(4) The pharmacy manager and owners or directors of a community pharmacy or a telepharmacy that does not stock IA drugs must complete a declaration attesting that Schedule IA drugs are never stocked on the premises;

(5) A pharmacy that is never open to the public and has no external signage identifying it as a pharmacy is exempt from the requirements in subsection (3).

**Operation of a Community Pharmacy Without a Full Pharmacist**

12. (1) Except as provided in subsection (2), a community pharmacy must not be open to the public unless a full pharmacist is present.

(2) A community pharmacy ~~that does not have a telepharmacy remote site licence~~ may operate without a full pharmacist present if all the following requirements are met:

(a) the registrar is notified of the hours during which a full pharmacist is not present;

(b) a security system prevents the public, support persons and other non-pharmacy staff from accessing the dispensary, the professional service area and the professional products area;

(c) a pharmacy technician is present and ensures that the pharmacy is not open to the public;

(d) Schedule I, II, and III drugs and controlled drug substances in a secure storage area are inaccessible to support persons, other non-pharmacy staff and the public;

(e) dispensed prescriptions waiting for pickup may be kept outside the dispensary if they are inaccessible, secure and invisible to the public and the requirements of section 12 of the *Community Pharmacy Standards of Practice* have been met;

(f) the hours when a full pharmacist is on duty are posted.

(3) If the requirements of subsection (2) are met, the following activities may be performed at a community pharmacy by anyone who is not a registrant:

(a) requests for prescriptions, orders for Schedule II and III drugs and telephone requests from patients to order a certain prescription may be placed in the dispensary area by dropping them through a slot in the barrier;

(b) orders from drug wholesalers, containing Schedule I, II and III drugs, may be received but must be kept secure and remain unopened.

**Outsource Prescription Processing**

13. (1) A community pharmacy may outsource prescription processing if

(a) all locations involved in the outsourcing are community pharmacies,

(b) all prescriptions dispensed are labeled and include an identifiable code that provides a complete audit trail for the dispensed drug, and

(c) a notice is posted informing patients that the preparation of their prescription may be outsourced to another pharmacy.

(2) The manager of an outsourcing community pharmacy must ensure that all applicable standards of practice are met in processing prescriptions at all locations involved in the outsourcing.

(3) In this section, "community pharmacy" includes a hospital pharmacy.

## PART III – Hospital Pharmacies

### Hospital Pharmacy Manager – Quality Management

14. (1) A hospital pharmacy's manager must develop, document and implement an ongoing quality management program that

(a) maintains and enforces policies and procedures to comply with all legislation applicable to the operation of a hospital pharmacy,

(b) monitors staff performance, equipment, facilities and adherence to the *Hospital Pharmacy Standards of Practice*,

(c) includes a process for reporting, documenting and following up on known, alleged and suspected errors, incidents and discrepancies,

(d) documents periodic audits of the drug distribution process,

(e) includes a process to review patient-oriented recommendations,

(f) includes a process that reviews a full pharmacist's documentation notes in the hospital's medical records,

(g) includes a process to evaluate drug use, and

(h) regularly updates policies and procedures for drug use control and patient-oriented pharmacy services in collaboration with the medical and nursing staff and appropriate committees.

(2) If sample drugs are used within a hospital, the hospital pharmacy's manager must ensure that the pharmacy oversees the procurement, storage and distribution of all sample drugs.

**After Hours Service**

15. (1) If continuous pharmacy services are not provided in a hospital, the hospital pharmacy's manager must ensure that urgently needed drugs and patient-oriented pharmacy services are available at all times by

(a) providing a cabinet which must

(i) be a locked cabinet or other secure enclosure located outside of the hospital pharmacy, to which only authorized persons may obtain access,

(ii) be stocked with a minimum supply of drugs most commonly required for urgent use,

(iii) not contain controlled drug substances unless they are provided by an automated dispensing system,

(iv) contain drugs that are packaged to ensure integrity of the drug and labeled with the drug name, strength, quantity, expiry date and lot number, and

(v) include a log in which drug withdrawals are documented, and

(b) arranging for a full pharmacist to be available for consultation on an on-call basis.

(2) When a hospital pharmacy or hospital pharmacy satellite is closed, the premises must be equipped with a security system that will detect unauthorized entry.

## PART IV – Telepharmacy

**Telepharmacy Licence~~Services~~**

16. (1) The registrar must not issue a telepharmacy licence to a central pharmacy unless~~may authorize a community pharmacy or hospital pharmacy to provide telepharmacy services, upon receipt of a completed application in Form 2 and if satisfied that the requirements of this section will be met.~~

(a) the proposed telepharmacy will be the only telepharmacy or community pharmacy located in the rural and remote community,

(b) the proposed telepharmacy is located at least 25 kilometers away from any other telepharmacy or community pharmacy,

(c) the proposed business name of the telepharmacy includes the word "telepharmacy",

(d) except for a pharmacy listed in Schedule F, the proposed telepharmacy does not have a license as a community pharmacy,

(e) the central pharmacy applicant and the telepharmacy will have the same owner, and

(f) the central pharmacy is in compliance, and the telepharmacy will be in compliance, with the *Telepharmacy Standards of Practice*.

(2) A telepharmacy licence issued under subsection (1) is valid only for the location and owner stated on the telepharmacy licence and is not transferrable.~~Telepharmacy services may only be provided in or through pharmacies authorized under this Part to provide telepharmacy services.~~

~~(3) A telepharmacy remote site must be under the direct supervision of a full pharmacist at the central pharmacy site.~~

~~(4) A telepharmacy remote site must be under the responsibility of the manager of the central pharmacy site.~~

~~(5) The *Community Pharmacy Standards of Practice* apply to a telepharmacy remote site, unless it is located in, or providing pharmacy services for, a hospital in which case the *Hospital Pharmacy Standards of Practice* apply.~~

~~(6) Full pharmacists at a central pharmacy site must comply with section 12 of the *Community Pharmacy Standards of Practice* by using video and audio links.~~

~~(7) A sign must be posted at the dispensary counter of a telepharmacy remote site advising patients and staff when the site is operating in telepharmacy mode.~~

~~(8) A telepharmacy remote site must not remain open and prescriptions must not be dispensed if~~

~~(a) an interruption in data, video or audio link occurs,~~

~~(a) a pharmacy technician is not on duty at the telepharmacy remote site, or~~

~~(a) a full pharmacist is not on duty at the central pharmacy site.~~

~~(9) Prescriptions dispensed at a telepharmacy remote site must be distinguishable from a prescription dispensed at the central pharmacy site and include a unique label and a unique identifier for the prescription.~~

~~(10) The manager of a central pharmacy site must~~

~~(a) inspect and audit each affiliated telepharmacy remote site at least 3 times each year,~~

~~(b) make a written record of all inspections and audits, and~~

~~(c) provide a copy of a record described in paragraph (b) to the college on request.~~

~~(11) There must be a policy and procedure manual which describes the specific telepharmacy operations that are in place to ensure the safe and effective distribution of pharmacy products and delivery of pharmaceutical care.~~

## Telepharmacy Operation

16.1 (1) A telepharmacy must not remain open and prescriptions must not be dispensed unless

(a) a full pharmacist at the central pharmacy is engaged in direct supervision of the telepharmacy in accordance with the *Telepharmacy Standards of Practice*, and

(b) subject to subsection (2), a pharmacy technician is physically present on duty at the telepharmacy.

(2) A telepharmacy listed in Schedule G is exempt from the requirements in subsection (1)(b).

(3) A telepharmacy must have a security system that prevents the public and non-pharmacy staff from accessing the professional services area and the dispensary area, including any area where personal health information is stored.

(4) Prescriptions and labels relating to prescriptions dispensed at a telepharmacy must identify the prescription as having been dispensed at that telepharmacy.

(4.1) Prescriptions and labels relating to prescriptions dispensed at a pharmacy listed in Schedule F must distinguish between those dispensed when it is operating as a telepharmacy from when it is operating as a community pharmacy.

(5) The manager of a central pharmacy, or a full pharmacist designated by the manager, must

(a) inspect and audit its telepharmacy at least 4 times each year, at intervals of not less than 2 months,

(b) record each inspection and audit in the prescribed form, and

(c) provide the inspection and audit records to the registrar immediately upon request.

(6) A telepharmacy listed in Schedule G must perform a monthly count of narcotics at the telepharmacy and retain a record of each monthly count signed by the supervising pharmacist for three years at both the central pharmacy and the telepharmacy location, and provide the signed record to the registrar immediately upon request.

(7) A telepharmacy must not continue to provide pharmacy services for more than 30 days after

(a) its location ceases to be a rural and remote community,

(b) a community pharmacy is established within the community, or

(c) a community pharmacy is established within 25 kilometers of the location of the telepharmacy.

(8) A telepharmacy must have a policy and procedure manual on site that outlines the methods for ensuring the safe and effective distribution of pharmacy products and delivery of pharmaceutical care by the telepharmacy.

(9) A telepharmacy must connect to PharmaNet independently of the central pharmacy with which it is associated.

## PART V – Pharmacy Education Sites

### Pharmacy Education Site Manager

17. (1) A pharmacy education site's manager must ensure that only registrants and instructors are present in the pharmacy education site.

(2) A pharmacy education site's manager must comply with section 3(2)(a), (d), (h), (o), (r) and (t)(ii) and (iii).

## PART VI – PharmaNet

### Application of Part

18. This Part applies to every pharmacy that connects to PharmaNet.

### Definitions

19. In this Part:

**"database"** means those portions of the provincial computerized pharmacy network and database referred to in section 13 of the *Act*;

**"in-pharmacy computer system"** means the computer hardware and software utilized to support pharmacy services in a pharmacy;

**"patient keyword"** means an optional confidential pass code selected by the patient which limits access to the patient's PharmaNet record until the pass code is provided to the registrant;

**"PharmaNet patient record"** means the patient record described in section 11(2) of the *Community Pharmacy Standards of Practice* and in the PharmaNet Professional and Software Compliance Standards as the "patient profile";

**"PharmaNet Professional and Software Compliance Standards"** means the document provided by the Ministry of Health Services specifying the requirements of an in-pharmacy computer system to connect to PharmaNet;

**"terminal"** means any electronic device connected to a computer system, which allows input or display of information contained within that computer system.

**Operation of PharmaNet**

20. A pharmacy must connect to PharmaNet and be equipped with the following:

(a) an in-pharmacy computer system which meets the requirements set out in the current PharmaNet Professional and Software Compliance Standards;

(b) a terminal that is capable of accessing and displaying patient records, located in an area of the pharmacy which

(i) is only accessible to registrants and support persons,

(ii) is under the direct supervision of a registrant, and

(iii) does not allow information to be visible to the public, unless intended to display information to a specific patient; and

(c) the computer software upgrades necessary to comply with changes to the PharmaNet Professional and Software Compliance Standards.

**Data Collection, Transmission of and Access to PharmaNet Data**

21. (1) A registrant must enter the prescription information and transmit it to PharmaNet at the time of dispensing and keep the PharmaNet patient record current.

(2) A registrant may collect and transmit patient record information to PharmaNet or access a patient's PharmaNet record only

(a) to dispense a drug,

(b) to provide patient consultation, or

(c) to evaluate a patient's drug usage.

(3) A registrant may collect and transmit patient record information to PharmaNet or access a patient's PharmaNet record only for the purposes of claims adjudication and payment by an insurer.

(4) A registrant must revise information in the PharmaNet database pertaining to corrected billings for prescriptions billed to the patient or a payment agency other than PharmaCare and record the reason for the revision within 90 days of the original entry on PharmaNet.

(5) A registrant must reverse information in the PharmaNet database, for any drug that is not released to the patient or the patient's representative, and record the reason for the reversal no later than 30 days from the date of the original entry of the prescription information in PharmaNet.

(6) If a registrant is unable to comply with the deadlines in subsections (4) or (5), he or she must provide the information required to make the correction to the college as soon as possible thereafter.

(7) At the request of the patient, a registrant must establish, delete or change the patient keyword.

(8) Where a patient or patient's representative requests an alteration to be made to the PharmaNet information, the registrant must

(a) correct the information, or

(b) if the registrant refuses to alter the information, he or she must inform the person requesting the change of his or her right to request correction under the *Personal Information Protection Act*.

**Confidentiality**

22. A registrant must take reasonable steps to confirm the identity of a patient, patient's representative, registrant or practitioner before providing any pharmacy service, including but not limited to

(a) establishing a patient record,

(b) updating a patient's clinical information,

(c) providing a printout of an in-pharmacy or requesting a PharmaNet patient record,

(d) establishing, deleting, or changing a patient keyword,

(e) viewing a patient record,

(f) answering questions regarding the existence and content of a patient record,

(g) correcting information, and

(h) disclosing relevant patient record information to another registrant for the purpose of dispensing a drug or device, and/or for the purpose of monitoring drug use.

# *Health Professions Act* - BYLAWS

## Schedule F

## Part 6 – Telepharmacy Standards of Practice

## Table of Contents



### Application

1. This Part applies to the operation of telepharmacies licenced under s. 9(1)(d) of the bylaws made under the *Pharmacy Operations and Drug Scheduling Act* ("PODSA Bylaws").

2. Part 1 of Schedule F (Community Pharmacy Standards of Practice) applies to central pharmacies and telepharmacies except that, in the case of any inconsistency between it and this Part, the provisions of this Part prevail.

### Definitions

3. In this Part:

**"central pharmacy"** has the same meaning as in section 1 of the PODSA Bylaws;

**"community pharmacy"** has the same meaning as in section 1 of the PODSA Bylaws;

**"direct supervision"** has the same meaning as in section 1 of the PODSA Bylaws;

**"supervising pharmacist"** means:

(a) the manager of a central pharmacy,
(b) a full pharmacist employed at the central pharmacy responsible for providing direct supervision of pharmacy services in a telepharmacy, or
(c) a full pharmacist who is physically present on duty at the telepharmacy.

**Direct Supervision**

4. (1) A supervising pharmacist must exercise direct supervision of persons performing pharmacy services at a telepharmacy that is commensurate with the qualifications and expertise of those persons and is of sufficient frequency and duration to satisfy the requirements under s. 3(2) of the PODSA Bylaws.

(2) A supervising pharmacist must be readily available at all times when a telepharmacy is open to:

(a) provide direction and support to persons performing pharmacy services at the telepharmacy; and

(b) provide pharmacist/patient consultation.

(3) A supervising pharmacist must be able to engage in direct supervision of the provision of pharmacy services at a telepharmacy independent of any action of or request by persons performing those services.

(4) Subject to subsection (5), telepharmacy staff may only perform the activities described in s. 4(1) of the Pharmacists Regulation while under direct, continuous real-time audio and visual observation and direction of a supervising pharmacist.

(5) Direct supervision does not require the supervising pharmacist to conduct real-time observation of a pharmacy technician performing work within his or her scope of practice.

**Receipt of Prescriptions and Transfer of Prescription Information**

5. (1) A prescription that is provided to a central pharmacy, whether electronically, verbally or in physical form, may be designated for pick-up at a telepharmacy whose licence that central pharmacy holds.

(2) An original physical prescription may be submitted to a telepharmacy and, upon receipt, must be stamped with the date of receipt and the name of the telepharmacy.

**Prescription Processing and Product Preparation**

6. (1) All prescription processing must occur at the central pharmacy unless a full pharmacist is physically present on duty at the telepharmacy.

(2) Each telepharmacy and central pharmacy must maintain a secure connection to the central pharmacy for transmission of prescription and personal health information.

**Patient Counselling**

7. Unless a full pharmacist is physically present on duty at the telepharmacy, the supervising pharmacist must provide full pharmacist/patient consultation by real-time audio and visual link and otherwise in accordance with the requirements of Part 1 of Schedule F of the Health Professions Act Bylaws.

**Documentation**

8. (1) Subject to subsection (2), all original and stamped prescriptions, patient records, invoices and documentation in respect of prescriptions must be stored at the central pharmacy and otherwise in accordance with the requirements of s. 8 of the PODSA Bylaws.

(2) The telepharmacy must transfer all original prescriptions, patient records, invoices and documentation in respect of prescriptions to the central pharmacy on a quarterly basis.

**College of Pharmacists of B.C.**

**FEE SCHEDULE**

**PODSA Bylaw "Schedule A"**

## PHARMACY

### LICENSURE FEES

| | | | |
|---|---|---|---|
| Community Pharmacy | Annual license fee. | ~~$ 2,001.00~~ | $ 2,250.00 |
| Hospital Pharmacy | Annual license fee. | ~~$ 2,001.00~~ | $ 2,250.00 |
| Pharmacy Education Site | Annual license fee. | ~~$ 315.00~~ | $ 550.00 |
| Telepharmacy | Annual license fee. | - | $ 2,250.00 |
| ~~Telepharmacy Service~~ | ~~Annual fee for each site receiving service, to be charged to Pharmacy providing service.~~ | ~~$ 210.00~~ | ~~$ 300.00~~ |
| Hospital Pharmacy Satellite | Annual fee for each satellite site, to be charged to Hospital Pharmacy. | ~~$ 210.00~~ | $ 300.00 |
| Application for New Pharmacy Licensure | Application valid for up to three years. Includes change of ownership. | ~~$ 525.00~~ | $ 550.00 |

### INSPECTION FEE

| | | |
|---|---|---|
| Follow-up site review(s) | Where 3 or more site reviews are required to address deficiencies. From visit 3 onwards, this fee applies for each additional visit. | $ 1,000.00 |

***NOTES:***

*1) Fees are non-refundable.*

*2) Fees are subject to GST.*

*3) Annual renewal notices of pharmacy licensure are sent at least thirty (30) days prior to the expiry date.*

**College of Pharmacists of B.C.**

**COMMUNITY PHARMACY AND TELEPHARMACY DIAGRAM AND PHOTOS/VIDEOS**

**PODSA Bylaw "Schedule C"**

## ITEMS

**Indicate the location of the following items on the diagram and/or submit photos or videos of the following items with Form 10/Form 11:**

| Category | Item | Reference & Requirements | Diagram | Photo/Video |
|---|---|---|---|---|
| External to Dispensary | External View of the Pharmacy (Street view including the External Signage) | **Community Pharmacy: *PODSA Bylaws* s.3(2)(p)**<br>The manager ensure the correct and consistent use of the community pharmacy operating name as it appears on the community pharmacy licence for all pharmacy identification on or in labels, directory listings, signage, packaging, advertising and stationery. | (Entrance to the pharmacy) | ✓ |
| | | **Telepharmacy: *PODSA Bylaws* s.3(2)(p.1)**<br>The manager must, if the pharmacy is a central pharmacy, ensure the correct and consistent use of each telepharmacy operating name as it appears on the telepharmacy licence for all pharmacy identification on or in labels, directory listings, signage, packaging, advertising and stationery associated with that telepharmacy.<br>**Telepharmacy: *PODSA Bylaws* s.16(1)(b)**<br>The registrar must not issue a telepharmacy licence to a central pharmacy unless the proposed business name of the telepharmacy includes the word "telepharmacy". | | |
| | Hours of operation sign | ***PODSA Bylaws* s.12(2)(f)**<br>The hours when a full pharmacist is on duty are posted. | | ✓ |
| | Professional products area for schedule 3 drugs (+ Lock and Leave barriers if the premises is opened for business while the pharmacy is closed) OR N/A | ***PODSA Drug Schedule Regulations* s.2(3)**<br>Schedule III drugs may be sold by a pharmacist to any person from the self-selection Professional Products Area of a licensed pharmacy.<br>***PODSA Bylaws* s.11(1)(a)**<br>In locations where a community pharmacy or telepharmacy does not comprise 100 per cent of the total area of the premises, the community pharmacy manager or the central pharmacy manager in the case of a telepharmacy must ensure that the professional products area extends not more than 25 feet from the perimeter of the dispensary.<br>***PODSA Bylaws* s.3(2)(j)**<br>The manager must ensure appropriate security and storage of all Schedule I, II, and III drugs and controlled drug substances for all aspects of pharmacy practice including operation of the pharmacy without a registrant present. | ✓ | ✓ |
| | Signage at 25 feet from dispensary OR N/A | ***PODSA Bylaws* s.11(1)(a)**<br>In locations where a community pharmacy or telepharmacy does not comprise 100 per cent of the total area of the premises, the community pharmacy manager or the central pharmacy manager in the case of a telepharmacy must ensure that the professional products area is visually distinctive from the remaining areas of the premises by signage. | ✓ | ✓ |
| | "Medication Information" Sign OR N/A | ***PODSA Bylaws* s.11(1)(b)**<br>In locations where a community pharmacy or telepharmacy does not comprise 100 per cent of the total area of the premises, the community pharmacy manager or the central pharmacy manager in the case of a telepharmacy must ensure that a sign reading "Medication Information" is clearly displayed to identify a consultation area or counter at which a member of the public can obtain a full pharmacist's advice. | ✓ | ✓ |
| Dispensary | Dispensary area | ***PODSA Bylaws* s.11(2)(a)**<br>The dispensary area of a community pharmacy or a telepharmacy must be at least 160 square feet.<br>**Telepharmacy: *PODSA Bylaws* s.11(3)**<br>A telepharmacy that was authorized by the registrar to provide pharmacy services as a telepharmacy remote site as of January 1, 2017 is exempted from the requirements in subsections (2)(a) and (c) until such time as it commences a renovation of all or part of the premises. | | ✓ |
| | Gate/door at the entrance into the dispensary | ***PODSA Bylaws* s.11(2)(b)**<br>The dispensary area of a community pharmacy or a telepharmacy must be inaccessible to the public by means of gates or doors across all entrances. | ✓ | ✓ |
| | Placeholder for College license | ***PODSA* s.2(4)**<br>The manager must display the College license in a place within the pharmacy where it is conspicuous to the public. | | ✓ |
| | Professional Service Area for Schedule 2 drugs | ***PODSA Drug Schedule Regulations* s.2(3)**<br>Schedule II drugs may be sold by a pharmacist on a non-prescription basis and which must be retained within the Professional Service Area of the pharmacy where there is no public access and no opportunity for patient self-selection. | (Shelving) | ✓ |

| Category | Item | Reference & Requirements | Diagram | Photo/Video |
|---|---|---|---|---|
| | **Patient consultation area** | ***PODSA Bylaws* s.11(4)**<br>In all new and renovated community pharmacies or telepharmacies, an appropriate area must be provided for patient consultation that<br>(a) ensures privacy and is conducive to confidential communication, and<br>(b) includes, but is not limited to, one of the following:<br>(i) a private consultation room, or<br>(ii) a semiprivate area with suitable barriers. | ✓ | ✓ |
| | **Dispensing counter and service counter** | ***PODSA Bylaws* s.11(2)(c)**<br>The dispensary area of a community pharmacy or a telepharmacy must include a dispensing counter with at least 30 square feet of clear working space, in addition to service counters.<br>**Telepharmacy: *PODSA Bylaws* s.11(3)**<br>A telepharmacy that was authorized by the registrar to provide pharmacy services as a telepharmacy remote site as of January 1, 2017 is exempted from the requirements in subsections (2)(a) and (c) until such time as it commences a renovation of all or part of the premises. | ✓ | ✓ |
| | **Computer terminals for prescription processing** | ***PODSA Bylaws* s.20(b)**<br>A pharmacy must connect to PharmaNet and be equipped with a terminal that is capable of accessing and displaying patient records, located in an area of the pharmacy which<br>(i) is only accessible to registrants and support persons,<br>(ii) is under the direct supervision of a registrant, and<br>(iii) does not allow information to be visible to the public, unless intended to display information to a specific patient. | ✓ | ✓ |
| | **Shelving** | ***PODSA Bylaws* s.11(2)(d)**<br>The dispensary area of a community pharmacy or a telepharmacy must contain adequate shelf and storage space. | ✓ | ✓ |
| **Security** | **Secure storage space** | ***PODSA Bylaws* s.11(4)**<br>All new and renovated community pharmacies and telepharmacies must have a separate and distinct area consisting of at least 40 square feet reserved as secure storage space. | ✓ | ✓ |
| | **Locked Metal Safe**<br>**OR**<br>**Safe Declaration** | ***PODSA Bylaws* s.11.1(1)(a)**<br>A community pharmacy or telepharmacy must keep Schedule IA drugs in a locked metal safe that is secured in place and equipped with a time delay lock set at a minimum of five minutes.<br>***PPP-74 Policy Statement #4***<br>The safe must be an actual metal safe, a "narcotics cabinet" is not sufficient. The safe must be securely anchored in place, preferably to the floor.<br>***PODSA Bylaws* s.11.1(4)**<br>The pharmacy manager and owners or directors of a community pharmacy or telepharmacy that does not stock IA drugs must complete a declaration attesting that Schedule IA drugs are never stocked on the premises. | ✓ | ✓ |
| | **Security camera system AND Surveillance signage** | ***PODSA Bylaws* s.11.1(1)(b)**<br>A community pharmacy or telepharmacy must install and maintain a security camera system that:<br>(i) has date/time stamp images that are archived and available for no less than 30 days, and<br>(ii) is checked daily for proper operation.<br>***PPP-74 Policy Statement #4***<br>Under the Personal Information Protection Act (PIPA) pharmacies are required to post visible and clear signage informing customers that the premise is monitored by cameras. | | ✓ |
| | **Motion sensors** | ***PODSA Bylaws* s.11.1(1)(c)**<br>A community pharmacy or telepharmacy must install and maintain motion sensors in the dispensary. | | ✓ |
| | **Monitored alarm OR N/A** | ***PODSA Bylaws* s.11.1(2)(a)**<br>When no full pharmacist is present and the premise is accessible to non-registrants, the dispensary area must be secured by a monitored alarm.<br>***PPP-74 Policy Statement #4***<br>Independent alarms for the dispensary are optional, when a full pharmacist is present at all times and the premise is accessible by non-registrants.<br>**Telepharmacy (in addition to the above):**<br>***PODSA Bylaws* s.11.1(2.2)**<br>For the purposes of subsection (2), a full pharmacist is deemed to be present at a telepharmacy when he or she is engaged in direct supervision of the telepharmacy.<br>***PODSA Bylaws* s.16.1(3)**<br>A telepharmacy must have a security system that prevents the public and non-pharmacy staff from accessing the professional services area and the dispensary area, including any area where personal health information is stored. | | ✓ |
| | **Physical barriers OR N/A** | ***PODSA Bylaws* s.11.1(2)(b)**<br>When no full pharmacist is present and the premise is accessible to non-registrants, schedule I and II drugs, controlled drug substances and personal health information, are secured by physical barriers. | ✓ | ✓ |

| Category | Item | Reference & Requirements | Diagram | Photo/Video |
|---|---|---|---|---|
| | | ***PPP-74 Policy Statement #4***<br>Physical barriers provide an additional layer of security and deter:<br>1. Unauthorized access to drugs, including but not limited to:<br>• All Schedule I, and II and, controlled drug substances and personal health information.<br>2. Unauthorized access to personal health information, including but not limited to:<br>• Hard copies of prescriptions,<br>• Filled prescriptions waiting to be picked up, and/or<br>• Labels, patient profiles, and any other personal health information documents waiting for disposal.<br>Physical barriers can be tailored to the needs and structure of the particular community pharmacy. Examples of physical barriers include: locked gates, grillwork, locked cabinets, locked doors, and locked shelving units.<br>When a full pharmacist is present at all times, physical barriers are optional.<br>**Telepharmacy (in addition to the above):**<br>***PODSA Bylaws* s.11.1(2.2)**<br>For the purposes of subsection (2), a full pharmacist is deemed to be present at a telepharmacy when he or she is engaged in direct supervision of the telepharmacy.<br>***PODSA Bylaws* s.16.1(3)**<br>A telepharmacy must have a security system that prevents the public and non-pharmacy staff from accessing the professional services area and the dispensary area, including any area where personal health information is stored. | | |
| **Equipment & Reference** | **Double stainless steel sink** | ***PODSA Bylaws* s.11(2)(e)**<br>The dispensary area of a community pharmacy or telepharmacy must contain a double stainless steel sink with hot and cold running water.<br>***PPP-59* Policy Statement #1**<br>The dispensary of all community pharmacies at a minimum must have the following equipment as per PODSA Bylaw 3(2)(w):<br>(n) double sink with running hot and cold water; | ✓ | ✓ |
| | **Equipment (basic):**<br>**1. Telephone**<br>**2. Refrigerator**<br>**3. Rx filing supplies**<br>**4. Rx balance**<br>**5. Metric weights**<br>**6. Glass graduates**<br>**7. Mortar**<br>**8. Pestle**<br>**9. Spatulas**<br>**10. Funnels**<br>**11. Stirring rods**<br>**12. Ointment slab/ parchment paper**<br>**13. Counting tray**<br>**14. Disposable drinking cups**<br>**15. Soap dispenser**<br>**16. Paper towel dispenser**<br>**17. Plastic/metal garbage containers**<br>**18. Plastic lining**<br>**19. Fax machine** | ***PODSA Bylaws* s.3(2)(w)**<br>The manager must ensure the pharmacy contains the reference material and equipment approved by the board from time to time.<br>***PPP-59* Policy Statement #1**;<br>The dispensary of all community pharmacies at a minimum must have the following equipment as per PODSA Bylaw 3(2)(w):<br>(a) telephone;<br>(b) refrigerator;<br>(c) prescription filing supplies;<br>***PPP-12* Policy Statement #3**<br>All prescription hard copies are to be bundled, pegged or otherwise grouped into manageable groups of prescriptions, and are to be enclosed within a jacket or cover.<br>(d) prescription balance having a sensitivity rating of 0.01;<br>(e) metric weights (10 mg to 50 g) for balances requiring weights or instruments with equivalent capability;<br>(f) metric scale glass graduates (a selection, including 10 ml size);<br>(g) mortar and pestle;<br>(h) Spatulas (metal and nonmetallic);<br>(i) funnels (glass or plastic);<br>(j) stirring rods (glass or plastic);<br>(k) ointment slab or parchment paper;<br>(l) counting tray;<br>(m) disposable drinking cups;<br>(o) soap dispenser and paper towel dispenser;<br>(p) plastic or metal garbage containers to be used with plastic liners;<br>(q) fax machine<br>***HPA Schedule F Part 1 s. 7(1)(b)***<br>The facsimile equipment is located within a secure area to protect the confidentiality of the prescription information | ✓ Fridge only | ✓ |
| | **Equipment (Cold Chain)**<br>**1. Thermometer**<br>**2. Temperature log** | ***PPP-68* Policy Statement:**<br>The Board of the College of Pharmacists of BC adopts the BCCDC guidelines on the Cold Chain Management of Biologicals. Refer to BCCDC's Communicable Disease Control Immunization Program: Section VI – Management of Biologicals.<br>***Communicable Disease Control Immunization Program Section VI – Management of Biologicals (2015)* s.3.3.2**<br>Use a constant temperature-recording device or digital minimum/maximum thermometer (with probe) to monitor both the current refrigerator temperature and the minimum/maximum temperatures reached.<br>At the start and end of each work day, record the minimum and maximum temperatures reached since the last monitoring, on the Temperature Form.<br>On the Temperature Log, record the date, time and three temperatures (the current refrigerator temperature, the minimum temperature reached since last check, and the maximum temperature reached since last check.) Also record the refrigerator dial setting. | | ✓ |

| Category | Item | Reference & Requirements | Diagram | Photo/Video |
|---|---|---|---|---|
| | **Equipment (Methadone)**<br>1. Calibrated device<br>2. Auxiliary labels<br>3. Containers for daily dose<br>4. Patient/Rx Log<br>**OR N/A** | ***PPP-66 Policy Guide MMT (2013)* Principle 3.1.1**<br>Methadone doses must be accurately measured in a calibrated device that minimizes the error rate to no greater than 0.1 ml.<br>***PPP-66 Policy Guide MMT (2013)* Principle 3.3.1 Guidelines**<br>All devices used to measure the methadone 10 mg/ml solutions should be distinctive and recognizable and must be used only to measure methadone solutions. Devices must be labeled with a "methadone only" label and a "poison" auxiliary label with the international symbol of the skull and cross bones.<br>***PPP-66 Policy Guide MMT (2013)* Principle 4.1.6**<br>With respect to take-home doses the first dose (whether it is stated on the prescription or not) must be a witnessed ingestion with all subsequent take-home doses dispensed in child-resistant containers with an explicit warning label indicating that the amount of drug in the container could cause serious harm or toxicity if taken by someone other than the patient.<br>***PPP-66 Policy Guide MMT (2013)* Principle 4.1.6 Guidelines**<br>Each dose must be dispensed in an individual, appropriately sized, child-resistant container.<br>***PPP-66 Policy Guide MMT (2013)* Principle 4.1.3**<br>Prior to releasing a methadone prescription, the patient and pharmacist must acknowledge receipt by signing a patient/ prescription-specific log. | | ✓ |
| | **References (CPBC)**<br>1. BC Pharmacy Practice Manual<br>2. ReadLinks | ***PODSA Bylaws* s.3(2)(w)**<br>The manager must ensure the pharmacy contains the reference material and equipment approved by the board from time to time.<br>***PPP-3* Electronic Database References**<br>Electronic database references are acceptable for any of the authorized choices within any of the required categories, provided that they are as comprehensive as the printed version and meet the same updating requirements.<br>***PPP-3* Policy Statement 1st Paragraph**<br>All community pharmacies are required to have the most current versions of the BC Pharmacy Practice Manual.<br>All community pharmacies are required to have the most recent three years of Read Links. | | ✓ |
| | **References (General)**<br>1. Compendium<br>2. Complementary/ Alternative<br>3. Dispensatory<br>4. Drug Interactions<br>5. Nonprescription Medication (2x)<br>6. Medical Dictionary<br>7. Pregnancy and Lactation<br>8. Pediatrics<br>9. Therapeutics | ***PODSA Bylaws* s.3(2)(w)**<br>The manager must ensure the pharmacy contains the reference material and equipment approved by the board from time to time.<br>***PPP-3* Electronic Database References**<br>Electronic database references are acceptable for any of the authorized choices within any of the required categories, provided that they are as comprehensive as the printed version and meet the same updating requirements.<br>***PPP-3* Page 2**<br>All community pharmacies at a minimum must have one of the following authorized library references in each of the categories listed as per PODSA Bylaw 3(2)(w).<br>[which are:<br>1. Compendium (current year);<br>2. Complementary/Alternative (within the last 4 years);<br>3. Dispensatory (within last 9 years);<br>4. Drug Interactions (in its entirety every 2 years, or continual updates);<br>5. Nonprescription Medication (most current issue of BOTH references required);<br>6. Medical Dictionary (within the last 15 years);<br>7. Pregnancy and Lactation (within the last 3 years);<br>8. Pediatrics (within the last 4 years);<br>9. Therapeutics (within last 4 years)] | | ✓ |
| | **References (if applicable)**<br>• Veterinary<br>• Psychiatric<br>• Geriatric<br>• Specialty compounding<br>• Methadone<br>o PPP-66<br>o CSPBC<br>o CAMH<br>o Monograph<br>**OR N/A** | ***PODSA Bylaws* s.3(2)(w)**<br>The manager must ensure the pharmacy contains the reference material and equipment approved by the board from time to time.<br>***PPP-3* Electronic Database References**<br>Electronic database references are acceptable for any of the authorized choices within any of the required categories, provided that they are as comprehensive as the printed version and meet the same updating requirements.<br>***PPP-3* Page 2**<br>In addition to the above list, pharmacies must be equipped with references relevant to their practices (e.g. Veterinary, Psychiatric, Geriatric).<br>***PPP-66* Required References**<br>In addition to the currently required pharmacy reference materials (PPP-3), pharmacies providing methadone maintenance treatment services must also maintain as required references the following:<br>(1) CPBC Methadone Maintenance Treatment Policy Guide (2013) and subsequent revisions,<br>(2) most recent version of the CPSBC Methadone and Buprenorphine: Clinical Practice Guideline for Opioid Use Disorder,<br>(3) most current edition of Opioid Agonist Maintenance Treatment: A Pharmacist's Guide to Methadone and Buprenorphine for Opioid Use Disorders, and<br>(4) product monographs for the commercially available 10mg/ml methadone oral preparations. | | ✓ |

| Category | Item | Reference & Requirements | Diagram | Photo/Video |
|---|---|---|---|---|
| **Prescriptions** | **Prescription hardcopy (i.e. the label/paper attached to the original prescription, which contains prescription information generated after transmitting to PharmaNet)** | ***HPA Bylaws Schedule F Part 1* s.6(4)(a) to (f)**<br>At the time of dispensing, a prescription must include the following additional information:<br>(a) the address of the patient;<br>(b) the identification number from the practitioner's regulatory college; (c) the prescription number;<br>(d) the date on which the prescription was dispensed;<br>(e) the manufacturer's drug identification number or the brand name of the product dispensed;<br>(f) the quantity dispensed. | | ✓ |
| | | **Telepharmacy (in addition to the above):**<br>***PODSA Bylaws* s.16.1(4)**<br>Prescriptions and labels relating to prescriptions dispensed at a telepharmacy must identify the prescription as having been dispensed at that telepharmacy.<br>***PODSA Bylaws* s.16.1(4.1)**<br>Prescriptions and labels relating to prescriptions dispensed at a pharmacy listed in Schedule F must distinguish between those dispensed when it is operating as a telepharmacy from when it is operating as a community pharmacy. | | |
| **Confidentiality** | **Shredder OR**<br>**Contract with a Document Destruction Company** | ***HPA Bylaws* s.75**<br>A registrant must ensure that records referred to in section 74 are disposed of only by (a) transferring the record to another registrant, or (b) effectively destroying a physical record by utilizing a shredder or by complete burning, or by (c) erasing information recorded or stored by electronic methods on tapes, disks or cassettes in a manner that ensures that the information cannot be reconstructed.<br>***HPA Bylaws* s.78**<br>A registrant must ensure that, if personal information about patients is transferred to any person or service organization for processing, storage or disposal, a contract is made with that person which includes an undertaking by the recipient that confidentiality and physical security will be maintained. | | ✓ |
| | **Offsite Storage Contract**<br>**OR N/A** | ***HPA Bylaws* s.74(b)**<br>A registrant must ensure that all records pertaining to his or her practice, and containing personal information about patients are safely and securely stored off site. | | ✓ |
| **Inventory Management** | **Drug Receiving Area** | ***PODSA Bylaws* s.5(3)**<br>All drug shipments must be delivered unopened to the pharmacy or a secure storage area. | ✓ | ✓ |
| | **Drugs** | ***PODSA Bylaws* s.11(2)(f)**<br>The dispensary area of a community pharmacy or a telepharmacy must contain an adequate stock of drugs to provide full dispensing services. | | ✓ |
| | **Storage area for non-usable and expired drugs** | ***PODSA Bylaws* s.5(4)**<br>Non-usable and expired drugs must be stored in a separate area of the pharmacy or a secure storage area until final disposal. | | ✓ |
| **Dispensed Products** | **Prescription product label**<br>**1. Single entity product**<br>**2. Multiple-entity product** | ***HPA Bylaws Schedule F Part 1* s.9(2)**<br>The label for all prescription drugs must include<br>(a) the name, address and telephone number of the pharmacy,<br>(b) the prescription number and dispensing date,<br>(c) the full name of the patient,<br>(d) the name of the practitioner,<br>(e) the quantity and strength of the drug,<br>(f) the practitioner's directions for use, and<br>(g) any other information required by good pharmacy practice.<br>***HPA Bylaws Schedule F Part 1* s.9(3)**<br>For a single-entity product, the label must include<br>(a) the generic name, and<br>(b) at least one of<br>(i) the brand name,<br>(ii) the manufacturer's name, or<br>(iii) the drug identification number (DIN).<br>***HPA Bylaws Schedule F Part 1* s.9(4)**<br>For a multiple-entity product, the label must include<br>(a) the brand name, or<br>(b) all active ingredients and at least one of<br>(i) the manufacturer's name or<br>(ii) the drug identification number (DIN). | | ✓ |
| | | **Telepharmacy (in addition to the above):**<br>***PODSA Bylaws* s.16.1(4)**<br>Prescriptions and labels relating to prescriptions dispensed at a telepharmacy must identify the prescription as having been dispensed at that telepharmacy. | | |

| Category | Item | Reference & Requirements | Diagram | Photo/Video |
|---|---|---|---|---|
| | | ***PODSA Bylaws* s.16.1(4.1)**<br>Prescriptions and labels relating to prescriptions dispensed at a pharmacy listed in Schedule F must distinguish between those dispensed when it is operating as a telepharmacy from when it is operating as a community pharmacy. | | |
| | **Filling supplies (e.g. vials and bottles including caps)** | ***HPA Bylaws Schedule F Part 1* s.10(4)**<br>All drugs must be dispensed in a container that is certified as child-resistant unless…. | | ✓ |
| **Pharmacy Manager's Responsibilities** | **Name Badge** | ***PODSA Bylaws* s.3(2)(m)**<br>A manager must ensure that each individual working in the pharmacy wears a badge that clearly identifies the individual's registrant class or other status. | | ✓ |
| | **Police & Procedure Manual** | ***PODSA Bylaws* s.3(2)(g)**<br>A manager must establish policies and procedures to specify the duties to be performed by registrants and pharmacy assistants.<br>***PODSA Bylaws* s.3(2)(h)**<br>A manager must establish procedures for<br>(i) inventory management,<br>(ii) product selection, and<br>(iii) proper destruction of unusable drugs and devices.<br>***PODSA Bylaws* s.3(2)(k)**<br>A manager must ensure there is a written drug recall procedure in place for pharmacy Inventory.<br>***PODSA Bylaws* s.3(2)(q)**<br>A manager must establish and maintain policies and procedures respecting pharmacy security.<br>***PPP-74 Policy Statement #1***<br>Pharmacy security policies and procedures should be included in the pharmacy's policy and procedure document. The policies and procedures should contain information on the following:<br>• Training,<br>• Pharmacy security equipment,<br>• Emergency responses,<br>• Incident review, and<br>• Pharmacy security evaluation<br>***PPP-74 Policy Statement #5***<br>An emergency response kit should include a step-by-step guide on what to do in the event of a robbery or break and enter and be available to all pharmacy staff.<br>***PODSA Bylaws* s.10(c)**<br>A community pharmacy's manager must develop, document and implement an ongoing quality management program that includes a process for reporting, documenting and following up on known, alleged and suspected errors, incidents and discrepancies<br>***HPA Bylaws* s.79**<br>A registrant must take appropriate measures to remedy any unauthorized access, use, disclosure or disposal of personal information about patients under this Part as soon as possible after the breach is discovered. | | ✓ (or document file) |
| | | **Telepharmacy (in addition to the above):**<br>***PODSA Bylaws* s.16.1(8)**<br>A telepharmacy must have a policy and procedure manual on site that that outlines the methods for ensuring the safe and effective distribution of pharmacy products and delivery of pharmaceutical care by the telepharmacy. | | |

**College of Pharmacists of B.C.**

**TELEPHARMACY ADDITIONAL PHOTOS/VIDEOS**

**PODSA Bylaw "Schedule E"**

## ITEMS

**Submit photos or videos of the following items with Form 11:**

| Category | Item | Reference and Requirements |
|---|---|---|
| **Prescriptions** | **Prescription stamp** | ***HPA Bylaws Schedule F Part 6 s.5(2)***<br>An original physical prescription may be submitted to a telepharmacy and, upon receipt, must be stamped with the date of receipt and the name of the telepharmacy. |
| **Central Pharmacy** | **Tool/technology enabling direct supervision on dispensary activities** | ***PODSA Bylaws* s.16.1(1)(a)**<br>A telepharmacy must not remain open and prescriptions must not be dispensed unless a full pharmacist at the central pharmacy is engaged in direct supervision of the telepharmacy in accordance with the *Telepharmacy Standards of Practice*.<br>***PODSA Bylaws Definitions***<br>"direct supervision" means real-time audio and visual observation by a full pharmacist of pharmacy services performed at a telepharmacy consistent with a pharmacy manager's responsibilities as set out in subsection 3(2).<br>***HPA Bylaws Schedule F Part 6* s.3**<br>"supervising pharmacist" means (a) the manager of a central pharmacy, (b) a full pharmacist employed at the central pharmacy responsible for providing direct supervision of pharmacy services in a telepharmacy, or (c) a full pharmacist who is physically present on duty at the telepharmacy.<br>***HPA Bylaws Schedule F Part 6* s.4(3)**<br>A supervising pharmacist must be able to engage in direct supervision of the provision of pharmacy services at a telepharmacy independent of any action of or request by persons performing those services. |
| | **Tool/technology used for transmitting prescription and personal health information between sites** | ***HPA Bylaws Schedule F Part 6* s.6(2)**<br>Each telepharmacy and central pharmacy must maintain a secure connection to the central pharmacy for transmission of prescription and personal health information. |
| | **Tool/technology used for processing prescriptions at the central pharmacy for prescriptions received at the telepharmacy** | ***HPA Bylaws Schedule F Part 6* s.6(1)**<br>All prescription processing must occur at the central pharmacy unless a full pharmacist is physically present on duty at the telepharmacy.<br>***HPA Bylaws Schedule F Part 6* s.6(2)**<br>Each telepharmacy and central pharmacy must maintain a secure connection to the central pharmacy for transmission of prescription and personal health information. |
| | **Tool/technology enabling direct supervision on product final check** | ***PODSA Bylaws* s.16.1(1)(a)**<br>A telepharmacy must not remain open and prescriptions must not be dispensed unless a full pharmacist at the central pharmacy is engaged in direct supervision of the telepharmacy in accordance with the *Telepharmacy Standards of Practice*.<br>***HPA Bylaws Schedule F Part 6* s.3**<br>"supervising pharmacist" means (a) the manager of a central pharmacy, (b) a full pharmacist employed at the central pharmacy responsible for providing direct supervision of pharmacy services in a telepharmacy, or (c) a full pharmacist who is physically present on duty at the telepharmacy.<br>***HPA Bylaws Schedule F Part 6* s.4(2)(a)**<br>A supervising pharmacist must be readily available at all times when a telepharmacy is open to provide direction and support to persons performing pharmacy services at the telepharmacy.<br>***HPA Bylaws Schedule F Part 6* s.4(4)**<br>A telepharmacy may only provide pharmacy services within the exclusive scope of practice of a registrant while under direct, continuous real-time audio and visual observation and direction of a supervising pharmacist.<br>***HPA Bylaws Schedule F Part 6* s.4(5)**<br>Direct supervision does not require the supervising pharmacist to conduct real-time observation of a pharmacy technician performing work within his or her scope of practice. |
| | **Tool/technology enabling direct pharmacist/patient consultation** | ***HPA Bylaws Schedule F Part 6* s.3**<br>"supervising pharmacist" means (a) the manager of a central pharmacy, (b) a full pharmacist employed at the central pharmacy responsible for providing direct supervision of pharmacy services in a telepharmacy, or (c) a full pharmacist who is physically present on duty at the telepharmacy.<br>***HPA Bylaws Schedule F Part 6* s.4(2)(b)**<br>A supervising pharmacist must be readily available at all times when a telepharmacy is open to provide pharmacist/patient consultation.<br>***HPA Bylaws Schedule F Part 6* s.7**<br>Unless a full pharmacist is physically present on duty at the telepharmacy, the supervising pharmacist must provide full pharmacist/patient consultation by real-time audio and visual link and otherwise in accordance with the requirements of Part 1 of Schedule F of the *Health Professions Act Bylaws*. |

| Category | Item | Reference and Requirements |
|---|---|---|
| | **Policy and procedure manual (document file acceptable)** | ***PODSA Bylaws* s.10(2)**<br>If a community pharmacy is a central pharmacy, the quality management program in subsection (1) must include all telepharmacies associated with the central pharmacy and must comply with the *Telepharmacy Standards of Practice.* |

**College of Pharmacists of B.C.**

**TELEPHARMACY AND COMMUNITY LICENCED SITES**

**PODSA Bylaw "Schedule F"**

| Telepharmacy | Address |
|---|---|
| Eagle Valley IDA Pharmacy LTD. | 317 Main St.<br>Sicamous BC V0E 2V0 |
| Barriere IDA Pharmacy | 4480 Barriere Town Rd<br>Barriere BC V0E 1E0 |
| Logan Lake IDA Drugmart | 108 Chartrand Ave.<br>Logan Lake BC V0K 1W0 |
| Boundary Pharmacy | 612 - 6th Avenue<br>Midway BC V0H 1M0 |

**College of Pharmacists of B.C.**

**TELEPHARMACY STAFF EXEMPTED SITES**

**PODSA Bylaw "Schedule G"**

| Telepharmacy | Address |
|---|---|
| Pharmasave Health Centre #074 - Telepharmacy Dease Lake | 7171 Highway #37<br>Dease Lake BC V0C 1L0 |
| Pharmasave Health Centre #075 - Telepharmacy Hudson's Hope | 10309 Kyllo Street<br>Hudson & 27 S Hope BC V0C 1V0 |
| Pharmasave Health Centre #076 - Telepharmacy Haida Gwaii | 2520 Harrison Ave.<br>Masset BC V0T 1M0 |
| Nisga'a Valley Pharmasave – Telepharmacy | C/o Nisga'a Valley Health Authority<br>4920 Tait Ave<br>New Aiyansh BC V0J 1A0 |
| Peoples Pharmacy #239 (Eff. Apr 1/17 – Gold River Pharmacy) | 375 Nimpkish Dr<br>Village Square Shopping Ctre<br>Gold River BC V0P 1G0 |
| Robson Valley Pharmacy | 1136 5th Ave<br>McBridge BC V0J 2E0 |
| Valemount IDA Pharmacy | 1163 5th Ave<br>Valemount BC V0E 2Z0 |
| Eagle Valley IDA Pharmacy LTD. | 317 Main St.<br>Sicamous BC V0E 2V0 |
| Barriere IDA Pharmacy | 4480 Barriere Town Rd<br>Barriere BC V0E 1E0 |
| Logan Lake IDA Drugmart | 108 Chartrand Ave.<br>Logan Lake BC V0K 1W0 |
| Boundary Pharmacy | 612 - 6th Avenue<br>Midway BC V0H 1M0 |
| New Denver Community Pharmacy | 309 6 Ave<br>New Denver BC V0G 1S0 |

# APPLICATION FOR TELEPHARMACY SERVICES

## APPLICANT INFORMATION

Company name _____

Central pharmacy _____

Address _____ Tel _____

_____ Fax _____

_____ _____ Email _____

*Postal Code*

## PROPOSED REMOTE SITE

Operating name _____ Tel _____

Address _____ Fax _____

_____ Email _____

_____ _____

*Postal Code*

Hours of operation for Telepharmacy _____

_____

## ~~PAYMENT OPTION~~

~~☐ Cheque/Money order *(payable to College of Pharmacists of BC)*~~ ~~☐ VISA~~ ~~☐ MasterCard~~

~~Card #~~ _____ ~~Exp ____ / ____~~

~~Cardholder name~~ _____

~~Cardholder signature~~ _____

| | |
|---|---|
| ~~Initial licence fee~~ | ~~210.00~~ |
| ~~GST~~ | ~~10.50~~ |
| ~~**Total**~~ | ~~**$220.50**~~ |

~~GST # R106953920~~

I attest that:

- ~~☐~~ The Pharmacy is in compliance with the Health Professions Act, the Pharmacy Operations and Drug Scheduling Act, the Pharmacists Regulation and the Bylaws of the College of Pharmacists of British Columbia made pursuant to these Acts.
- ~~☐~~ I have read and understood the Pharmacy Licensure in British Columbia – Information Guide and Resources package.

_____ Name (please print)

_____ Signature

_____ Position

_____ Date

The College collects the personal information on this application form to process the application and administer the College's related activities. The collection is authorized by the *Pharmacy Operations and Drug Scheduling Act*, *Health Professions Act*, and *Freedom of Information and Protection of Privacy Act*. Should you have any questions about the collection, please contact the College's Privacy Officer at 604-733-2440 or 1-800-663-1940 or privacy@bcpharmacists.org

# APPLICATION FOR TELEPHARMACY SERVICES

## APPLICATION REQUIREMENT CHECKLIST

**Application must be received by the College Office <u>at least 60 days</u> prior to the planned operation of the pharmacy.**

**Application must be approved PRIOR to commencement of telepharmacy services.**

**The following must be submitted together with this application:**

- Diagram detailing the layout of the telepharmacy services at the remote site
- Copy of the final Policy and Procedure Manual which outlines specific telepharmacy operations (see template on College website at www.bcpharmacists.org)

PharmaNet connection for both sites? ☐ Yes ☐ No

# APPLICATION FOR TELEPHARMACY SERVICES

## PAYMENT OPTION

Pharmacy Name _____

☐ Cheque/Money order *(payable to College of Pharmacists of BC)* ☐ VISA ☐ MasterCard

Card # _____ Exp ____ / ____

Cardholder name _____

Cardholder signature _____

| | |
|---|---|
| Initial Licence fee | ~~210.00~~ 300.00 |
| GST | ~~10.50~~ 15.00 |
| **Total** | **~~$220.50~~ 315.00** |
| | GST # R106953920 |



**For office use ONLY**

iMIS ID: _____ Finance stamp:

Lic initials: _____

Date to Finance: _____

College of Pharmacists of British Columbia

# APPLICATION FOR NEW TELEPHARMACY LICENCE

Community

**Form 2**



## 1. TELEPHARMACY INFORMATION

| | | | |
|---|---|---|---|
| **Proposed Operating Name** | | **Proposed Opening Date** MMM \| DD \| YYYY | |
| **Telepharmacy Address** | **City** | **Province** BC | **Postal Code** |
| **Mailing Address (if different from above)** | **City** | **Province** | **Postal Code** |
| **Email Address** | **Phone Number** | **Fax Number** | |
| **Website** | | **Software Vendor (for dispensing)** | |
| **Pharmacy Technician Name** | | **Registration Number (BC)** | |
| **OWNER'S INFORMATION** | | | |
| **Name of Company on Notice of Articles/BC Company Summary** | | **BC Incorporation Number** | |
| **NEXT CLOSEST COMMUNITY PHARMACY/TELEPHARMACY** | | | |
| **Pharmacy Name** | | **City** | |
| **Approximate Distance from Proposed Telepharmacy Location (KM):** | | | |

## 2. CENTRAL PHARMACY INFORMATION

| | | | |
|---|---|---|---|
| **Operating Name** | | **PharmaCare Code** | |
| **Pharmacy Address** | **City** | **Province** BC | **Postal Code** |
| **Email Address** | **Phone Number** | **Fax Number** | |
| **Manager Name** | | **Registration Number (BC)** | |
| **OWNER'S INFORMATION** | | | |
| **Name of Company on Notice of Articles/BC Company Summary** | | **BC Incorporation Number** | |

## 3. PRIMARY CONTACT PERSON

| | | |
|---|---|---|
| **Name** | **Position/Title** | |
| **Email Address** | **Phone Number** | **Fax Number** |

College of Pharmacists of British Columbia

# APPLICATION FOR NEW TELEPHARMACY LICENCE

Community

**Form 2**



| 4. APPLICANT INFORMATION | |
|---|---|
| **Name of Authorized Representative** | **Position/Title of Authorized Representative** |
| **Signature** | **Date**<br>MMM \| DD \| YYYY |

The College collects the personal information on this application form to process the application and administer the College's related activities. The collection is authorized by the *Pharmacy Operations and Drug Scheduling Act*, *Health Professions Act*, and *Freedom of Information and Protection of Privacy Act*. Should you have any questions about the collection, please contact the College's Privacy Officer at 604-733-2440 or 1-800-663-1940 or privacy@bcpharmacists.org

College of Pharmacists of British Columbia

# APPLICATION FOR NEW TELEPHARMACY LICENCE

Community

**Form 2**



## 5. PAYMENT INFORMATION

| **Telepharmacy (Remote Site) Proposed Operating Name** (Auto-populate) | **Central Pharmacy Operating Name** (Auto-populate) |
|---|---|

**Method of Payment:** ☐ Cheque/Money order *(payable to College of Pharmacists of BC)* ☐ VISA ☐ MasterCard

| **Card Number** | **Expiry Date (MM/YY)** |
|---|---|
| **Cardholder Name** | |
| **Cardholder Signature** | |

| | |
|---|---|
| Application fee | $ 550.00 |
| Initial licence fee | $ 2250.00 |
| GST | $ 140.00 |
| **Total** | **$ 2940.00** |
| GST # | R106953920 |

**For office use ONLY**

iMIS ID: Finance stamp:

Lic initials:

Date to Finance:

College of Pharmacists of British Columbia

# PHARMACY PRE-OPENING INSPECTION REPORT

## TELEPHARMACY

| 1. TELEPHARMACY INFORMATION | | | | |
|---|---|---|---|---|
| **Operating Name** | | **PharmaCare Code** | | **Proposed Opening Date** MMM \| DD \| YYYY |
| **Telepharmacy Address** | **City** | **Province** BC | **Postal Code** | **Software Vendor (for dispensing)** |
| **Email Address** | **Phone Number** | **Fax Number** | | **Website** |

| 2. CENTRAL PHARMACY INFORMATION | | | | |
|---|---|---|---|---|
| **Operating Name** | | | | **PharmaCare Code** |
| **Pharmacy Address** | **City** | **Province** BC | **Postal Code** | **Software Vendor (for dispensing)** |
| **Email Address** | **Phone Number** | **Fax Number** | | **Website** |



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## 3. PHARMACY SERVICES

| TYPE | YES | NO | TYPE | YES | NO | If "YES", PROVIDE PHARMACY NAME(S) INVOLVED |
|---|---|---|---|---|---|---|
| Methadone (Pain) | | | Contracts - BC Transplant | | | |
| Methadone (Maintenance) | | | Contracts - Center for Excellence | | | |
| Compounding (Specialty) | | | Other - Delivery | | | |
| Compounding (Sterile Product) | | | Other - Internet | | | |
| Compliance Packaging | | | Other - Drive Thru | | | |
| Clinical - Injection Drug Administration | | | Residential Care Services | | | |
| Clinical - Medication Management/Review | | | Centralized Prescription Processing Services | | | Provided to: |
| Clinical - Education Clinics | | | Outsourced Prescription Processing Services | | | Received from: |
| Contracts - Renal Agencies | | | | | | |

## 4. HOURS OF OPERATION

| TYPE | SUN | MON | TUE | WED | THU | FRI | SAT |
|---|---|---|---|---|---|---|---|
| TELEPHARMACY | | | | | | | |
| Telepharmacy Hours | | | | | | | |
| Pharmacy Hours | | | | | | | |
| Lock & Leave Hours | | | | | | | |
| CENTRAL PHARMACY | | | | | | | |
| Pharmacy Hours | | | | | | | |
| Lock & Leave Hours | | | | | | | |



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| 5. TELEPHARMACY ROSTER* | | | | |
|---|---|---|---|---|
| **STAFF** | **REGISTRATION #** | **FIRST NAME/INFORMAL NAME** | **LAST NAME** | **REGISTRATION CLASS** |
| **Pharmacy Manager** | | | | ☒ Pharmacist<br>☐ Pharmacy Technician |
| **Staff #1** | | | | ☐ Pharmacist<br>☐ Pharmacy Technician |
| **Staff #2** | | | | ☐ Pharmacist<br>☐ Pharmacy Technician |
| **Staff #3** | | | | ☐ Pharmacist<br>☐ Pharmacy Technician |
| **Staff #4** | | | | ☐ Pharmacist<br>☐ Pharmacy Technician |
| **Staff #5** | | | | ☐ Pharmacist<br>☐ Pharmacy Technician |
| **Staff #6** | | | | ☐ Pharmacist<br>☐ Pharmacy Technician |
| **Staff #7** | | | | ☐ Pharmacist<br>☐ Pharmacy Technician |

*Include all registrant staff who may be providing pharmacy services or performing inspections/audits at the telepharmacy at any time

## 6. PRE-OPENING INSPECTION

**Confirm whether your new telepharmacy currently complies with each of the following requirements.**

- **If compliant, mark "✓" under the "Compliant" column and submit digital evidence (e.g. photos/videos) along with this form. Refer to the Licensure Guide for further details.**
- **If not applicable, enter "N/A" under the "Compliant" column and provide the reason in the comment field.**

# External to Dispensary

| # | Item | Reference and Requirements | Compliant | Comment | CPBC Use |
|---|---|---|---|---|---|
| 1a | **External view of the pharmacy (street view including the external signage)** | ***PODSA Bylaws* s.3(2)(p.1)**<br>The manager must, if the pharmacy is a central pharmacy, ensure the correct and consistent use of each telepharmacy operating name as it appears on the telepharmacy licence for all pharmacy identification on or in labels, directory listings, signage, packaging, advertising and stationery associated with that telepharmacy.<br>***PODSA Bylaws* s.16(1)(b)**<br>The registrar must not issue a telepharmacy licence to a central pharmacy unless the proposed business name of the telepharmacy includes the word "telepharmacy". | | | |
| 1b | **Hours of operation sign** | ***PODSA Bylaws* s.12(2)(f)**<br>The hours when a full pharmacist is on duty are posted. | | | |



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| # | Item | Reference and Requirements | Compliant | Comment | CPBC Use |
|---|---|---|---|---|---|
| 1c | **Professional products area for schedule 3 drugs**<br>**(+ Lock-and-Leave barriers if the premise is open for business while the pharmacy is closed)**<br>**OR N/A** | ***PODSA Drug Schedule Regulations* s.2(3)**<br>Schedule III drugs may be sold by a pharmacist to any person from the self-selection Professional Products Area of a licensed pharmacy.<br>***PODSA Bylaws* s.11(1)(a)**<br>In locations where a community pharmacy or telepharmacy does not comprise 100 per cent of the total area of the premises, the community pharmacy manager or the central pharmacy manager in the case of a telepharmacy must ensure that the professional products area extends not more than 25 feet from the perimeter of the dispensary.<br>***PODSA Bylaws* s.3(2)(j)**<br>The manager must ensure appropriate security and storage of all Schedule I, II, and III drugs and controlled drug substances for all aspects of pharmacy practice including operation of the pharmacy without a registrant present. | | | |
| 1d | **Signage at 25 feet from dispensary**<br>**OR N/A** | ***PODSA Bylaws* s.11(1)(a)**<br>In locations where a community pharmacy or telepharmacy does not comprise 100 per cent of the total area of the premises, the community pharmacy manager or the central pharmacy manager in the case of a telepharmacy must ensure that the professional products area is visually distinctive from the remaining areas of the premises by signage. | | | |
| 1e | **"Medication Information" Sign OR N/A** | ***PODSA Bylaws* s.11(1)(b)**<br>In locations where a community pharmacy or telepharmacy does not comprise 100 per cent of the total area of the premises, the community pharmacy manager or the central pharmacy manager in the case of a telepharmacy must ensure that a sign reading "Medication Information" is clearly displayed to identify a consultation area or counter at which a member of the public can obtain a full pharmacist's advice. | | | |

# Dispensary

| # | Item | Reference and Requirements | Compliant | Comment | CPBC Use |
|---|---|---|---|---|---|
| 2a | **Dispensary area** | ***PODSA Bylaws* s.11(2)(a)**<br>The dispensary area of a community pharmacy or telepharmacy must be at least 160 square feet.<br>***PODSA Bylaws* s.11(3)**<br>A telepharmacy that was authorized by the registrar to provide pharmacy services as a telepharmacy remote site as of January 1, 2017 is exempted from the requirements in subsections (2)(a) and (c) until such time as it commences a renovation of all or part of the premises. | | | |
| 2b | **Gate/door at the entrance into the dispensary** | ***PODSA Bylaws* s.11(2)(b)**<br>The dispensary area of a community pharmacy or telepharmacy must be inaccessible to the public by means of gates or doors across all entrances. | | | |
| 2c | **Placeholder for College license** | ***PODSA* s.2(4)**<br>The manager must display the College license in a place within the pharmacy or telepharmacy where it is conspicuous to the public. | | | |
| 2d | **Professional service area for Schedule 2 drugs** | ***PODSA Drug Schedule Regulations* s.2(3)**<br>Schedule II drugs may be sold by a pharmacist on a non-prescription basis and which must be retained within the Professional Service Area of the pharmacy or telepharmacy where there is no public access and no opportunity for patient self-selection. | | | |
| 2e | **Patient consultation area** | ***PODSA Bylaws* s.11(4)**<br>In all new and renovated community pharmacies or telepharmacies, an appropriate area must be provided for patient consultation that<br>(a) ensures privacy and is conducive to confidential communication, and | | | |



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| # | Item | Reference and Requirements | Compliant | Comment | CPBC Use |
|---|---|---|---|---|---|
| | | (b) includes, but is not limited to, one of the following:<br>(i) a private consultation room, or<br>(ii) a semiprivate area with suitable barriers. | | | |
| 2f | Dispensing counter and service counter | ***PODSA Bylaws* s.11(2)(c)**<br>The dispensary area of a community pharmacy or telepharmacy must include a dispensing counter with at least 30 square feet of clear working space, in addition to service counters.<br>***PODSA Bylaws* s.11(3)**<br>A telepharmacy that was authorized by the registrar to provide pharmacy services as a telepharmacy remote site as of January 1, 2017 is exempted from the requirements in subsections (2)(a) and (c) until such time as it commences a renovation of all or part of the premises. | | | |
| 2g | Computer terminals for prescription processing | ***PODSA Bylaws* s.20(b)**<br>A pharmacy must connect to PharmaNet and be equipped with a terminal that is capable of accessing and displaying patient records, located in an area of the pharmacy which<br>(i) is only accessible to registrants and support persons,<br>(ii) is under the direct supervision of a registrant, and<br>(iii) does not allow information to be visible to the public, unless intended to display information to a specific patient. | | | |
| 2f | Shelving | ***PODSA Bylaws* s.11(2)(d)**<br>The dispensary area of a community pharmacy or telepharmacy must contain adequate shelf and storage space. | | | |

# Security

| # | Item | Reference and Requirements | Compliant | Comment | CPBC Use |
|---|---|---|---|---|---|
| 3a | Secure storage space | ***PODSA* s.11(5)**<br>All new and renovated community pharmacies and telepharmacies must have a separate and distinct area consisting of at least 40 square feet reserved as secure storage space. | | | |
| 3b | ☐ Locked metal safe<br>OR<br>☐ Safe declaration | ***PODSA Bylaws* s.11.1(1)(a)**<br>A community pharmacy or telepharmacy must keep Schedule IA drugs in a locked metal safe that is secured in place and equipped with a time delay lock set at a minimum of five minutes.<br>***PPP-74 Policy Statement #4***<br>The safe must be an actual metal safe, a "narcotics cabinet" is not sufficient. The safe must be securely anchored in place, preferably to the floor.<br>***PODSA Bylaws* s.11.1(4)**<br>The pharmacy manager and owners or directors of a community pharmacy or telepharmacy that does not stock IA drugs must complete a declaration attesting that Schedule IA drugs are never stocked on the premises. | | | |
| 3c | Security camera system<br>AND<br>Surveillance signage | ***PODSA Bylaws* s.11.1(1)(b)**<br>A community pharmacy or telepharmacy must install and maintain a security camera system that:<br>(i) has date/time stamp images that are archived and available for no less than 30 days, and<br>(ii) is checked daily for proper operation.<br>***PPP-74 Policy Statement #4***<br>Under the Personal Information Protection Act (PIPA) pharmacies are required to post visible and clear signage informing customers that the premise is monitored by cameras. | | | |
| 3d | Motion sensors | ***PODSA Bylaws* s.11.1(1)(c)**<br>A community pharmacy or telepharmacy must install and maintain motion sensors in the dispensary. | | | |



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| # | Item | Reference and Requirements | Compliant | Comment | CPBC Use |
|---|---|---|---|---|---|
| 3e | **Monitored alarm**<br>**OR N/A** | ***PODSA Bylaws* s.11.1(2)(a)**<br>When no full pharmacist is present and the premise is accessible to non-registrants, the dispensary area must be secured by a monitored alarm.<br>***PODSA Bylaws* s.11.1(2.2)**<br>For the purposes of subsection (2), a full pharmacist is deemed to be present at a telepharmacy when he or she is engaged in direct supervision of the telepharmacy.<br>***PPP-74 Policy Statement #4***<br>Independent alarms for the dispensary are optional, when a full pharmacist is present at all times and the premise is accessible by non-registrants.<br>***PODSA Bylaws* s.16.1(3)**<br>A telepharmacy must have a security system that prevents the public and non-pharmacy staff from accessing the professional services area and the dispensary area, including any area where personal health information is stored. | | | |
| 3f | **Physical barriers**<br>**OR N/A** | ***PODSA Bylaws* s.11.1(2)(b)**<br>When no full pharmacist is present and the premise is accessible to non-registrants, schedule I and II drugs, controlled drug substances and personal health information, are secured by physical barriers.<br>***PODSA Bylaws* s.11.1(2.2)**<br>For the purposes of subsection (2), a full pharmacist is deemed to be present at a telepharmacy when he or she is engaged in direct supervision of the telepharmacy.<br>***PPP-74 Policy Statement #4***<br>Physical barriers provide an additional layer of security and deter:<br>1. Unauthorized access to drugs, including but not limited to:<br>• All Schedule I, and II and, controlled drug substances and personal health information.<br>2. Unauthorized access to personal health information, including but not limited to:<br>• Hard copies of prescriptions,<br>• Filled prescriptions waiting to be picked up, and/or<br>• Labels, patient profiles, and any other personal health information documents waiting for disposal.<br>Physical barriers can be tailored to the needs and structure of the particular community pharmacy. Examples of physical barriers include: locked gates, grillwork, locked cabinets, locked doors, and locked shelving units.<br>When a full pharmacist is present at all times, physical barriers are optional.<br>***PODSA Bylaws* s.16.1(3)**<br>A telepharmacy must have a security system that prevents the public and non-pharmacy staff from accessing the professional services area and the dispensary area, including any area where personal health information is stored. | | | |

# Equipment and References

| # | Item | Reference and Requirements | Compliant | Comment | CPBC Use |
|---|---|---|---|---|---|
| 4a | **Double stainless steel sink** | ***PODSA Bylaws* s.11(2)(e)**<br>The dispensary area of a community pharmacy or telepharmacy must contain a double stainless steel sink with hot and cold running water.<br>***PPP-59* Policy Statement #1**<br>The dispensary of all community pharmacies and telepharmacies at a minimum must have the following equipment as per PODSA Bylaw 3(2)(w):<br>(n) double sink with running hot and cold water; | | | |



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| # | Item | Reference and Requirements | Compliant | Comment | CPBC Use |
|---|---|---|---|---|---|
| 4b | **Equipment:**<br>1. Telephone<br>2. Refrigerator<br>3. Rx filing supplies<br>4. Rx balance<br>5. Metric weights<br>6. Glass graduates<br>7. Mortar<br>8. Pestle<br>9. Spatulas<br>10. Funnels<br>11. Stirring rods<br>12. Ointment slab/ parchment paper<br>13. Counting tray<br>14. Disposable drinking cups<br>15. Soap dispenser<br>16. Paper towel dispenser<br>17. Plastic/metal garbage containers<br>18. Plastic lining<br>19. Fax machine | ***PODSA Bylaws* s.3(2)(w)**<br>The manager must ensure the pharmacy contains the reference material and equipment approved by the board from time to time.<br>***PPP-59* Policy Statement #1**;<br>The dispensary of all community pharmacies and telepharmacies at a minimum must have the following equipment as per PODSA Bylaw 3(2)(w):<br>(a) telephone;<br>(b) refrigerator;<br>(c) prescription filing supplies;<br>***PPP-12* Policy Statement #3**<br>All prescription hard copies are to be bundled, pegged or otherwise grouped into manageable groups of prescriptions, and are to be enclosed within a jacket or cover.<br>(d) prescription balance having a sensitivity rating of 0.01;<br>(e) metric weights (10 mg to 50 g) for balances requiring weights or instruments with equivalent capability;<br>(f) metric scale glass graduates (a selection, including 10 ml size);<br>(g) mortar and pestle;<br>(h) Spatulas (metal and non-metallic);<br>(i) funnels (glass or plastic);<br>(j) stirring rods (glass or plastic);<br>(k) ointment slab or parchment paper;<br>(l) counting tray;<br>(m) disposable drinking cups;<br>(o) soap dispenser and paper towel dispenser;<br>(p) plastic or metal garbage containers to be used with plastic liners;<br>(q) fax machine<br>***HPA Schedule F Part 1 s. 7(1)(b)***<br>The facsimile equipment is located within a secure area to protect the confidentiality of the prescription information | | | A<br>B<br>C<br>D<br>E<br>F<br>G<br>H<br>I<br>J<br>K<br>L<br>M<br>O<br>P<br>Q |
| 4c | **Equipment (Cold Chain)**<br>1. Thermometer<br>2. Temperature log | ***PPP-68* Policy Statement:**<br>The Board of the College of Pharmacists of BC adopts the BCCDC guidelines on the Cold Chain Management of Biologicals. Refer to BCCDC's Communicable Disease Control Immunization Program: Section VI – Management of Biologicals.<br>***Communicable Disease Control Immunization Program Section VI – Management of Biologicals (2015)* s.3.3.2**<br>Use a constant temperature-recording device or digital minimum/maximum thermometer (with probe) to monitor both the current refrigerator temperature and the minimum/maximum temperatures reached.<br>At the start and end of each work day, record the minimum and maximum temperatures reached since the last monitoring, on the Temperature Form.<br>On the Temperature Log, record the date, time and three temperatures (the current refrigerator temperature, the minimum temperature reached since last check, and the maximum temperature reached since last check.) Also record the refrigerator dial setting. | | | TMM<br>TLOG |



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| # | Item | Reference and Requirements | Compliant | Comment | CPBC Use |
|---|---|---|---|---|---|
| 4d | **Equipment (Methadone)**<br>1. Calibrated device<br>2. Auxiliary labels<br>3. Containers for daily dose<br>4. Patient/Rx Log<br>**OR N/A** | ***PPP-66 Policy Guide MMT (2013)* Principle 3.1.1**<br>Methadone doses must be accurately measured in a calibrated device that minimizes the error rate to no greater than 0.1 ml.<br>***PPP-66 Policy Guide MMT (2013)* Principle 3.3.1 Guidelines**<br>All devices used to measure the methadone 10 mg/ml solutions should be distinctive and recognizable and must be used only to measure methadone solutions. Devices must be labeled with a "methadone only" label and a "poison" auxiliary label with the international symbol of the skull and cross bones.<br>***PPP-66 Policy Guide MMT (2013)* Principle 4.1.6**<br>With respect to take-home doses the first dose (whether it is stated on the prescription or not) must be a witnessed ingestion with all subsequent take-home doses dispensed in child-resistant containers with an explicit warning label indicating that the amount of drug in the container could cause serious harm or toxicity if taken by someone other than the patient.<br>***PPP-66 Policy Guide MMT (2013)* Principle 4.1.6 Guidelines**<br>Each dose must be dispensed in an individual, appropriately sized, child-resistant container.<br>***PPP-66 Policy Guide MMT (2013)* Principle 4.1.3**<br>Prior to releasing a methadone prescription, the patient and pharmacist must acknowledge receipt by signing a patient/ prescription-specific log. | | | DEV<br>AUX1<br>AUX 2<br>DOSE<br>MLOG |
| 4e | **References (CPBC)**<br>1. BC Pharmacy Practice Manual<br>2. ReadLinks | ***PODSA Bylaws* s.3(2)(w)**<br>The manager must ensure the pharmacy contains the reference material and equipment approved by the board from time to time.<br>***PPP-3* Electronic Database References**<br>Electronic database references are acceptable for any of the authorized choices within any of the required categories, provided that they are as comprehensive as the printed version and meet the same updating requirements.<br>***PPP-3* Policy Statement 1st Paragraph**<br>All community pharmacies are required to have the most current versions of the BC Pharmacy Practice Manual.<br>All community pharmacies are required to have the most recent three years of Read Links. | | | BPPM<br>RL |
| 4f | **References (General)**<br>1. Compendium<br>2. Complementary/ Alternative<br>3. Dispensatory<br>4. Drug Interactions<br>5. Nonprescription Medication (2x)<br>6. Medical Dictionary<br>7. Pregnancy and Lactation<br>8. Pediatrics<br>9. Therapeutics | ***PODSA Bylaws* s.3(2)(w)**<br>The manager must ensure the pharmacy contains the reference material and equipment approved by the board from time to time.<br>***PPP-3* Electronic Database References**<br>Electronic database references are acceptable for any of the authorized choices within any of the required categories, provided that they are as comprehensive as the printed version and meet the same updating requirements.<br>***PPP-3* Page 2**<br>All community pharmacies and telepharmacies at a minimum must have one of the following authorized library references in each of the categories listed as per PODSA Bylaw 3(2)(w).<br>[which are:<br>1. Compendium (current year);<br>2. Complementary/Alternative (within the last 4 years);<br>3. Dispensatory (within last 9 years);<br>4. Drug Interactions (in its entirety every 2 years, or continual updates);<br>5. Nonprescription Medication (most current issue of BOTH references required);<br>6. Medical Dictionary (within the last 15 years);<br>7. Pregnancy and Lactation (within the last 3 years);<br>8. Pediatrics (within the last 4 years);<br>9. Therapeutics (within last 4 years)] | | | CPS<br>ALT<br>DIS<br>DI<br>OTC1<br>OTC2<br>MD<br>P/L<br>PED<br>TH |



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| # | Item | Reference and Requirements | Compliant | Comment | CPBC Use |
|---|---|---|---|---|---|
| 4g | **References (if applicable)**<br>☐ Veterinary<br>☐ Psychiatric<br>☐ Geriatric<br>☐ Specialty compounding<br>☐ Methadone<br>○ PPP-66<br>○ CSPBC<br>○ CAMH<br>○ Monograph<br>**OR N/A** | ***PODSA Bylaws* s.3(2)(w)**<br>The manager must ensure the pharmacy contains the reference material and equipment approved by the board from time to time.<br>***PPP-3* Electronic Database References**<br>Electronic database references are acceptable for any of the authorized choices within any of the required categories, provided that they are as comprehensive as the printed version and meet the same updating requirements.<br>***PPP-3* Page 2**<br>In addition to the above list, pharmacies must be equipped with references relevant to their practices (e.g. Veterinary, Psychiatric, Geriatric).<br>***PPP-66* Required References**<br>In addition to the currently required pharmacy reference materials (PPP-3), pharmacies providing methadone maintenance treatment services must also maintain as required references the following:<br>(1) CPBC Methadone Maintenance Treatment Policy Guide (2013) and subsequent revisions,<br>(2) most recent version of the CPSBC Methadone and Buprenorphine: Clinical Practice Guideline for Opioid Use Disorder,<br>(3) most current edition of Opioid Agonist Maintenance Treatment: A Pharmacist's Guide to Methadone and Buprenorphine for Opioid Use Disorders, and<br>(4) product monographs for the commercially available 10mg/ml methadone oral preparations. | | | VET<br>PSY<br>GER<br>CMP<br>MET1<br>MET2<br>MET3<br>MET4 |

# Prescription

| # | Item | Reference and Requirements | Compliant | Comment | CPBC Use |
|---|---|---|---|---|---|
| 5a | **Prescription hardcopy (i.e. the label/paper attached to the original prescription, which contains prescription information generated after transmitting to PharmaNet)** | ***HPA Bylaws Schedule F Part 1 s.6(4)(a) to (f)***<br>At the time of dispensing, a prescription must include the following additional information:<br>(a) the address of the patient;<br>(b) the identification number from the practitioner's regulatory college;<br>(c) the prescription number;<br>(d) the date on which the prescription was dispensed;<br>(e) the manufacturer's drug identification number or the brand name of the product dispensed;<br>(f) the quantity dispensed.<br>***PODSA Bylaws* s.16.1(4)**<br>Prescriptions and labels relating to prescriptions dispensed at a telepharmacy must identify the prescription as having been dispensed at that telepharmacy.<br>***PODSA Bylaws* s.16.1(4.1)**<br>Prescriptions and labels relating to prescriptions dispensed at a pharmacy listed in Schedule F must distinguish between those dispensed when it is operating as a telepharmacy from when it is operating as a community pharmacy. | | | A<br>B<br>C<br>D<br>E<br>F<br>TPY |
| 5b | **Prescription stamp** | ***HPA Bylaws Schedule F Part 6 s.5(2)***<br>An original physical prescription may be submitted to a telepharmacy and, upon receipt, must be stamped with the date of receipt and the name of the telepharmacy. | | | |



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# Confidentiality

| # | Item | Reference and Requirements | Compliant | Comment | CPBC Use |
|---|---|---|---|---|---|
| 6a | ☐ **Shredder**<br>**OR**<br>☐ **Contract with a document destruction company** | ***HPA Bylaws* s.75**<br>A registrant must ensure that records referred to in section 74 are disposed of only by (a) transferring the record to another registrant, or (b) effectively destroying a physical record by utilizing a shredder or by complete burning, or by (c) erasing information recorded or stored by electronic methods on tapes, disks or cassettes in a manner that ensures that the information cannot be reconstructed.<br>***HPA Bylaws* s.78**<br>A registrant must ensure that, if personal information about patients is transferred to any person or service organization for processing, storage or disposal, a contract is made with that person which includes an undertaking by the recipient that confidentiality and physical security will be maintained. | | | |
| 6b | **Offsite storage contract**<br>**OR N/A** | ***HPA Bylaws* s.74(b)**<br>A registrant must ensure that all records pertaining to his or her practice, and containing personal information about patients are safely and securely stored off site. | | | |

# Inventory Management

| # | Item | Reference and Requirements | Compliant | Comment | CPBC Use |
|---|---|---|---|---|---|
| 7a | **Drug receiving area** | ***PODSA Bylaws* s.5(3)**<br>All drug shipments must be delivered unopened to the pharmacy or a secure storage area. | | | |
| 7b | **Drugs** | ***PODSA Bylaws* s.11(2)(f)**<br>The dispensary area of a community pharmacy must contain an adequate stock of drugs to provide full dispensing services. | | | |
| 7c | **Storage area for non-usable and expired drugs** | ***PODSA Bylaws* s.5(4)**<br>Non-usable and expired drugs must be stored in a separate area of the pharmacy or a secure storage area until final disposal. | | | |

# Dispensed Products

| # | Item | Reference and Requirements | Compliant | Comment | CPBC Use |
|---|---|---|---|---|---|
| 8a | **Prescription product label**<br>**1. Single-entity product**<br>**2. Multiple-entity product** | ***HPA Bylaws Schedule F Part 1* s.9(2)**<br>The label for all prescription drugs must include<br>(a) the name, address and telephone number of the pharmacy,<br>(b) the prescription number and dispensing date,<br>(c) the full name of the patient,<br>(d) the name of the practitioner,<br>(e) the quantity and strength of the drug,<br>(f) the practitioner's directions for use, and<br>(g) any other information required by good pharmacy practice.<br>***HPA Bylaws Schedule F Part 1* s.9(3)**<br>For a single-entity product, the label must include<br>(a) the generic name, and<br>(b) at least one of | | | A<br>B<br>C<br>D<br>E<br>F<br>G |



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| # | Item | Reference and Requirements | Compliant | Comment | CPBC Use |
|---|---|---|---|---|---|
| | | (i) the brand name,<br>(ii) the manufacturer's name, or<br>(iii) the drug identification number (DIN).<br>***HPA Bylaws Schedule F Part 1* s.9(4)**<br>For a multiple-entity product, the label must include<br>(a) the brand name, or<br>(b) all active ingredients and at least one of<br>(i) the manufacturer's name or<br>(ii) the drug identification number (DIN).<br>***PODSA Bylaws* s.16.1(4)**<br>Prescriptions and labels relating to prescriptions dispensed at a telepharmacy must identify the prescription as having been dispensed at that telepharmacy.<br>***PODSA Bylaws* s.16.1(4.1)**<br>Prescriptions and labels relating to prescriptions dispensed at a pharmacy listed in Schedule F must distinguish between those dispensed when it is operating as a telepharmacy from when it is operating as a community pharmacy. | | | A<br>B<br>---<br>A<br>B |
| **8b** | **Filling supplies (e.g. vials and bottles including caps)** | ***HPA Bylaws Schedule F Part 1* s.10(4)**<br>All drugs must be dispensed in a container that is certified as child-resistant unless…. | | | |

# Pharmacy Manager's Responsibilities

| # | Item | Reference and Requirements | Compliant | Comment | CPBC Use |
|---|---|---|---|---|---|
| **9a** | **Name badge** | ***PODSA Bylaws* s.3(2)(m)**<br>A manager must ensure that each individual working in the pharmacy wears a badge that clearly identifies the individual's registrant class or other status. | | | |
| **9b** | **Policy & procedure manual** | ***PODSA Bylaws* s.3(2)(g)**<br>A manager must establish policies and procedures to specify the duties to be performed by registrants and pharmacy assistants.<br>***PODSA Bylaws* s.3(2)(h)**<br>A manager must establish procedures for (i) inventory management, (ii) product selection, and (iii) proper destruction of unusable drugs and devices.<br>***PODSA Bylaws* s.3(2)(k)**<br>A manager must ensure there is a written drug recall procedure in place for pharmacy Inventory.<br>***PODSA Bylaws* s.3(2)(q)**<br>A manager must establish and maintain policies and procedures respecting pharmacy security.<br>***PPP-74 Policy Statement #1***<br>Pharmacy security policies and procedures should be included in the pharmacy's policy and procedure document. The policies and procedures should contain information on the following:<br>• Training,<br>• Pharmacy security equipment,<br>• Emergency responses,<br>• Incident review, and<br>• Pharmacy security evaluation<br>***PPP-74 Policy Statement #5***<br>An emergency response kit should include a step-by-step guide on what to do in the event of a robbery or break and enter and be available to all pharmacy staff. | | | R/PA<br>INV<br>SEL<br>DES<br>R/C<br>SEC |



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| # | Item | Reference and Requirements | Compliant | Comment | CPBC Use |
|---|---|---|---|---|---|
| | | ***PODSA Bylaws* s.10(1)(c)**<br>A community pharmacy's manager must develop, document and implement an ongoing quality management program that includes a process for reporting, documenting and following up on known, alleged and suspected errors, incidents and discrepancies.<br>***HPA Bylaws* s.79**<br>A registrant must take appropriate measures to remedy any unauthorized access, use, disclosure or disposal of personal information about patients under this Part as soon as possible after the breach is discovered.<br>***PODSA Bylaws* s.16.1(8)**<br>A telepharmacy must have a policy and procedure manual on site that that outlines the methods for ensuring the safe and effective distribution of pharmacy products and delivery of pharmaceutical care by the telepharmacy. | | | QMP<br>BRE<br>TPY |

# Central Pharmacy

| # | Item | Reference and Requirements | Compliant | Details (Mandatory field) | CPBC Use |
|---|---|---|---|---|---|
| **10a** | **Tool/technology enabling direct supervision on dispensary activities** | ***PODSA Bylaws* s.16.1(1)(a)**<br>A telepharmacy must not remain open and prescriptions must not be dispensed unless a full pharmacist at the central pharmacy is engaged in direct supervision of the telepharmacy in accordance with the *Telepharmacy Standards of Practice*.<br>***PODSA Bylaws Definitions***<br>"direct supervision" means real-time audio and visual observation by a full pharmacist of pharmacy services performed at a telepharmacy consistent with a pharmacy manager's responsibilities as set out in subsection 3(2).<br>***HPA Bylaws Schedule F Part 6* s.3**<br>"supervising pharmacist" means the manager of a central pharmacy or a full pharmacist employed at the central pharmacy responsible for providing direct supervision of pharmacy services in a telepharmacy or, where a full pharmacist is physically present on duty at the telepharmacy, that full pharmacist<br>***HPA Bylaws Schedule F Part 6* s.4(3)**<br>A supervising pharmacist must be able to engage in direct supervision of the provision of pharmacy services at a telepharmacy independent of any action of or request by persons performing those services. | | **Name of tool/technology:**<br>**Describe in details how compliance is met:** | |
| **10b** | **Tool/technology used for transmitting prescription and personal health information between sites** | ***HPA Bylaws Schedule F Part 6* s.6(2)**<br>Each telepharmacy and central pharmacy must maintain a secure connection to the central pharmacy for transmission of prescription and personal health information. | | **Name of tool/technology:**<br>**Describe in details how compliance is met:** | |



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| # | Item | Reference and Requirements | Compliant | Details (Mandatory field) | CPBC Use |
|---|---|---|---|---|---|
| 10c | **Tool/technology used for processing prescriptions at the central pharmacy for prescriptions received at the telepharmacy** | ***PODSA Bylaws* s.16.1(10)**<br>A telepharmacy must connect to PharmaNet independently of the central pharmacy with which it is associated.<br>***HPA Bylaws Schedule F Part 6* s.6(1)**<br>All prescription processing must occur at the central pharmacy unless a full pharmacist is physically present on duty at the telepharmacy. | | **Name of tool/technology:**<br>**Describe in details how compliance is met:** | |
| 10d | **Tool/technology enabling direct supervision on product final check** | ***PODSA Bylaws* s.16.1(1)(a)**<br>A telepharmacy must not remain open and prescriptions must not be dispensed unless a full pharmacist at the central pharmacy is engaged in direct supervision of the telepharmacy in accordance with the *Telepharmacy Standards of Practice*.<br>***HPA Bylaws Schedule F Part 6* s.3**<br>"supervising pharmacist" means the manager of a central pharmacy or a full pharmacist employed at the central pharmacy responsible for providing direct supervision of pharmacy services in a telepharmacy or, where a full pharmacist is physically present on duty at the telepharmacy, that full pharmacist<br>***HPA Bylaws Schedule F Part 6* s.4(2)(a)**<br>A supervising pharmacist must be readily available at all times when a telepharmacy is open to provide direction and support to persons performing pharmacy services at the telepharmacy.<br>***HPA Bylaws Schedule F Part 6* s.4(4)**<br>A telepharmacy may only provide pharmacy services within the exclusive scope of practice of a registrant while under direct, continuous real-time audio and visual observation and direction of a supervising pharmacist.<br>***HPA Bylaws Schedule F Part 6* s.4(5)**<br>Direct supervision does not require the supervising pharmacist to conduct real-time observation of a pharmacy technician performing work within his or her scope of practice. | | **Name of tool/technology:**<br>**Describe in details how compliance is met:** | |
| 10d | **Tool/technology enabling direct pharmacist/patient consultation** | ***HPA Bylaws Schedule F Part 6* s.3**<br>"supervising pharmacist" means the manager of a central pharmacy or a full pharmacist employed at the central pharmacy responsible for providing direct supervision of pharmacy services in a telepharmacy or, where a full pharmacist is physically present on duty at the telepharmacy, that full pharmacist<br>***HPA Bylaws Schedule F Part 6* s.4(2)(b)**<br>A supervising pharmacist must be readily available at all times when a telepharmacy is open to provide pharmacist/patient consultation.<br>***HPA Bylaws Schedule F Part 6* s.7**<br>The supervising pharmacist must provide full pharmacist/patient consultation by real-time audio and visual link and otherwise in accordance with the requirements of Part 1 of Schedule F of the Health Professions Act Bylaws. | | **Name of tool/technology:**<br>**Describe in details how compliance is met:** | |
| 10e | **Policy and procedure manual** | ***PODSA Bylaws* s.10(2)**<br>If a community pharmacy is a central pharmacy, the quality management program in subsection (1) must include all telepharmacies associated with the central pharmacy and must comply with the *Telepharmacy Standards of Practice.* | | | |



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| 7. INFORMATION OF THE PERSON WHO COMPLETED THE PRE-OPENING INSPECTION | | |
|---|---|---|
| **Last Name** | **First Name** | **Pre-Opening Inspection Completion Date** |
| **Relationship of the person named above to the telepharmacy:** ☐ Pharmacy Manager ☐ Owner (Registrant) ☐ Owner (Non-Registrant) ☐ College Inspector | | |
| **Email address of the person named above** | **Phone number of the person named above** | **Fax number of the person named above** |
| ☐ I hereby declare that the information provided above including the accompanying digital evidence is true and correct to the best of my knowledge. If any of the above information is found to be false, untrue, misleading or misrepresenting, I am aware that I may be referred to the Inquiry Committee and the pharmacy licence may not be issued. | | |
| **Signature** | | **Date** MMM \| DD \| YYYY |

The College collects the personal information on this application form to process the application and administer the College's related activities. The collection is authorized by the *Pharmacy Operations and Drug Scheduling Act*, *Health Professions Act*, and *Freedom of Information and Protection of Privacy Act*. Should you have any questions about the collection, please contact the College's Privacy Officer at 604-733-2440 or 1-800-663-1940 or privacy@bcpharmacists.org



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College of Pharmacists of British Columbia

# APPLICATION FOR TELEPHARMACY LICENCE RENEWAL

Community

**Form 12**



## 1. TELEPHARMACY INFORMATION

| | | | |
|---|---|---|---|
| **Operating Name** | | **PharmaCare Code** | |
| **Telepharmacy Address** | **City** | **Province** BC | **Postal Code** |
| **Email Address** | **Phone Number** | **Fax Number** | |
| **Website** | | **Software Vendor (for dispensing)** | |
| **Pharmacy Technician Name** | | **Registration Number (BC)** | |
| **OWNER'S INFORMATION** | | | |
| **Name of Company on Notice of Articles/BC Company Summary** | | **BC Incorporation Number** | |
| **NEXT CLOSEST COMMUNITY PHARMACY/TELEPHARMACY** | | | |
| **Pharmacy/Telepharmacy Name** | | **City** | |
| **Approximate Distance from Proposed Telepharmacy Location (KM):** | | | |

## 2. CENTRAL PHARMACY INFORMATION

| | | | |
|---|---|---|---|
| **Operating Name** | | **PharmaCare Code** | |
| **Pharmacy Address** | **City** | **Province** BC | **Postal Code** |
| **Email Address** | **Phone Number** | **Fax Number** | |
| **Manager Name** | | **Registration Number (BC)** | |
| **OWNER'S INFORMATION** | | | |
| **Name of Company on Notice of Articles/BC Company Summary** | | **BC Incorporation Number** | |

## 3. APPLICANT INFORMATION

| | |
|---|---|
| **Name of Authorized Representative** | **Position/Title of Authorized Representative** |
| **Signature** | **Date** MMM \| DD \| YYYY |

The College collects the personal information on this application form to process the application and administer the College's related activities. The collection is authorized by the *Pharmacy Operations and Drug Scheduling Act*, *Health Professions Act*, and *Freedom of Information and Protection of Privacy Act*. Should you have any questions about the collection, please contact the College's Privacy Officer at 604-733-2440 or 1-800-663-1940 or privacy@bcpharmacists.org

College of Pharmacists of British Columbia

# APPLICATION FOR TELEPHARMACY LICENCE RENEWAL

Community

**Form 12**



## 4. PAYMENT INFORMATION

| **Telepharmacy (Remote Site) Operating Name** (Auto-populate) | **Central Pharmacy Operating Name** (Auto-populate) |
|---|---|

**Method of Payment:** ☐ Cheque/Money order *(payable to College of Pharmacists of BC)* ☐ VISA ☐ MasterCard

| **Card Number** | **Expiry Date (MM/YY)** |
|---|---|
| **Cardholder Name** | |
| **Cardholder Signature** | |

| | |
|---|---|
| Licence fee | $ 2250.00 |
| GST | $ 112.50 |
| **Total** | **$ 2362.50** |
| GST # | R106953920 |

**For office use ONLY**

iMIS ID: Finance stamp:

Lic initials:

Date to Finance:

College of Pharmacists of British Columbia

# 5. Scope of PODSA Modernization – Phase 1

Presented by:

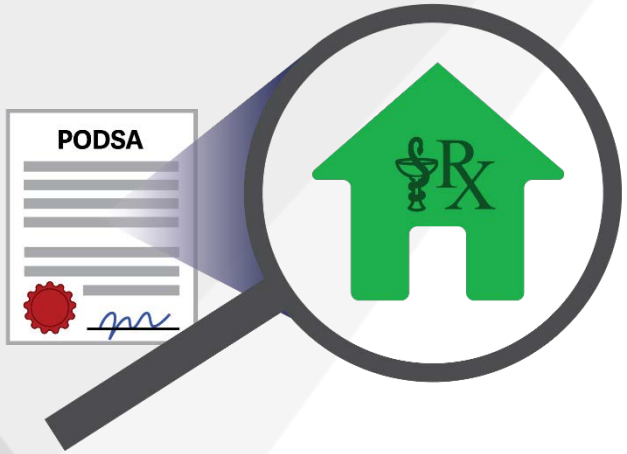
**Doreen Leong**

Director, Registration, Licensure & PharmaNet

College of Pharmacists of British Columbia

# New Pharmacy Ownership Requirements

Province of BC approved amendments to the *Pharmacy Operations and Drug Scheduling Act* in May 2016




Amendments require College to:

- know identity of all pharmacy owners
- determine suitability for pharmacy ownership based on provincial eligibility requirements
- hold owners and managers accountable for ensuring pharmacies are compliant with legislative requirements (PODSA & HPA)

New requirements come into effect March 1, 2018

College of Pharmacists of British Columbia

# What's happening to prepare?

- Assessing how to operationalize new requirements, incorporating into pharmacy licensing process
- Drafting PODSA bylaw amendments to reflect new provincial pharmacy ownership requirements
- Developing new PODSA forms, business processes, IT processes
- Engaging with stakeholders to inform bylaws and licence processes
- Developing resources and information to support the transition

College of Pharmacists of British Columbia

# What are the Amendments to the *Act* ?

## Summary of Bill 6 Explanatory Notes

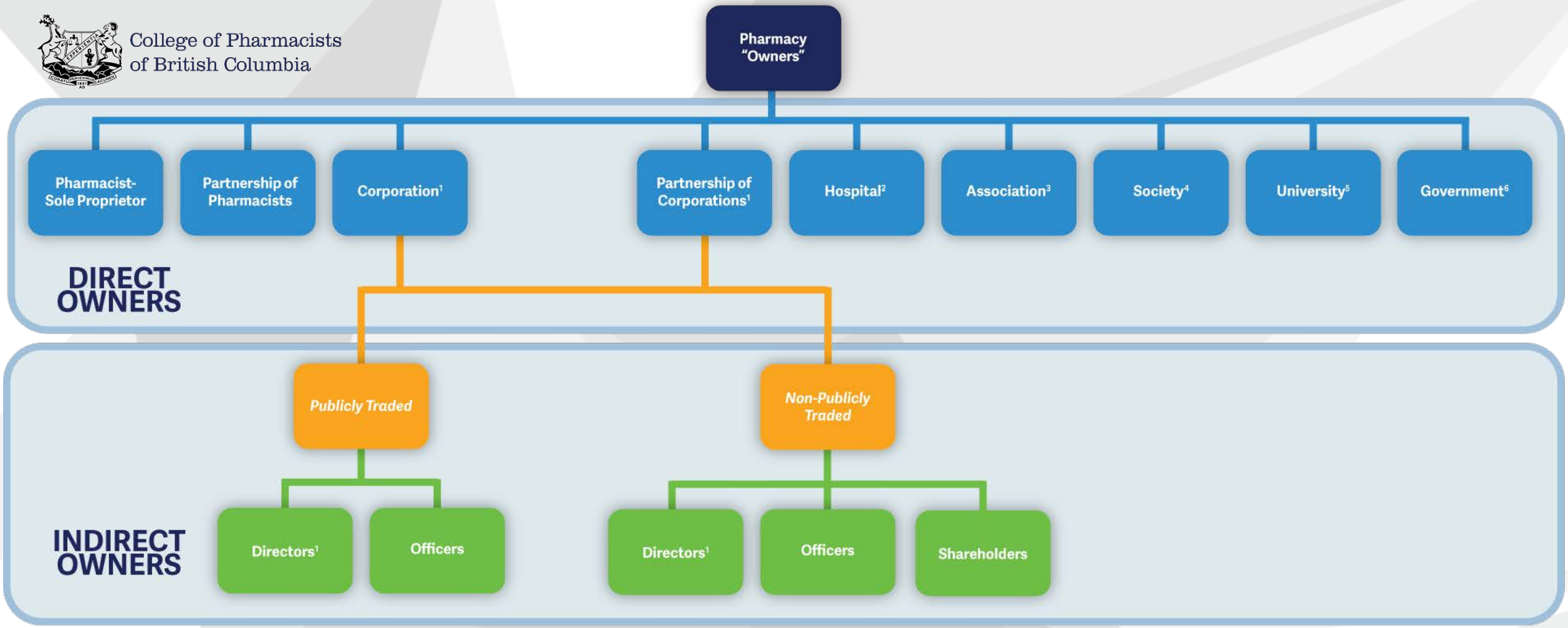
- Distinguishes between "direct owners" and "indirect owners"
- Broadens the meaning of "pharmacy" and "pharmacy licence"
- Harmonizes requirements and processes for issuing, renewing and reinstating a pharmacy licence
- Sets eligibility requirements to hold a pharmacy licence
- Establishes a new Application Committee to review licence applications that do not meet the requirements of the Act and bylaws
- Clarifies that ownership of a pharmacy must be direct
- Adds requirements for direct owners, indirect owners and managers to provide Criminal Record History
- Requires direct owners, indirect owners and managers to comply with duties under *Pharmacy Operations and Drug Scheduling Act* and *Health Professions Act*
- Requires direct owners, indirect owners and managers to give notice to the Registrar if certain events occur
- Applications received before the amendments come into force for pharmacy licences on or after March 1, 2018 will need to meet the new requirements

College of Pharmacists of British Columbia

# Types of Pharmacy Ownership

- Types of pharmacy ownership allowed in BC are set in the amendments to the *Act*
- *Act* distinguishes between direct owners and indirect owners
- Information required for pharmacy licensure depends on a pharmacy's ownership type
- Majority of pharmacies are owned by corporations (or partnerships of corporations)
- Important for owners to be able to determine ownership type to ensure they meet requirements for opening a new pharmacy or renewing a pharmacy licence

College of Pharmacists of British Columbia




1 incorporated under the *Company Act* or the *Business Corporations Act* in which the majority of the directors in the corporation are pharmacists
2 as defined in the *Hospital Act* (including health authorities)
3 incorporated under the *Cooperative Association Act*
4 defined in the *Societies Act*
5 defined in the *University Act* or Thompson Rivers University
6 the City of Vancouver or a municipality, or the government

College of Pharmacists of British Columbia

# Roles and Responsibilities of Direct Owners, Indirect Owners and Managers

- Direct owners, indirect owners and managers must comply with duties under the *Pharmacy Operations and Drug Scheduling Act* and *Health Professions Ac*t and the College's bylaws under these acts
- Direct owners, indirect owners and managers are all responsible for ensuring their pharmacies are compliant with legislative requirements
- Non-registrant direct and indirect owners will also be subject to inquiry and discipline
- Managers will continue to actively participate in the day-to-day management of the pharmacy

College of Pharmacists of British Columbia

# Eligibility Criteria

- New pharmacy ownership requirements set by the Province of BC establish clear eligibility criteria to hold a pharmacy licence
- Owners and managers need to meet the eligibility criteria in the *Act*, in addition to requirements in the College's bylaws
- Allows the College to better protect the public by determining the suitability of an owner or manager based on eligibility criteria

College of Pharmacists of British Columbia

# Who would be ineligible?

**Direct owners, indirect owners and managers would be ineligible if any of the following apply:**

- subject to a limitation imposed by the discipline committee that precludes them from being an owner or manager
- has been subject to an information or billing contravention
- within the previous 6 years, had a judgment entered against him or her in a court proceeding related to commercial or business activities that occurred in relation to the provision of drugs or devices, or substances or related services within the meaning of the *Pharmaceutical Services Act*
- within the previous 6 years, has had their registration as a pharmacist suspended or cancelled or has had limits or conditions imposed on their practice of pharmacy
- within the previous 6 years, has been convicted of an offence under the Criminal Code
- within the previous 6 years, has been convicted of an offence prescribed under the *Pharmaceutical Services Act*

College of Pharmacists of British Columbia

# Application Committee

**Where an application for a pharmacy licence does not meet the eligibility criteria in the *Act* and the requirements in the bylaws, the Registrar must refer the application to the Application Committee.**

**Application Committee can:**

- request additional information or evidence from the direct owner, indirect owner and proposed manager
- issue, renew or reinstate the pharmacy licence
- issue, renew or reinstate the pharmacy licence with conditions
- refuse to issue, renew, or reinstate the pharmacy licence

College of Pharmacists of British Columbia

# Criminal Record History

- Criminal Record History required under PODSA
  is different from Criminal Record Check (under HPA) that is required for registrants
- PODSA requires a more comprehensive criminal
  record history be provided
  - Criminal Records Review Program only provides confirmation of a check done for a registrant under the *Criminal Records Review Act*
  - Does not meet new PODSA requirements, and does not allow for Criminal Record History of non-registrants

every 5 years for direct owners, indirect owners and managers

- Pharmacists who are owners (direct or indirect) or managers will need to provide a Criminal Record History for pharmacy licence (PODSA requirements) AND undergo a Criminal Record Check for Pharmacist Registration (HPA requirements)
- College will use a vendor that will meet the new requirements while supporting a timely and efficient process
  for obtaining a Criminal Record History

College of Pharmacists of British Columbia

# Pharmacy Licensing Process

- New pharmacy licensing requirements come into effect March 1, 2018
- Direct  owners, indirect owners and managers are required to meet new eligibility requirements and College bylaws once changes come into effect
- Direct owner must apply for a new pharmacy licence or renewal
- Responsibility of renewing a pharmacy licence shifts from manager to the direct owner

College of Pharmacists of British Columbia

# Transition Period (March 2018 - February 2019)

- To bring all pharmacies into compliance with new requirements, pharmacies will initially need to submit the information necessary to demonstrate they meet the new eligibility criteria
- Type of pharmacy ownership will determine what information is required as part of pharmacy licence renewal process
- Transition process will be established to bring all pharmacies into compliance with the new requirements through the annual pharmacy licence renewal
- Criminal Record History will be required for direct owners, indirect owners and managers

College of Pharmacists of British Columbia

# Renewals (March 1, 2019 onwards)

- Following transition period, process for pharmacy licence renewals will be streamlined
- Information provided previously through transition period will be available to review
- Direct owners, indirect owners and managers will only be required to review and update pharmacy ownership information and attest to meeting the eligibility requirements
- Every 5 years direct owners, indirect owners and managers are required to provide new Criminal Record History

College of Pharmacists of British Columbia

# *What information is required for Pharmacy Licence Renewal?*

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of British Col

## RENEWAL TRANSITION

**March 2018 - February 2019**

1) Application for pharmacy licence renewal
2) Licence fee
3) Proof of eligibility from pharmacy manager
4) Criminal record history from pharmacy manager
5) Business licence (if applicable)

## RENEWAL POST TRANSITION

1) Application for pharmacy licence renewal
2) Licence fee
3) Attestation of eligibility by pharmacy manager
4) Criminal record history from pharmacy manager every 5 years
5) Business licence (if applicable)

**PHARMACIS**
**SOLE PROPRE**
(1 owner - must b
pharmacist)

y)

College of Pharmacists of British Columbia

# CORPORATION
(Majority of directors must be pharmacists)

## PHARMACIST - SOLE PROPREITOR
(1 owner - must be a pharmacist)

### RENEWAL TRANSITION
1) Proof of eligibility from sole proprietor ***(if not pharmacy manager)***
2) Criminal record history from sole proprietor ***(if not pharmacy manager)***

### RENEWAL POST TRANSITION
1) Attestation of eligibility by sole proprietor ***(if not pharmacy manager)***
2) Criminal record history from sole proprietor ***(if not pharmacy manager)*** every 5 years

## PARTNERSHIP OF PHARMACISTS
(more than 1 owner, all

### RENEWAL TRANSITION
1) Proof of
2) Crimina

## CORPORATION
(Majority of directors

### RENEWAL TRANSITION
**March 2018 - February 2019**
1) BC Company Summary
2) Proof of eligibility from each director and officer
3) Criminal record history from each director and officer
4) Power(s) of attorney (if applicable)

### RENEWAL POST TRANSITION
1) BC Company Summary
2) Attestation of eligibility by each director and officer
3) Criminal record history from each director and officer every 5 years

## HOSPITAL
(Health Authority)

College of Pharmaci
of British Columbia

# RENEWAL TRANSITION

**March 2018 - February 2019**

1) Securities (shareholders) register

2) Proof of eligibility by each shareholder

3) Criminal record history from each shareholder

# RENEWAL POST TRANSITION

1) Attestation of eligibility by each shareholder

2) Criminal record history from each shareholder every 5 years

College of Pharmac
of British Columbia

## RENEWAL TRANSITION

**March 2018 - February 2019**

1) Proof of eligibility by each director, officer, and shareholder of parent company

2) Criminal record history from each director, officer, and shareholder of parent company

## RENEWAL POST TRANSITION

1) Attestation of eligibility by each director, officer, and shareholder of parent company

2) Criminal record history from each director, officer, and shareholder of parent company every 5 years

years

College of Pharmacists of British Columbia

# New Pharmacy Applications

- All new pharmacy licence applications must be made by the direct owner and must meet the new requirements starting March 1, 2018
- Type of pharmacy ownership will determine what information is required as part of pharmacy licensing process
- Identity of all pharmacy owners (direct and indirect) and their Criminal Record History required
- All pharmacy managers also need to provide Criminal Record History
- Information will be used to determine suitability for pharmacy ownership based on eligibility criteria

College of Pharmacists of British Columbia

# *What information is required for New Pharmacy Licence Applications?*

College of Pharmacists of British Columbia

# NEW APPLICATION

1) Application for new pharmacy licence
2) Fee(s)
3) Diagram
4) Proof of eligibility from pharmacy manager
5) Criminal record history from pharmacy manager
6) Pre-opening report and photos
7) Business licence (if applicable)

**PHARMACIST - SOLE PROPREITOR**
(1 owner - must be a pharmacist)

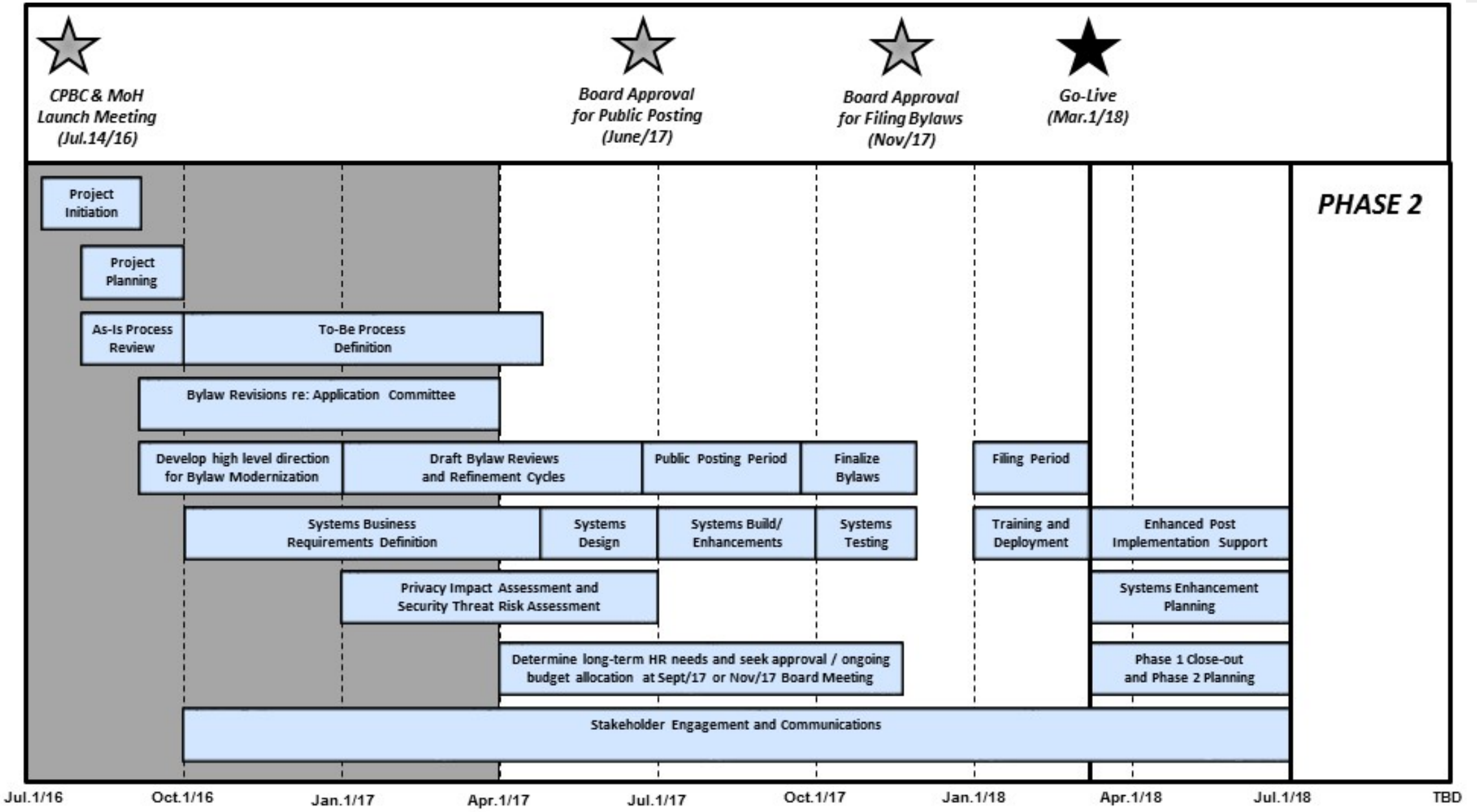
**HOSPITAL**
(Health Authority)

College of Pharmacists of British Columbia

# Summary of Changes

- All direct owners and indirect owners to be identified as part of pharmacy licensing process
- Direct owners must apply for a new pharmacy licence and for a pharmacy licence renewal
- Direct owners, indirect owners and managers must meet the eligibility criteria
- Criminal Record History required for all direct owners, indirect owners and managers
- Pharmacists who are owners and managers will need to provide both a Criminal Record History (PODSA) and undergo a Criminal Record Check (HPA)

# Overall Timeline (as of April 2017)



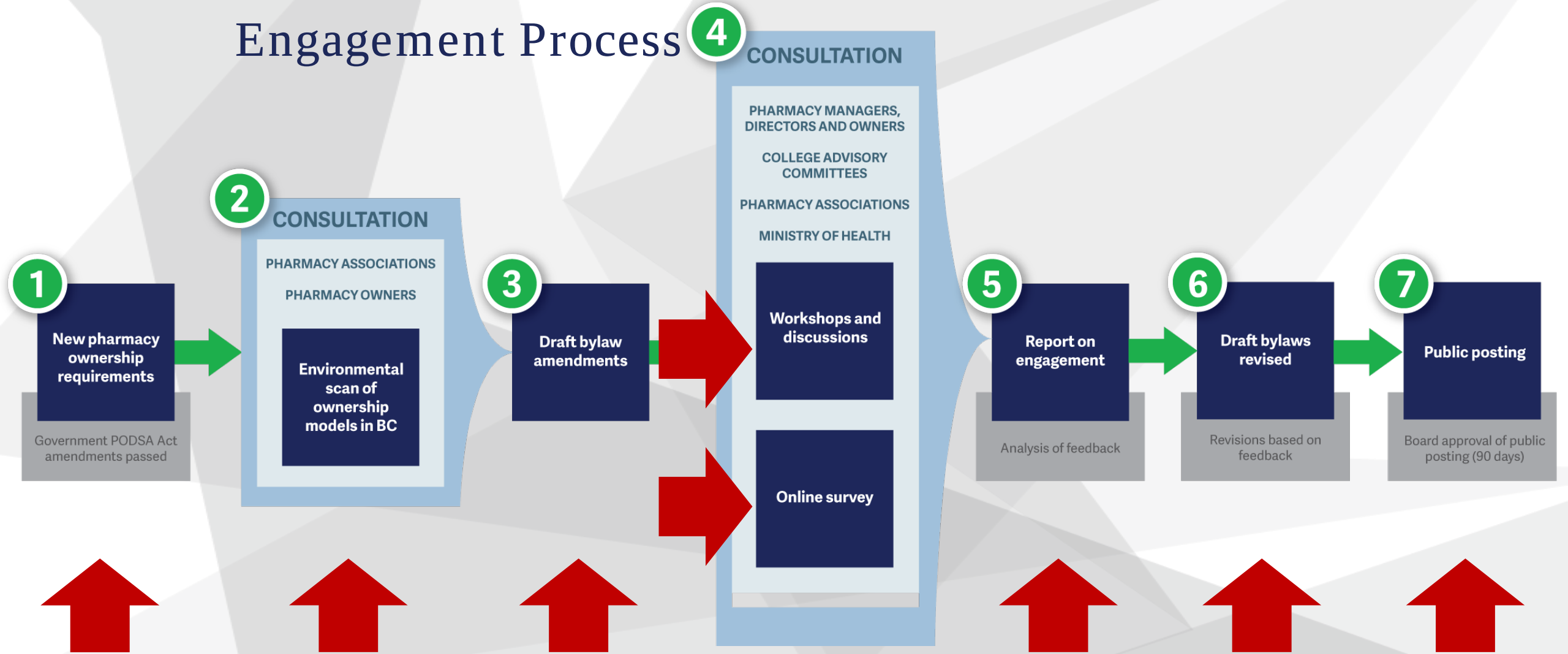
College of Pharmacists of British Columbia

# Project Status Updates

- **Overall scope, schedule and budget are currently on track**
- **Deliverables completed to date include:**
  - Project Charter and Plan
  - Engagement & Communications Strategies
  - As-Is Process Flows
  - Application Committee added to HPA Bylaws
  - Drafted PODSA Bylaws, Forms and Schedules

College of Pharmacists of British Columbia

# Engagement Process



College of Pharmacists of British Columbia

# Key Next Steps

- Refine draft Bylaws, Forms and Schedules following stakeholder engagement; seeking Board approval in June
- Complete To-Be Process Flows
- Complete Systems Requirements and engage consultants for development
- Complete Privacy Impact Assessment
- Review Information Sharing Agreement with Ministry of Health, if applicable
- Analyze long-term human resource needs
- Develop resources to support owners and pharmacy managers during and after the transition period

College of Pharmacists of British Columbia

# Questions

**ownership@bcpharmacists.org**

**BCPharmacists.org/ownership**

College of Pharmacists of British Columbia

# BOARD MEETING
# April 21, 2017

## 6. Governance Committee
## b) Committee Terms of Reference

## DECISIONS REQUIRED

### Recommended Board Motions:

1. *Approve the following amendment:*

**Term of appointment**

- Appointments are determined by the Board and will not exceed ~~2~~3 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.

*To the following committees' terms of reference:*

Audit and Finance
Community Pharmacy Advisory
Discipline
Ethics Advisory
Governance
Hospital Pharmacy Advisory
Inquiry
Jurisprudence Examination
Legislation Review
Practice Review
Quality Assurance
Registration
Residential Care Advisory

2. *Approve the following amendments to the Drug Administration Committee's terms of Reference:*

**Mandate**

To review, develop and recommend the standards, limits and conditions under which a registrant may administer a drug or substance to patients and to maintain patient safety and public protection with respect to authorized pharmacist's administration of injections or administration of drugs by intranasal route to patients.

**Term of appointment**

Pharmacist ~~A~~appointments are determined by the Board and will not exceed ~~2~~3 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.

## Background

The Governance Committee is recommending a minor change to the 'Term of Appointment' section of all committee terms of reference. The amendment increases the maximum allowable appointment from two years, to three years.

The Drug Administration Committee (DAC) terms of reference requires an additional change to align with what already exists in legislation. Previously, legislation was passed that expanded drug administration to include by intranasal route, however, the terms of reference was not updated to reflect that change.

| **Appendix** | |
|---|---|
| 1 | Committee Terms of Reference |

# AUDIT AND FINANCE COMMITTEE

## Background

The Board has established the Audit and Finance Committee (Committee).

## Authority

Health Professions Act, s. 19(1)(t); HPA Bylaws s. 19.

## Mandate

To provide recommendations to the Board relating to the annual audit and financial management of the College.

## Responsibilities

***Annual Audit***
***Planning, preparation and results***

- Provide oversight of the annual College audit.

***Financial oversight***

- Provide oversight of the financial management of the College.

## Reporting relationship

The committee as a whole reports through the chair to the Board. The committee must submit a report of its activities to the Board annually, or as required by the Board.

## Membership

- At least 3 but no more than 5 Board members appointed by the Board.
- Must include the Board chair, the Board vice-chair and a public representative.

## Term of appointment

- Appointments are determined by the Board and will not exceed 2 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.
- A member appointed to the committee ceases to be a member if they are no longer a Board member.
- Any committee member may resign upon written notification to the registrar. Committee members who are absent for more than three committee meetings per year automatically forfeit membership on the committee. The chair has the discretion to approve, in advance, an extended absence of any committee member.

## Committee officers

The chair and vice chair of the Audit and Finance Committee will be determined annually.

## Voting rights

Each committee member is entitled to one vote on all matters coming before the committee.

## Meeting procedures

| | |
|---|---|
| *Schedule:* | At least four times annually to address the tasks identified in the attached Schedule A. |
| *Format:* | In person, by teleconference or by videoconference. |
| *Agenda:* | Developed by College staff in consultation with the committee chair with input from committee members. |
| *Attendees:* | The Registrar and COO should attend. Other College staff and the external auditors will be invited as needed to participate in specific meetings. |
| *Quorum:* | At least 3 committee members. |
| *Minutes:* | Drafted by College staff for review and approval at the next committee meeting; filed at the College office. |
| *Secretariat Support:* | Provided by the College e.g. meeting coordination, preparation and distribution of materials. |

## Conflict of interest disclosure

Members must declare conflicts of interest at any time a conflict of interest or potential conflict of interest arises.

A conflict of interest refers to situations in which personal, occupational or financial considerations may affect or appear to affect the objectivity or fairness of decisions related to the committee activities. A conflict of interest may be real, potential or perceived in nature. Individuals must declare potential conflicts to the chair of the committee and must either absent themselves from the discussion and voting, or put the decision to the committee on whether they should absent themselves.

## Confidentiality

Each committee member must sign a confidentiality agreement at the time of each appointment indicating their agreement to maintain the confidentiality, security and integrity of all materials during and after their term on the committee.

## Amendment to terms of reference

The Board may amend the committee terms of reference at any time, and should formally review the terms of reference on an annual basis.

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- Any committee member may resign upon written notification to the registrar. Committee members who are absent for more than three committee meetings per year automatically forfeit membership on the committee. The chair has the discretion to approve, in advance, an extended absence of any committee member.

## Committee officers

The chair and vice chair of the Audit and Finance Committee will be determined annually.

## Voting rights

Each committee member is entitled to one vote on all matters coming before the committee.

## Meeting procedures

| | |
|---|---|
| *Schedule:* | At least four times annually to address the tasks identified in the attached Schedule A. |
| *Format:* | In person, by teleconference or by videoconference. |
| *Agenda:* | Developed by College staff in consultation with the committee chair with input from committee members. |
| *Attendees:* | The Registrar and COO should attend. Other College staff and the external auditors will be invited as needed to participate in specific meetings. |
| *Quorum:* | At least 3 committee members. |
| *Minutes:* | Drafted by College staff for review and approval at the next committee meeting; filed at the College office. |
| *Secretariat Support:* | Provided by the College e.g. meeting coordination, preparation and distribution of materials. |

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## Amendment to terms of reference

The Board may amend the committee terms of reference at any time, and should formally review the terms of reference on an annual basis.

# COMMUNITY PHARMACY ADVISORY COMMITTEE

## Background

The Board has established the Community Pharmacy Advisory Committee.

## Authority

Health Professions Act (HPA) s. 19(1)(t); HPA Bylaws s. 19.

## Mandate

To provide recommendations to the Board or the Registrar on matters relating to community pharmacy practice.

## Responsibilities

- To meet from time to time to review issues related to the practice of pharmacy that have been directed to the committee by the Board or the Registrar.
- Assist in the development of policies, procedures, guidelines and proposed legislation pertaining to community pharmacy practice and standards.
- Assist in the development of information materials for circulation to practicing registrants.
- Recommend appropriate action to the Board or the Registrar regarding community pharmacy practice issues.
- Work collaboratively with other College practice advisory committees to ensure a cohesive approach to common practice issues.

## Reporting relationship

The committee as a whole must submit a report of its activities through the chair to the Board annually or as required by the Board.

## Membership

- At least six full pharmacists or pharmacy technicians appointed by the Board who are practicing in community pharmacy (there must be representation from both groups of registrants).

## Term of appointment

- Appointments are determined by the Board and will not exceed 2 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.
- A registrant appointed to the committee ceases to be a member if they are no longer a full pharmacist or pharmacy technician in good standing or if they become a College employee.
- Any committee member may resign upon written notification to the chair. Committee members who are absent for more than three committee meetings per year automatically forfeit membership on the committee. The chair has the discretion to approve, in advance, an extended absence of any committee member.

## Committee officers

Board appoints a committee chair and vice-chair from among the members of the committee.

## Voting rights

Each committee member is entitled to one vote on all matters coming before the committee.

## Meeting procedures

| | |
|---|---|
| *Schedule:* | As required to fulfill its mandate and responsibilities. |
| *Format:* | In person, by teleconference or by videoconference. |
| *Agenda:* | Developed by College staff in consultation with the committee chair with input from committee members. |
| *Attendees:* | Only Community Pharmacy Advisory Committee members and College staff are entitled to attend committee meetings, with the exception of invited guests. |
| *Quorum:* | A majority of the committee. |
| *Minutes:* | Drafted by College staff for review and approval at next committee meeting; filed at the College office. |
| *Secretariat Support:* | Provided by the College, including meeting coordination, preparation and distribution of materials and drafting meeting minutes. |

## Conflict of interest disclosure

Members must declare conflicts of interest prior to the discussion of individual files or at any time a conflict of interest or potential conflict of interest arises.

A conflict of interest refers to situations in which personal, occupational or financial considerations may affect or appear to affect the objectivity or fairness of decisions related to the committee activities. A conflict of interest may be real, potential or perceived in nature. Individuals must declare potential conflicts to the chair of the committee and must either absent themselves from the discussion and voting, or put the decision to the committee on whether they should absent themselves.

## Confidentiality

Each committee member must sign a confidentiality agreement at the time of each appointment indicating their agreement to maintain the confidentiality, security and integrity of all materials during and after their term on the committee.

## Remuneration

Committee members may claim honoraria and expense reimbursement in accordance with the Board's policy and guidelines for claiming committee expenses.

## Amendment to terms of reference

The Board may amend committee terms of reference at any time and from time to time.

# COMMUNITY PHARMACY ADVISORY COMMITTEE

## Background

The Board has established the Community Pharmacy Advisory Committee.

## Authority

Health Professions Act (HPA) s. 19(1)(t); HPA Bylaws s. 19.

## Mandate

To provide recommendations to the Board or the Registrar on matters relating to community pharmacy practice.

## Responsibilities

- To meet from time to time to review issues related to the practice of pharmacy that have been directed to the committee by the Board or the Registrar.
- Assist in the development of policies, procedures, guidelines and proposed legislation pertaining to community pharmacy practice and standards.
- Assist in the development of information materials for circulation to practicing registrants.
- Recommend appropriate action to the Board or the Registrar regarding community pharmacy practice issues.
- Work collaboratively with other College practice advisory committees to ensure a cohesive approach to common practice issues.

## Reporting relationship

The committee as a whole must submit a report of its activities through the chair to the Board annually or as required by the Board.

## Membership

- At least six full pharmacists or pharmacy technicians appointed by the Board who are practicing in community pharmacy (there must be representation from both groups of registrants).

## Term of appointment

- Appointments are determined by the Board and will not exceed ~~2~~3 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.
- A registrant appointed to the committee ceases to be a member if they are no longer a full pharmacist or pharmacy technician in good standing or if they become a College employee.
- Any committee member may resign upon written notification to the chair. Committee members who are absent for more than three committee meetings per year automatically forfeit membership on the committee. The chair has the discretion to approve, in advance, an extended absence of any committee member.

## Committee officers

Board appoints a committee chair and vice-chair from among the members of the committee.

## Voting rights

Each committee member is entitled to one vote on all matters coming before the committee.

## Meeting procedures

| | |
|---|---|
| *Schedule:* | As required to fulfill its mandate and responsibilities. |
| *Format:* | In person, by teleconference or by videoconference. |
| *Agenda:* | Developed by College staff in consultation with the committee chair with input from committee members. |
| *Attendees:* | Only Community Pharmacy Advisory Committee members and College staff are entitled to attend committee meetings, with the exception of invited guests. |
| *Quorum:* | A majority of the committee. |
| *Minutes:* | Drafted by College staff for review and approval at next committee meeting; filed at the College office. |
| *Secretariat Support:* | Provided by the College, including meeting coordination, preparation and distribution of materials and drafting meeting minutes. |

## Conflict of interest disclosure

Members must declare conflicts of interest prior to the discussion of individual files or at any time a conflict of interest or potential conflict of interest arises.

A conflict of interest refers to situations in which personal, occupational or financial considerations may affect or appear to affect the objectivity or fairness of decisions related to the committee activities. A conflict of interest may be real, potential or perceived in nature. Individuals must declare potential conflicts to the chair of the committee and must either absent themselves from the discussion and voting, or put the decision to the committee on whether they should absent themselves.

## Confidentiality

Each committee member must sign a confidentiality agreement at the time of each appointment indicating their agreement to maintain the confidentiality, security and integrity of all materials during and after their term on the committee.

## Remuneration

Committee members may claim honoraria and expense reimbursement in accordance with the Board's policy and guidelines for claiming committee expenses.

## Amendment to terms of reference

The Board may amend committee terms of reference at any time and from time to time.

# DRUG ADMINISTRATION COMMITTEE

## Background

The Board is required to establish a Drug Administration Committee.

## Authority

Health Professions Act (HPA) s. 19(1)(t); HPA Bylaws sections 18 and 19; HPA Pharmacists Regulation.

## Mandate

To review, develop and recommend the standards, limits and conditions under which a registrant may administer a drug or substance to patients and to maintain patient safety and public protection with respect to authorized pharmacist's administration of injections to patients.

## Responsibilities

- Must review, develop and recommend to the Board standards, limits and conditions respecting the performance by practising pharmacists of restricted activities under section 4(1) (c.1) of the Pharmacists Regulation for the purposes of preventing diseases, disorders and conditions.

- May review the role of practising pharmacists in regard to the performance of restricted activities under section 4(1) (c.1) of the Pharmacists Regulation.

- May make recommendations to the Board, for submission to the Ministry of Health Services, respecting the standards, limits and conditions for practice and any other requirements it considers necessary or appropriate to support the performance by practising pharmacists of restricted activities under section 4(1) (c.1) of the Pharmacists Regulation for the purposes of treating diseases, disorders and conditions.

- May consult, as it considers necessary or appropriate, with registrants or other individuals who have expertise relevant to drug administration by injection or on any other matter considered by the committee.

## Reporting relationship

The committee as a whole reports through the chair to the Board. The committee must submit a report of its activities to the Board annually, or as required by the Board.

## Membership

- At least 4 and no more than 7 persons appointed by the Board.

- Must include, one full pharmacist, one medical practitioner confirmed by the College of Physicians and Surgeons of British Columbia as suitable for membership on the committee, one registered nurse confirmed by the College of Registered Nurses of British Columbia as suitable for membership on the committee, and one person nominated by the Ministry of Health Services.

## Term of appointment

Appointments are determined by the Board and will not exceed 2 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.

A registrant appointed to the committee ceases to be a member if they are no longer a full pharmacist or pharmacy technician in good standing or if they become a College employee.

Any committee member may resign upon written notification to the registrar. Committee members who are absent for more than three committee meetings per year automatically forfeit membership on the committee. The chair has the discretion to approve, in advance, an extended absence of any committee member

## Committee officers

Board appoints a committee chair and vice-chair from among the members of the committee.

## Voting rights

Each member, including each public representative, is entitled to one vote on all matters coming before the committee.

## Meeting procedures

| | |
|---|---|
| *Schedule:* | As required to fulfill mandate and responsibilities; to be determined at first meeting. |
| *Format:* | In person, by teleconference or by videoconference. |
| *Agenda:* | Developed by College staff in consultation with the committee chair with input from committee members. |
| *Attendees:* | Only Injection Drug Administration Committee members and College staff are entitled to attend committee meetings, unless specifically invited by the committee as a guest. |
| *Quorum:* | A majority of the committee. |
| *Minutes:* | Drafted by College staff for review and approval at next committee meeting; filed at the College office. |
| *Secretariat Support:* | Provided by the College, including meeting coordination, preparation and distribution of materials and drafting meeting minutes. |

## Conflict of interest disclosure

Members must declare conflicts of interest prior to the discussion of individual files or at any time a conflict of interest or potential conflict of interest arises.

A conflict of interest refers to situations in which personal, occupational or financial considerations may affect or appear to affect the objectivity or fairness of decisions related to the committee activities. A conflict of interest may be real, potential or perceived in nature. Individuals must declare potential conflicts to the chair of the committee and must either absent themselves from the discussion and voting, or put the decision to the committee on whether they should absent themselves.

## Confidentiality

Members must declare conflicts of interest at any time a conflict of interest or potential conflict of interest arises.

Each committee member must sign a confidentiality agreement at the time of each appointment indicating their agreement to maintain the confidentiality, security and integrity of all materials during and after their term on the committee.

## Remuneration

Committee members may claim honoraria and expense reimbursement in accordance with the Board's policy and guidelines for claiming committee expenses.

## Amendment to terms of reference

The Board may amend committee terms of reference at any time and from time to time.

# DRUG ADMINISTRATION COMMITTEE

## Background

The Board is required to establish a Drug Administration Committee.

## Authority

Health Professions Act (HPA) s. 19(1)(t); HPA Bylaws sections 18 and 19; HPA Pharmacists Regulation.

## Mandate

To review, develop and recommend the standards, limits and conditions under which a registrant may administer a drug or substance to patients and to maintain patient safety and public protection with respect to authorized pharmacist's administration of injections or administration of drugs by intranasal route to patients.

## Responsibilities

- Must review, develop and recommend to the Board standards, limits and conditions respecting the performance by practising pharmacists of restricted activities under section 4(1) (c.1) of the Pharmacists Regulation for the purposes of preventing diseases, disorders and conditions.
- May review the role of practising pharmacists in regard to the performance of restricted activities under section 4(1) (c.1) of the Pharmacists Regulation.
- May make recommendations to the Board, for submission to the Ministry of Health Services, respecting the standards, limits and conditions for practice and any other requirements it considers necessary or appropriate to support the performance by practising pharmacists of restricted activities under section 4(1) (c.1) of the Pharmacists Regulation for the purposes of treating diseases, disorders and conditions.
- May consult, as it considers necessary or appropriate, with registrants or other individuals who have expertise relevant to drug administration by injection or on any other matter considered by the committee.

## Reporting relationship

The committee as a whole reports through the chair to the Board. The committee must submit a report of its activities to the Board annually, or as required by the Board.

## Membership

- At least 4 and no more than 7 persons appointed by the Board.
- Must include, one full pharmacist, one medical practitioner confirmed by the College of Physicians and Surgeons of British Columbia as suitable for membership on the committee, one registered nurse confirmed by the College of Registered Nurses of British Columbia as suitable for membership on the committee, and one person nominated by the Ministry of Health.

## Term of appointment

Pharmacist ~~A~~appointments are determined by the Board and will not exceed ~~2~~3 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.

A registrant appointed to the committee ceases to be a member if they are no longer a full pharmacist or pharmacy technician in good standing or if they become a College employee.

Any committee member may resign upon written notification to the registrar. Committee members who are absent for more than three committee meetings per year automatically forfeit membership on the committee. The chair has the discretion to approve, in advance, an extended absence of any committee member

## Committee officers

Board appoints a committee chair and vice-chair from among the members of the committee.

## Voting rights

Each member, including each public representative, is entitled to one vote on all matters coming before the committee.

## Meeting procedures

| | |
|---|---|
| *Schedule:* | As required to fulfill mandate and responsibilities; to be determined at first meeting. |
| *Format:* | In person, by teleconference or by videoconference. |
| *Agenda:* | Developed by College staff in consultation with the committee chair with input from committee members. |
| *Attendees:* | Only Injection Drug Administration Committee members and College staff are entitled to attend committee meetings, unless specifically invited by the committee as a guest. |
| *Quorum:* | A majority of the committee. |
| *Minutes:* | Drafted by College staff for review and approval at next committee meeting; filed at the College office. |
| *Secretariat Support:* | Provided by the College, including meeting coordination, preparation and distribution of materials and drafting meeting minutes. |

## Conflict of interest disclosure

Members must declare conflicts of interest prior to the discussion of individual files or at any time a conflict of interest or potential conflict of interest arises.

A conflict of interest refers to situations in which personal, occupational or financial considerations may affect or appear to affect the objectivity or fairness of decisions related to the committee activities. A conflict of interest may be real, potential or perceived in nature. Individuals must declare potential conflicts to the chair of the committee and must either absent themselves from the discussion and voting, or put the decision to the committee on whether they should absent themselves.

## Confidentiality

Members must declare conflicts of interest at any time a conflict of interest or potential conflict of interest arises.

Each committee member must sign a confidentiality agreement at the time of each appointment indicating their agreement to maintain the confidentiality, security and integrity of all materials during and after their term on the committee.

## Remuneration

Committee members may claim honoraria and expense reimbursement in accordance with the Board's policy and guidelines for claiming committee expenses.

## Amendment to terms of reference

The Board may amend committee terms of reference at any time and from time to time.

# DISCIPLINE COMMITTEE

## Background

The Board is required to establish a Discipline Committee.

## Authority

Health Professions Act (HPA) sections 19(10(t) and 38; HPA Bylaws sections 16 and 19 Pharmacy Operations and Drug Scheduling Act (PODSA), Part 3.

## Mandate

Hear and make a determination of a matter referred to the committee regarding a registrants conduct, competency and/or ability to practice, pursuant to legislation.

## Responsibilities

- Conduct hearings of a matter.
- Determine disposition of the matter.
- Inform respondents, complainants and the public about action taken.
- Inform respondents and complainants about the discipline process as applicable.

## Reporting relationship

The committee as a whole reports through the chair to the Board. The committee must submit a report of its activities to the Board annually, or as required by the Board.

## Membership

- At least six full pharmacists or pharmacy technicians appointed by the Board (there must be representation from both groups of registrants).
- At least 1/3 of its members must consist of public representatives, at least one of whom must be an appointed Board member.

## Panels

- The committee may meet in panels of at least 3 persons but not more than 5 persons, and each panel must include at least 1/3 public representatives, at least 1 full pharmacist for pharmacist hearings and at least 1 technician for technician hearings.
- The chair (or the vice chair in the absence of the chair) of the discipline committee must appoint the members of a panel and must designate a chair of the panel.
- The panel may exercise any power, duty or function of the discipline committee.

## Term of appointment

- Appointments are determined by the Board and will not exceed 2 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.
- A registrant appointed to the committee ceases to be a member if they are no longer a full pharmacist or pharmacy technician in good standing or if they become a College employee.
- Any committee member may resign upon written notification to the chair. Committee members who are absent for more than three committee meetings per year automatically forfeit membership on the committee. The chair has the discretion to approve, in advance, an extended absence of any committee member.

## Committee officers

Board appoints a committee chair and vice-chair from among the members of the committee.

## Voting rights

Each member, including each public representative, is entitled to one vote on all matters coming before the committee or a panel of the committee.

## Meeting procedures

| | |
|---|---|
| *Schedule:* | As required to fulfill its mandate and responsibilities. |
| *Format:* | In person or by teleconference. |
| *Hearing agenda:* | Developed by discipline panel chair. |
| *Attendees:* | Discipline hearings must be in public unless otherwise directed by the discipline committee. |
| *Quorum:* | A majority of the committee or all members of a panel. |

## Conflict of interest disclosure

Members must declare conflicts of interest prior to the discussion of individual files or at any time a conflict of interest or potential conflict of interest arises.

A conflict of interest refers to situations in which personal, occupational or financial considerations may affect or appear to affect the objectivity or fairness of decisions related to the committee activities. A conflict of interest may be real, potential or perceived in nature. Individuals must declare potential conflicts to the chair of the committee and must either absent themselves from the discussion and voting, or put the decision to the committee on whether they should absent themselves.

## Confidentiality

Each committee member must sign a confidentiality agreement at the time of each appointment indicating their agreement to maintain the confidentiality, security and integrity of all materials during and after their term on the committee.

Any public notification required by legislation will be made by the registrar at the direction of the discipline committee.

## Remuneration

Committee members may claim honouraria and expense reimbursement in accordance with the Board's policy and guidelines for claiming committee expenses.

## Amendment to terms of reference

The Board may amend committee terms of reference from time to time.

# DISCIPLINE COMMITTEE

## Background

The Board is required to establish a Discipline Committee.

## Authority

Health Professions Act (HPA) sections 19(10(t) and 38; HPA Bylaws sections 16 and 19 Pharmacy Operations and Drug Scheduling Act (PODSA), Part 3.

## Mandate

Hear and make a determination of a matter referred to the committee regarding a registrants conduct, competency and/or ability to practice, pursuant to legislation.

## Responsibilities

- Conduct hearings of a matter.
- Determine disposition of the matter.
- Inform respondents, complainants and the public about action taken.
- Inform respondents and complainants about the discipline process as applicable.

## Reporting relationship

The committee as a whole reports through the chair to the Board. The committee must submit a report of its activities to the Board annually, or as required by the Board.

## Membership

- At least six full pharmacists or pharmacy technicians appointed by the Board (there must be representation from both groups of registrants).
- At least 1/3 of its members must consist of public representatives, at least one of whom must be an appointed Board member.

## Panels

- The committee may meet in panels of at least 3 persons but not more than 5 persons, and each panel must include at least 1/3 public representatives, at least 1 full pharmacist for pharmacist hearings and at least 1 technician for technician hearings.
- The chair (or the vice chair in the absence of the chair) of the discipline committee must appoint the members of a panel and must designate a chair of the panel.
- The panel may exercise any power, duty or function of the discipline committee.

## Term of appointment

- Appointments are determined by the Board and will not exceed ~~2~~3 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.
- A registrant appointed to the committee ceases to be a member if they are no longer a full pharmacist or pharmacy technician in good standing or if they become a College employee.
- Any committee member may resign upon written notification to the chair. Committee members who are absent for more than three committee meetings per year automatically forfeit membership on the committee. The chair has the discretion to approve, in advance, an extended absence of any committee member.

## Committee officers

Board appoints a committee chair and vice-chair from among the members of the committee.

## Voting rights

Each member, including each public representative, is entitled to one vote on all matters coming before the committee or a panel of the committee.

## Meeting procedures

| | |
|---|---|
| *Schedule:* | As required to fulfill its mandate and responsibilities. |
| *Format:* | In person or by teleconference. |
| *Hearing agenda:* | Developed by discipline panel chair. |
| *Attendees:* | Discipline hearings must be in public unless otherwise directed by the discipline committee. |
| *Quorum:* | A majority of the committee or all members of a panel. |

## Conflict of interest disclosure

Members must declare conflicts of interest prior to the discussion of individual files or at any time a conflict of interest or potential conflict of interest arises.

A conflict of interest refers to situations in which personal, occupational or financial considerations may affect or appear to affect the objectivity or fairness of decisions related to the committee activities. A conflict of interest may be real, potential or perceived in nature. Individuals must declare potential conflicts to the chair of the committee and must either absent themselves from the discussion and voting, or put the decision to the committee on whether they should absent themselves.

## Confidentiality

Each committee member must sign a confidentiality agreement at the time of each appointment indicating their agreement to maintain the confidentiality, security and integrity of all materials during and after their term on the committee.

Any public notification required by legislation will be made by the registrar at the direction of the discipline committee.

## Remuneration

Committee members may claim honouraria and expense reimbursement in accordance with the Board's policy and guidelines for claiming committee expenses.

## Amendment to terms of reference

The Board may amend committee terms of reference from time to time.

# ETHICS ADVISORY COMMITTEE

## Background

The Board has established the Ethics Advisory Committee.

## Authority

Health Professions Act (HPA) s. 19(1)(t); HPA Bylaws s. 19.

## Mandate

To provide recommendations to the Board or the Registrar on matters relating to the Code of Ethics, Conflict of Interest Standards and any other related policies or guidelines.

## Responsibilities

- To meet from time to time to provide advice and guidance regarding ethical questions and dilemmas that have been directed to the committee from the Board or the Registrar.
- Review and recommend updates to the Code of Ethics and Conflict of Interest Standards as necessary.
- Consult on education program proposals relating to ethics issues.

## Reporting relationship

The committee as a whole must submit a report of its activities through the chair to the Board annually or as required by the Board.

## Membership

- At least six full pharmacists or pharmacy technicians appointed by the Board (there must be representation from both groups of registrants).
- A credentialed ethicist (ie; doctorate in philosophy with a specialization in medical or bioethics or a doctorate in philosophy with experience in medical ethics, such as a chair or committee member of an ethics review Board).
- One public member

## Term of appointment

- Appointments are determined by the Board and will not exceed 2 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.
- A registrant appointed to the committee ceases to be a member if they are no longer a full pharmacist or pharmacy technician in good standing or if they become a College employee.
- Any committee member may resign upon written notification to the chair. Committee members who are absent for more than three committee meetings per year automatically forfeit membership on the committee. The chair has the discretion to approve, in advance, an extended absence of any committee member.

## Committee officers

Board appoints a committee chair and vice-chair from among the members of the committee.

## Voting rights

Each committee member is entitled to one vote on all matters coming before the committee.

## Meeting procedures

*Schedule:* As required to fulfill its mandate and responsibilities.

*Format:* In person, by teleconference or by videoconferencing.

*Agenda:* Developed by College staff in consultation with the committee chair with input from committee members.

*Attendees:* Only Ethics Advisory Committee members and College staff are entitled to attend committee meetings, with the exception of invited guests.

*Quorum:* A majority of the committee.

*Minutes:* Drafted by College staff for review and approval at next committee meeting; filed at the College office.

*Secretariat Support:* Provided by the College, including meeting coordination, preparation and distribution of materials and drafting meeting minutes.

## Conflict of interest disclosure

Members must declare conflicts of interest prior to the discussion of individual files or at any time a conflict of interest or potential conflict of interest arises.

A conflict of interest refers to situations in which personal, occupational or financial considerations may affect or appear to affect the objectivity or fairness of decisions related to the committee activities. A conflict of interest may be real, potential or perceived in nature. Individuals must declare potential conflicts to the chair of the committee and must either absent themselves from the discussion and voting, or put the decision to the committee on whether they should absent themselves.

## Confidentiality

Each committee member must sign a confidentiality agreement at the time of each appointment indicating their agreement to maintain the confidentiality, security and integrity of all materials during and after their term on the committee.

## Remuneration

Committee members may claim honoraria and expense reimbursement in accordance with the Board's policy and guidelines for claiming committee expenses.

## Amendment to terms of reference

The Board may amend committee terms of reference at any time and from time to time.

# ETHICS ADVISORY COMMITTEE

## Background

The Board has established the Ethics Advisory Committee.

## Authority

Health Professions Act (HPA) s. 19(1)(t); HPA Bylaws s. 19.

## Mandate

To provide recommendations to the Board or the Registrar on matters relating to the Code of Ethics, Conflict of Interest Standards and any other related policies or guidelines.

## Responsibilities

- To meet from time to time to provide advice and guidance regarding ethical questions and dilemmas that have been directed to the committee from the Board or the Registrar.
- Review and recommend updates to the Code of Ethics and Conflict of Interest Standards as necessary.
- Consult on education program proposals relating to ethics issues.

## Reporting relationship

The committee as a whole must submit a report of its activities through the chair to the Board annually or as required by the Board.

## Membership

- At least six full pharmacists or pharmacy technicians appointed by the Board (there must be representation from both groups of registrants).
- A credentialed ethicist (ie; doctorate in philosophy with a specialization in medical or bioethics or a doctorate in philosophy with experience in medical ethics, such as a chair or committee member of an ethics review Board).
- One public member

## Term of appointment

- Appointments are determined by the Board and will not exceed ~~2~~3 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.
- A registrant appointed to the committee ceases to be a member if they are no longer a full pharmacist or pharmacy technician in good standing or if they become a College employee.
- Any committee member may resign upon written notification to the chair. Committee members who are absent for more than three committee meetings per year automatically forfeit membership on the committee. The chair has the discretion to approve, in advance, an extended absence of any committee member.

## Committee officers

Board appoints a committee chair and vice-chair from among the members of the committee.

## Voting rights

Each committee member is entitled to one vote on all matters coming before the committee.

## Meeting procedures

| | |
|---|---|
| *Schedule:* | As required to fulfill its mandate and responsibilities. |
| *Format:* | In person, by teleconference or by videoconferencing. |
| *Agenda:* | Developed by College staff in consultation with the committee chair with input from committee members. |
| *Attendees:* | Only Ethics Advisory Committee members and College staff are entitled to attend committee meetings, with the exception of invited guests. |
| *Quorum:* | A majority of the committee. |
| *Minutes:* | Drafted by College staff for review and approval at next committee meeting; filed at the College office. |
| *Secretariat Support:* | Provided by the College, including meeting coordination, preparation and distribution of materials and drafting meeting minutes. |

## Conflict of interest disclosure

Members must declare conflicts of interest prior to the discussion of individual files or at any time a conflict of interest or potential conflict of interest arises.

A conflict of interest refers to situations in which personal, occupational or financial considerations may affect or appear to affect the objectivity or fairness of decisions related to the committee activities. A conflict of interest may be real, potential or perceived in nature. Individuals must declare potential conflicts to the chair of the committee and must either absent themselves from the discussion and voting, or put the decision to the committee on whether they should absent themselves.

## Confidentiality

Each committee member must sign a confidentiality agreement at the time of each appointment indicating their agreement to maintain the confidentiality, security and integrity of all materials during and after their term on the committee.

## Remuneration

Committee members may claim honoraria and expense reimbursement in accordance with the Board's policy and guidelines for claiming committee expenses.

## Amendment to terms of reference

The Board may amend committee terms of reference at any time and from time to time.

# GOVERNANCE COMMITTEE

## Background

The Board has established the Governance Committee.

## Authority

Health Professions Act (HPA) s. 19(1)(t); HPA Bylaws s. 19.

## Mandate

To provide recommendations to the Board on matters relating to Board governance.

## Responsibilities

- Review Board policies and manuals and recommend revisions to these documents.
- Review and make recommendations regarding Board member orientation and ongoing development.
- Review and make recommendations on policies and practices related to the recruitment, election and/or appointment of Board and committee members.
- Provide advice and guidance on Board evaluations, including Board meeting evaluations.
- Assess and make recommendations regarding the governance-related needs of the Board.

## Reporting relationship

The committee as a whole reports through the chair to the Board. The committee must submit a report of its activities to the Board annually, or as required by the Board.

## Membership

- At least 3 but no more than 5 Board members appointed by the Board.
- Must include at least one public representative.

## Term of appointment

- Appointments are determined by the Board and will not exceed 2 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.
- A member appointed to the committee ceases to be a member if they are no longer a Board member.
- Any committee member may resign upon written notification to the registrar. Committee members who are absent for more than three committee meetings per year automatically forfeit membership on the committee. The chair has the discretion to approve, in advance, an extended absence of any committee member.

## Committee officers

Board appoints a committee chair and vice-chair from among the members of the committee.

## Voting rights

Each committee member is entitled to one vote on all matters coming before the committee.

## Meeting procedures

*Schedule:* At least three times annually to fulfill its mandate and responsibilities.

*Format:* In person, by teleconference or by videoconference.

*Agenda:* Developed by College staff in consultation with the committee chair with input from committee members.

*Attendees:* Only Governance Committee members and College staff are entitled to attend committee meetings, with the exception of invited guests.

*Quorum:* A majority of the committee.

*Minutes:* Drafted by College staff for review and approval at next committee meeting; filed at the College office.

*Secretariat Support:* Provided by the College, including meeting coordination, preparation and distribution of materials and drafting meeting minutes.

## Conflict of interest disclosure

Members must declare conflicts of interest at any time a conflict of interest or potential conflict of interest arises.

A conflict of interest refers to situations in which personal, occupational or financial considerations may affect or appear to affect the objectivity or fairness of decisions related to the committee activities. A conflict of interest may be real, potential or perceived in nature. Individuals must declare potential conflicts to the chair of the committee and must either absent themselves from the discussion and voting, or put the decision to the committee on whether they should absent themselves.

## Confidentiality

Each committee member must sign a confidentiality agreement at the time of each appointment indicating their agreement to maintain the confidentiality, security and integrity of all materials during and after their term on the committee.

## Remuneration

Committee members may claim honoraria and expense reimbursement in accordance with the Board's policy and guidelines for claiming committee expenses.

## Amendment to terms of reference

The Board may amend committee terms of reference at any time and from time to time.

# GOVERNANCE COMMITTEE

## Background

The Board has established the Governance Committee.

## Authority

Health Professions Act (HPA) s. 19(1)(t); HPA Bylaws s. 19.

## Mandate

To provide recommendations to the Board on matters relating to Board governance.

## Responsibilities

- Review Board policies and manuals and recommend revisions to these documents.
- Review and make recommendations regarding Board member orientation and ongoing development.
- Review and make recommendations on policies and practices related to the recruitment, election and/or appointment of Board and committee members.
- Provide advice and guidance on Board evaluations, including Board meeting evaluations.
- Assess and make recommendations regarding the governance-related needs of the Board.

## Reporting relationship

The committee as a whole reports through the chair to the Board. The committee must submit a report of its activities to the Board annually, or as required by the Board.

## Membership

- At least 3 but no more than 5 Board members appointed by the Board.
- Must include at least one public representative.

## Term of appointment

- Appointments are determined by the Board and will not exceed ~~2~~3 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.
- A member appointed to the committee ceases to be a member if they are no longer a Board member.
- Any committee member may resign upon written notification to the registrar. Committee members who are absent for more than three committee meetings per year automatically forfeit membership on the committee. The chair has the discretion to approve, in advance, an extended absence of any committee member.

## Committee officers

Board appoints a committee chair and vice-chair from among the members of the committee.

## Voting rights

Each committee member is entitled to one vote on all matters coming before the committee.

## Meeting procedures

| | |
|---|---|
| *Schedule:* | At least three times annually to fulfill its mandate and responsibilities. |
| *Format:* | In person, by teleconference or by videoconference. |
| *Agenda:* | Developed by College staff in consultation with the committee chair with input from committee members. |
| *Attendees:* | Only Governance Committee members and College staff are entitled to attend committee meetings, with the exception of invited guests. |
| *Quorum:* | A majority of the committee. |
| *Minutes:* | Drafted by College staff for review and approval at next committee meeting; filed at the College office. |
| *Secretariat Support:* | Provided by the College, including meeting coordination, preparation and distribution of materials and drafting meeting minutes. |

## Conflict of interest disclosure

Members must declare conflicts of interest at any time a conflict of interest or potential conflict of interest arises.

A conflict of interest refers to situations in which personal, occupational or financial considerations may affect or appear to affect the objectivity or fairness of decisions related to the committee activities. A conflict of interest may be real, potential or perceived in nature. Individuals must declare potential conflicts to the chair of the committee and must either absent themselves from the discussion and voting, or put the decision to the committee on whether they should absent themselves.

## Confidentiality

Each committee member must sign a confidentiality agreement at the time of each appointment indicating their agreement to maintain the confidentiality, security and integrity of all materials during and after their term on the committee.

## Remuneration

Committee members may claim honoraria and expense reimbursement in accordance with the Board's policy and guidelines for claiming committee expenses.

## Amendment to terms of reference

The Board may amend committee terms of reference at any time and from time to time.

# HOSPITAL PHARMACY ADVISORY COMMITTEE

## Background

The Board has established the Hospital Pharmacy Advisory Committee.

## Authority

Health Professions Act (HPA) s. 19(1)(t); HPA Bylaws s. 19.

## Mandate

To provide recommendations to the Board or the Registrar on matters relating to hospital pharmacy practice issues.

## Responsibilities

- To meet from time to time to review issues related to the practice of hospital pharmacy that have been directed to the committee by the Board or the Registrar.
- Assist in the development of policies, procedures, guidelines and proposed legislation pertaining to hospital pharmacy practice and standards.
- Assist in the development of information materials for circulation to practicing registrants.
- Recommend appropriate action to the Board or the Registrar regarding hospital pharmacy practice issues.
- Work collaboratively with other College practice advisory committees to ensure a cohesive approach to common practice issues.

## Reporting relationship

The committee as a whole must submit a report of its activities through the chair to the Board annually or as requested by the Board.

## Membership

- At least six full pharmacists or pharmacy technicians appointed by the Board who are practicing in hospital pharmacy (there must be representation from both groups of registrants).

## Term of appointment

- Appointments are determined by the Board and will not exceed 2 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.
- A registrant appointed to the committee ceases to be a member if they are no longer a full pharmacist or pharmacy technician in good standing or if they become a College employee.
- Any committee member may resign upon written notification to the registrar. Committee members who are absent for more than three committee meetings per year automatically forfeit membership on the committee. The chair has the discretion to approve, in advance, an extended absence of any committee member.

## Committee officers

Board appoints a committee chair and vice-chair from among the members of the committee.

## Voting rights

Each committee member is entitled to one vote on all matters coming before the committee.

## Meeting procedures

| | |
|---|---|
| *Schedule:* | As required to fulfill its mandate and responsibilities. |
| *Format:* | In person, by teleconference or by videoconferencing. |
| *Agenda:* | Developed by College staff in consultation with the committee chair with input from committee members. |
| *Attendees:* | Only Hospital Pharmacy Advisory Committee members and College staff are entitled to attend committee meetings, with the exception of invited guests. |
| *Quorum:* | A majority of the committee. |
| *Minutes:* | Drafted by College staff for review and approval at next committee meeting; filed at the College office. |
| *Secretariat Support:* | Provided by the College, including meeting coordination, preparation and distribution of materials and drafting meeting minutes. |

## Conflict of interest disclosure

Members must declare conflicts of interest prior to the discussion of individual files or at any time a conflict of interest or potential conflict of interest arises.

A conflict of interest refers to situations in which personal, occupational or financial considerations may affect or appear to affect the objectivity or fairness of decisions related to the committee activities. A conflict of interest may be real, potential or perceived in nature. Individuals must declare potential conflicts to the chair of the committee and must either absent themselves from the discussion and voting, or put the decision to the committee on whether they should absent themselves.

## Confidentiality

Each committee member must sign a confidentiality agreement at the time of each appointment indicating their agreement to maintain the confidentiality, security and integrity of all materials during and after their term on the committee.

## Remuneration

Committee members may claim honoraria and expense reimbursement in accordance with the Board's policy and guidelines for claiming committee expenses.

## Amendment to terms of reference

The Board may amend committee terms of reference at any time and from time to time.

# HOSPITAL PHARMACY ADVISORY COMMITTEE

## Background

The Board has established the Hospital Pharmacy Advisory Committee.

## Authority

Health Professions Act (HPA) s. 19(1)(t); HPA Bylaws s. 19.

## Mandate

To provide recommendations to the Board or the Registrar on matters relating to hospital pharmacy practice issues.

## Responsibilities

- To meet from time to time to review issues related to the practice of hospital pharmacy that have been directed to the committee by the Board or the Registrar.
- Assist in the development of policies, procedures, guidelines and proposed legislation pertaining to hospital pharmacy practice and standards.
- Assist in the development of information materials for circulation to practicing registrants.
- Recommend appropriate action to the Board or the Registrar regarding hospital pharmacy practice issues.
- Work collaboratively with other College practice advisory committees to ensure a cohesive approach to common practice issues.

## Reporting relationship

The committee as a whole must submit a report of its activities through the chair to the Board annually or as requested by the Board.

## Membership

- At least six full pharmacists or pharmacy technicians appointed by the Board who are practicing in hospital pharmacy (there must be representation from both groups of registrants).

## Term of appointment

- Appointments are determined by the Board and will not exceed ~~2~~3 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.
- A registrant appointed to the committee ceases to be a member if they are no longer a full pharmacist or pharmacy technician in good standing or if they become a College employee.
- Any committee member may resign upon written notification to the registrar. Committee members who are absent for more than three committee meetings per year automatically forfeit membership on the committee. The chair has the discretion to approve, in advance, an extended absence of any committee member.

## Committee officers

Board appoints a committee chair and vice-chair from among the members of the committee.

## Voting rights

Each committee member is entitled to one vote on all matters coming before the committee.

## Meeting procedures

| | |
|---|---|
| *Schedule:* | As required to fulfill its mandate and responsibilities. |
| *Format:* | In person, by teleconference or by videoconferencing. |
| *Agenda:* | Developed by College staff in consultation with the committee chair with input from committee members. |
| *Attendees:* | Only Hospital Pharmacy Advisory Committee members and College staff are entitled to attend committee meetings, with the exception of invited guests. |
| *Quorum:* | A majority of the committee. |
| *Minutes:* | Drafted by College staff for review and approval at next committee meeting; filed at the College office. |
| *Secretariat Support:* | Provided by the College, including meeting coordination, preparation and distribution of materials and drafting meeting minutes. |

## Conflict of interest disclosure

Members must declare conflicts of interest prior to the discussion of individual files or at any time a conflict of interest or potential conflict of interest arises.

A conflict of interest refers to situations in which personal, occupational or financial considerations may affect or appear to affect the objectivity or fairness of decisions related to the committee activities. A conflict of interest may be real, potential or perceived in nature. Individuals must declare potential conflicts to the chair of the committee and must either absent themselves from the discussion and voting, or put the decision to the committee on whether they should absent themselves.

## Confidentiality

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## Remuneration

Committee members may claim honoraria and expense reimbursement in accordance with the Board's policy and guidelines for claiming committee expenses.

## Amendment to terms of reference

The Board may amend committee terms of reference at any time and from time to time.

# INQUIRY COMMITTEE

## Background

The Board is required to establish an Inquiry Committee.

## Authority

Health Professions Act (HPA) sections 19(1)(t) and 33; HPA Bylaws sections 15 and 19; Pharmacy Operations and Drug Scheduling Act (PODSA), Part 3.

## Mandate

Investigate complaints and concerns regarding a registrants conduct, competency and/or ability to practice and decide on an appropriate course of action pursuant to legislation.

## Responsibilities

- Investigate complaints on its own motion or raised by a complainant within timelines as prescribed by the Minister.
- Investigate registrants that fail to authorize a criminal records review check as well as registrants presenting a risk of physical or sexual abuse to the vulnerable sector as determined by the Registrar of the Criminal Records Review Act.
- Make dispositions on matters investigated.
- Inform registrants, complainants, the public and the Health Professions Review Board (as required) about the inquiry process and complaint outcomes.

## Reporting relationship

The committee as a whole reports through the chair to the Board. The committee must submit a report of its activities to the Board annually, or as required by the Board.

## Membership

- At least six full pharmacists or pharmacy technicians appointed by the Board (there must be representation from both groups of registrants).
- At least 1/3 of its members must consist of public representatives, at least one of whom must be an appointed Board member.

## Panels

- The committee may meet in panels of at least 3 persons but not more than 5 persons, and each panel must include at least 1/3 public representatives, at least 1 full pharmacist for pharmacist complaints and at least 1 technician for technician complaints.
- The chair (or the vice chair in the absence of the chair) of the inquiry committee must appoint the members of a panel and must designate a chair of the panel.
- The panel may exercise any power, duty or function of the inquiry committee.

## Term of appointment

- Appointments are determined by the Board and will not exceed 2 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.
- A registrant appointed to the committee ceases to be a member if they are no longer a full pharmacist or pharmacy technician in good standing or if they become a College employee.
- Any committee member may resign upon written notification to the registrar. Committee members who are absent for more than three committee meetings per year automatically forfeit membership on the committee. The chair has the discretion to approve, in advance, an extended absence of any committee member.

## Committee officers

Board appoints a committee chair and vice-chair from among the members of the committee.

## Voting rights

Each member, including each public representative, is entitled to one vote on all matters coming before the committee or a panel of the committee.

## Meeting procedures

| | |
|---|---|
| *Schedule*: | As required to fulfill its mandate and responsibilities. |
| *Format*: | In person, by teleconference or by videoconference. |
| *Agenda*: | Developed by College staff and approved by the Chair. |
| *Attendees*: | Only Inquiry Committee members, College staff and inspectors, legal advisors as required and registrants upon request are entitled to attend committee and panel meetings. |
| *Quorum*: | A majority of the committee or all members of a panel. |
| *Minutes*: | Drafted by College staff for review and approval by the Chair or Vice Chair; filed at the College office. |
| *Secretariat support*: | Provided by the College including meeting coordination, preparation and distribution of materials and drafting meeting minutes. |

## Conflict of interest disclosure

Members must declare conflicts of interest prior to the discussion of individual files or at any time a conflict of interest or potential conflict of interest arises.

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## Confidentiality

Each committee member must sign a confidentiality agreement at the time of each appointment indicating his/her agreement to maintain the confidentiality, security and integrity of all materials during and after their term on the Committee.

## Remuneration

Committee members may claim honouraria and expense reimbursement in accordance with the Board's policy and guidelines for claiming committee expenses.

## Amendment to terms of reference

The Board may amend committee terms of reference from time to time.

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## Mandate

Investigate complaints and concerns regarding a registrants conduct, competency and/or ability to practice and decide on an appropriate course of action pursuant to legislation.

## Responsibilities

- Investigate complaints on its own motion or raised by a complainant within timelines as prescribed by the Minister.
- Investigate registrants that fail to authorize a criminal records review check as well as registrants presenting a risk of physical or sexual abuse to the vulnerable sector as determined by the Registrar of the Criminal Records Review Act.
- Make dispositions on matters investigated.
- Inform registrants, complainants, the public and the Health Professions Review Board (as required) about the inquiry process and complaint outcomes.

## Reporting relationship

The committee as a whole reports through the chair to the Board. The committee must submit a report of its activities to the Board annually, or as required by the Board.

## Membership

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- The chair (or the vice chair in the absence of the chair) of the inquiry committee must appoint the members of a panel and must designate a chair of the panel.
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## Remuneration

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## Amendment to terms of reference

The Board may amend committee terms of reference from time to time.

# JURISPRUDENCE EXAMINATION SUBCOMMITTEE

## Background

The Board has established the Jurisprudence Examination Subcommittee to assist the Registration Committee with the development of and revisions to the Jurisprudence Examination.

## Authority

Health Professions Act (HPA), s.19(1)(t).

## Mandate

To ensure that the Jurisprudence Examination remains a valid and reliable assessment instrument.

## Responsibilities

- Develop, update and maintain Jurisprudence Examination blueprint and content.
- Establish and validate the assessment, the processes, and the standards.
- Develop recommendations and policies for review and approval by the Registration Committee.
- Review correspondence and appeals pertaining to the examination questions and acceptable answers, and recommend outcomes for the Registration Committee's approval.

## Reporting relationship

The subcommittee as a whole reports through the chair to the Registration Committee. The subcommittee must submit a report of its activities to the Registration Committee annually, or as required by the Registration Committee.

## Membership

- At least six full pharmacists or pharmacy technicians appointed by the Board (there must be representation from both groups of registrants).

## Term of appointment

- Appointments are determined by the Board and will not exceed 2 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.
- A registrant appointed to the subcommittee ceases to be a member if they are no longer a full pharmacist or pharmacy technician in good standing or if they become a College employee.
- Any subcommittee member may resign upon written notification to the registrar. Subcommittee members who are absent for more than three subcommittee meetings per year automatically forfeit membership on the subcommittee. The chair has the discretion to approve, in advance, an extended absence of any subcommittee member.

## Subcommittee officers

The Board appoints a subcommittee chair and vice-chair from among the members of the subcommittee. The subcommittee members will recommend to the Board the appointment of new subcommittee members as vacancies or extraordinary needs arise.

## Voting rights

Each subcommittee member is entitled to one vote on all matters coming before the subcommittee.

## Meeting procedures

| | |
|---|---|
| *Schedule:* | As required to fulfill its mandate and responsibilities. |
| *Format:* | In person, by teleconference or by videoconference. |
| *Agenda:* | Developed by College staff in consultation with the subcommittee chair, with input from subcommittee members. |
| *Attendees:* | Only Jurisprudence Examination Subcommittee members and College staff are entitled to attend subcommittee and panel meetings, unless specifically invited by the subcommittee chair as a guest. |
| *Quorum:* | A majority of the subcommittee. |
| *Minutes:* | Drafted by College staff for review and approval at next subcommittee meeting; filed at the College office. |
| *Secretariat support:* | Provided by the College, including meeting coordination, preparation and distribution of materials and drafting meeting minutes. |

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## Confidentiality

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## Remuneration

Committee members may claim honoraria and expense reimbursement in accordance with the Board's policy and guidelines for claiming committee expenses.

## Amendment to terms of reference

The Board may amend subcommittee terms of reference at any time and from time to time.

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## Voting rights

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## Meeting procedures

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| *Schedule:* | As required to fulfill its mandate and responsibilities. |
| *Format:* | In person, by teleconference or by videoconference. |
| *Agenda:* | Developed by College staff in consultation with the subcommittee chair, with input from subcommittee members. |
| *Attendees:* | Only Jurisprudence Examination Subcommittee members and College staff are entitled to attend subcommittee and panel meetings, unless specifically invited by the subcommittee chair as a guest. |
| *Quorum:* | A majority of the subcommittee. |
| *Minutes:* | Drafted by College staff for review and approval at next subcommittee meeting; filed at the College office. |
| *Secretariat support:* | Provided by the College, including meeting coordination, preparation and distribution of materials and drafting meeting minutes. |

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## Remuneration

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## Amendment to terms of reference

The Board may amend subcommittee terms of reference at any time and from time to time.

# LEGISLATION REVIEW COMMITTEE

## Background

The Board has established the Legislation Review Committee.

## Authority

Health Professions Act (HPA) s. 19(1)(t); HPA Bylaws s. 19.

## Mandate

To provide recommendations to the Board and the Registrar on matters relating to pharmacy legislation and policy review.

## Responsibilities

- Provide advice and guidance regarding proposed legislation/policy changes that have been directed to the committee from the Board, Board committees or College staff.
- Identify priorities for change within the legislation review planning cycle.
- Determine if broader external stakeholder consultation is required.
- The chair of the committee presents priorities to the Board for approval.
- Approve final draft of proposed legislation/policy prior to presentation to the Board.
- The chair, with support from the Director of Policy and Legislation, presents revised documents to the Board for approval.
- Review public posting comments as necessary.

## Reporting relationship

The committee as a whole reports through the chair to the Board. The committee must submit a report of its activities to the Board annually, or as required by the Board.

## Membership

- At least 3 but no more than 5 Board members appointed by the Board.
- Must include at least one full pharmacist, one full pharmacy technician, and one public representative.

## Term of appointment

- Appointments are determined by the Board and will not exceed 2 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.
- A member appointed to the committee ceases to be a member if they are no longer a Board member.
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- Any committee member may resign upon written notification to the registrar. Committee members who are absent for more than three committee meetings per year automatically forfeit membership on the committee. The chair has the discretion to approve, in advance, an extended absence of any committee member.

## Committee officers

The Board will appointment a chair from amongst the committee's members for a term of one year.

## Voting rights

Each committee member is entitled to one vote on all matters coming before the committee.

## Meeting procedures

| | |
|---|---|
| *Schedule:* | As required to fulfill its mandate and responsibilities. |
| *Format:* | In person, by teleconference or by videoconference. |
| *Agenda:* | Developed by College staff in consultation with the committee chair with input from committee members. |
| *Attendees:* | Only Committee members and College staff are entitled to attend committee meetings, with the exception of invited guests. |
| *Quorum:* | A majority of the committee. |
| *Minutes:* | Drafted by College staff for review and approval at next committee meeting; filed at the College office. |
| *Secretariat Support:* | Provided by the College, including meeting coordination, preparation and distribution of materials and drafting meeting minutes. |

## Conflict of interest disclosure

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## Confidentiality

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## Remuneration

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## Amendment to terms of reference

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## Background

The Board has established the Legislation Review Committee.

## Authority

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## Mandate

To provide recommendations to the Board and the Registrar on matters relating to pharmacy legislation and policy review.

## Responsibilities

- Provide advice and guidance regarding proposed legislation/policy changes that have been directed to the committee from the Board, Board committees or College staff.
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- Review public posting comments as necessary.

## Reporting relationship

The committee as a whole reports through the chair to the Board. The committee must submit a report of its activities to the Board annually, or as required by the Board.

## Membership

- At least 3 but no more than 5 Board members appointed by the Board.
- Must include at least one full pharmacist, one full pharmacy technician, and one public representative.

## Term of appointment

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## Committee officers

The Board will appointment a chair from amongst the committee's members for a term of one year.

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Each committee member is entitled to one vote on all matters coming before the committee.

## Meeting procedures

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## Remuneration

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## Amendment to terms of reference

The Board may amend committee terms of reference at any time and from time to time.

# PRACTICE REVIEW COMMITTEE

## Background

The Board has established the Practice Review Committee to develop and maintain the Pharmacy Review and the Pharmacy Professionals' Review components of the Practice Review Program (PRP).

## Authority

Health Professions Act (HPA) s. 19(1)(t) and HPA Bylaws sections 15.1 and 19.

## Mandate

To monitor standards of practice to enhance the quality of pharmacy care for British Columbians.

## Responsibilities

- Develop and update the PRP processes and policies for approval by the Board as required including but not limited to processes and policies that:
    - outline the Pharmacy Review component;
    - outline the Pharmacy Professionals' Review component;
    - outline follow-up and remediation.
- On a yearly basis review the statistics and outcomes and feedback of the PRP, determine recommendations for improvement and report to the Board as applicable.
- Liaise with the Hospital Pharmacy Advisory Committee, Community Pharmacy Advisory Committee and Residential Care Advisory Committee to make recommendations on current and outstanding issues pertaining to the PRP.
- Liaise with Health Authorities, owners and directors and other stakeholders to address current and outstanding issues pertaining to the PRP.
- Review s.17(1) PODSA and 28(1) HPA reports and determine whether to refer matters arising from that review to the Inquiry Committee, Quality Assurance Committee or Registrar.

## Reporting relationship

The committee as a whole reports to the Board and must submit a report of its activities to the Board annually, or as required by the Board.

## Membership

- At least six full pharmacists or pharmacy technicians appointed by the Board (there must be representation from both groups of registrants).
- At least 1/3 of its members must consist of public representatives at least one of whom must be an appointed Board member.

## Panels

- The committee may meet in panels of at least 3 persons but not more than 5 persons, and each panel must include at least 1/3 public representatives.
- The Chair must appoint the members of a panel and must designate a chair for each panel.
- The panel may exercise any power, duty or function of the Practice Review Committee.

## Term of appointment

- Appointments are determined by the Board and will not exceed 2 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.
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## Committee officers

Board appoints a committee chair and vice-chair from among the members of the committee.

## Voting rights

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## Meeting procedures

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| *Schedule:* | As required to fulfill its mandate and responsibilities. |
| *Format:* | In person, by teleconference or by videoconference. |
| *Agenda:* | Developed by College staff in consultation with the committee chair with input from committee members. |
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| *Minutes:* | Drafted by College staff for review and approval at next committee meeting; filed at the College office. |
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## Confidentiality

Each committee member must sign a confidentiality agreement at the time of each appointment indicating their agreement to maintain the confidentiality, security and integrity of all materials during and after their term on the committee.

## Remuneration

Committee members may claim honoraria and expense reimbursement in accordance with the Board's policy and guidelines for claiming committee expenses.

## Amendment to terms of reference

The Board may amend committee terms of reference at any time and from time to time.

# QUALITY ASSURANCE COMMITTEE

## Background

The Board is required to establish a Quality Assurance Committee.

## Authority

Health Professions Act (HPA) sections 19(1)(t) and 26.1 and HPA Bylaws sections 17 and 19.

## Mandate

To ensure that registrants are competent to practice and to promote high practice standards amongst registrants.

## Responsibilities

- Assess standards of practice and make recommendations to enhance the quality of practice and reduce incompetent, impaired or unethical practice amongst registrants.
- Establish and maintain a quality assurance program to promote high practice standards among registrants and continuous learning and professional development.
- Recommend standards of practice for continuing competency for the Board's approval.
- Establish and maintain a quality assurance program in accordance with current testing standards and assessment practices.
- Develop, update and maintain the CE-Plus content, requirements, and forms.
- Establish standards for monitoring and auditing CE-Plus submissions for compliance with requirements.
- Establish sub-committees and ad hoc working groups for Board appointment, to develop, administer and maintain assessments for the purposes of the quality assurance program.

## Reporting relationship

The committee as a whole reports through the chair to the Board. The committee must submit a report of its activities to the Board annually, or as required by the Board.

## Membership

- At least six full pharmacists or pharmacy technicians appointed by the Board (there must be representation from both groups of registrants).
- At least 1/3 of its members must consist of public representatives, at least one of whom must be an appointed Board member.

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## Panels

- The committee may meet in panels of at least 3 persons but not more than 5 persons, and each panel must include at least 1/3 public representatives.
- The chair of the quality assurance committee must appoint the members of a panel and must designate a chair of the panel
- The panel may exercise any power, duty or function of the quality assurance committee.

## Term of appointment

- Appointments are determined by the Board and will not exceed 2 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.
- A registrant appointed to the committee ceases to be a member if they are no longer a full pharmacist or pharmacy technician in good standing or if they become a College employee.
- Any committee member may resign upon written notification to the registrar. Committee members who are absent for more than three committee meetings per year automatically forfeit membership on the committee. The chair has the discretion to approve, in advance, an extended absence of any committee member.

## Committee officers

Board appoints a committee chair and vice-chair from among the members of the committee.

## Voting rights

Each Quality Assurance Committee member, including each public representative, is entitled to one vote on all matters coming before the committee or a panel of the committee.

## Meeting procedures

| | |
|---|---|
| *Schedule:* | At least three times annually. |
| *Format:* | In person, by teleconference or by videoconference. |
| *Agenda:* | Developed by College staff in consultation with the committee chair, with input from committee members. |
| *Panels:* | The committee chair, who also designates the panel chair, must appoint panel members. A panel of a committee may exercise any power, duty or function of the committee. |
| *Attendees:* | Only Quality Assurance Committee members and College staff are entitled to attend committee and panel meetings, unless specifically invited by the committee or panel chair as a guest. |
| *Quorum:* | A majority of the committee or all members of a panel. |
| *Minutes:* | Drafted by College staff for review and approval at next committee meeting; filed at the College office. |
| *Secretariat support:* | Provided by the College, including meeting coordination, preparation and distribution of materials and drafting meeting minutes. |

## Conflict of interest disclosure

Members must declare conflicts of interest prior to the discussion of individual files or at any time a conflict of interest or potential conflict of interest arises.

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## Confidentiality

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## Remuneration

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# QUALITY ASSURANCE COMMITTEE

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- Establish sub-committees and ad hoc working groups for Board appointment, to develop, administer and maintain assessments for the purposes of the quality assurance program.

## Reporting relationship

The committee as a whole reports through the chair to the Board. The committee must submit a report of its activities to the Board annually, or as required by the Board.

## Membership

- At least six full pharmacists or pharmacy technicians appointed by the Board (there must be representation from both groups of registrants).
- At least 1/3 of its members must consist of public representatives, at least one of whom must be an appointed Board member.

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## Panels

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- The chair of the quality assurance committee must appoint the members of a panel and must designate a chair of the panel
- The panel may exercise any power, duty or function of the quality assurance committee.

## Term of appointment

- Appointments are determined by the Board and will not exceed ~~2~~3 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.
- A registrant appointed to the committee ceases to be a member if they are no longer a full pharmacist or pharmacy technician in good standing or if they become a College employee.
- Any committee member may resign upon written notification to the registrar. Committee members who are absent for more than three committee meetings per year automatically forfeit membership on the committee. The chair has the discretion to approve, in advance, an extended absence of any committee member.

## Committee officers

Board appoints a committee chair and vice-chair from among the members of the committee.

## Voting rights

Each Quality Assurance Committee member, including each public representative, is entitled to one vote on all matters coming before the committee or a panel of the committee.

## Meeting procedures

| | |
|---|---|
| *Schedule:* | At least three times annually. |
| *Format:* | In person, by teleconference or by videoconference. |
| *Agenda:* | Developed by College staff in consultation with the committee chair, with input from committee members. |
| *Panels:* | The committee chair, who also designates the panel chair, must appoint panel members. A panel of a committee may exercise any power, duty or function of the committee. |
| *Attendees:* | Only Quality Assurance Committee members and College staff are entitled to attend committee and panel meetings, unless specifically invited by the committee or panel chair as a guest. |
| *Quorum:* | A majority of the committee or all members of a panel. |
| *Minutes:* | Drafted by College staff for review and approval at next committee meeting; filed at the College office. |
| *Secretariat support:* | Provided by the College, including meeting coordination, preparation and distribution of materials and drafting meeting minutes. |

## Conflict of interest disclosure

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## Confidentiality

Each committee member must sign a confidentiality agreement at the time of each appointment indicating their agreement to maintain the confidentiality, security and integrity of all materials during and after their term on the committee.

## Remuneration

Committee members may claim honoraria and expense reimbursement in accordance with the Board's policy and guidelines for claiming committee expenses.

## Amendment to terms of reference

The Board may amend committee terms of reference at any time and from time to time.

# REGISTRATION COMMITTEE

## Background

The Board is required to establish a Registration Committee.

## Authority

Health Professions Act (HPA) sections 19(1)(m.4) and 19(1)(t) and HPA Bylaws sections 14 and 19.

## Mandate

To ensure that registrants meet the conditions or requirements for registration as a Member of the College.

## Responsibilities

- Review all matters relating to applicants for registration and determine applicants' eligibility for registration including establishing the conditions and requirements for registration.
- Grant registration, including reinstatement and registration renewal, to all individuals who satisfy the Registration Committee that they are qualified to be a registrant, including payment of required fees.
- Develop policies and requirements with respect to the registration of new, renewing and reinstating registrants.
- Set, administer and maintain policies on all matters related to assessment competencies, standards, principles, selection or design and processes.
- Establish sub-committees and ad hoc working groups for Board appointment, to develop, administer and maintain assessments for the purposes of the registration processes.
- Inform registrants, complainants and the Health Professions Review Board (as required) about the registration process and outcomes.

## Reporting relationship

The committee as a whole reports through the chair to the Board. The committee must submit a report of its activities to the Board annually, or as required by the Board.

## Membership

- At least six full pharmacists or pharmacy technicians appointed by the Board (there must be representation from both groups of registrants).
- At least 1/3 of its members must consist of public representatives, at least one of whom must be an appointed Board member.

## Panels

- The committee may meet in panels of at least 3 persons but not more than 5 persons, and each panel must include at least 1/3 public representatives, at least 1 full pharmacist for pharmacist applications and at least 1 pharmacy technician for pharmacy technician applications.
- The chair of the registration committee must appoint the members of a panel and must designate a chair of the panel.
- The panel may exercise any power, duty or function of the registration committee.

## Term of appointment

- Appointments are determined by the Board and will not exceed 2 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.
- A registrant appointed to the committee ceases to be a member if they are no longer a full pharmacist or pharmacy technician in good standing or if they become a College employee.
- Any committee member may resign upon written notification to the registrar. Committee members who are absent for more than three committee meetings per year automatically forfeit membership on the committee. The chair has the discretion to approve, in advance, an extended absence of any committee member.

## Committee officers

Board appoints a committee chair and vice-chair from among the members of the committee.

## Voting rights

Each member, including each public representative, is entitled to one vote on all matters coming before the committee or a panel of the committee.

## Meeting procedures

| | |
|---|---|
| *Schedule:* | At least three times annually. |
| *Format:* | In person, by teleconference, or by videoconference. |
| *Agenda:* | Developed by College staff in consultation with the committee chair with input from committee members. |
| *Panels:* | The committee chair, who also designates the panel chair, must appoint panel members. A panel of a committee may exercise any power, duty or function of that committee. |
| *Attendees:* | Only Registration Committee members and College staff are entitled to attend committee and panel meetings, unless specifically invited by the committee or panel chair as a guest. |
| *Quorum:* | A majority of the committee or all members of a panel |
| *Minutes:* | Drafted by College staff for review and approval at next committee meeting; filed at the College office |
| *Secretariat Support:* | Provided by the College, including meeting coordination, preparation and distribution of materials and drafting meeting minutes. |

## Conflict-of-interest disclosure

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## Amendment to terms of reference

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## Background

The Board is required to establish a Registration Committee.

## Authority

Health Professions Act (HPA) sections 19(1)(m.4) and 19(1)(t) and HPA Bylaws sections 14 and 19.

## Mandate

To ensure that registrants meet the conditions or requirements for registration as a Member of the College.

## Responsibilities

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## Reporting relationship

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## Membership

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## Panels

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## Term of appointment

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## Committee officers

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## Voting rights

Each member, including each public representative, is entitled to one vote on all matters coming before the committee or a panel of the committee.

## Meeting procedures

| | |
|---|---|
| *Schedule:* | At least three times annually. |
| *Format:* | In person, by teleconference, or by videoconference. |
| *Agenda:* | Developed by College staff in consultation with the committee chair with input from committee members. |
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| *Attendees:* | Only Registration Committee members and College staff are entitled to attend committee and panel meetings, unless specifically invited by the committee or panel chair as a guest. |
| *Quorum:* | A majority of the committee or all members of a panel |
| *Minutes:* | Drafted by College staff for review and approval at next committee meeting; filed at the College office |
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## Remuneration

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## Amendment to terms of reference

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# RESIDENTIAL CARE PHARMACY ADVISORY COMMITTEE

## Background

The Board has established the Residential Care Pharmacy Advisory Committee.

## Authority

Health Professions Act (HPA) s. 19(1)(t); HPA Bylaws s. 19.

## Mandate

To provide recommendations to the Board or the Registrar on matters relating to residential care pharmacy practice issues.

## Responsibilities

- To meet from time to time to review issues related to the practice of pharmacy for residential care facilities and homes that have been directed to the committee by the Board or the Registrar.
- Assist in the development of policies, guidelines and proposed legislation pertaining to residential care pharmacy practice and standards.
- Assist in the development of information materials for circulation to practicing registrants.
- Recommend appropriate action to the Board or the Registrar regarding residential care pharmacy practice issues.
- Work collaboratively with other College practice advisory committees to ensure a cohesive approach to common practice issues.

## Reporting relationship

The committee as a whole must submit a report of its activities through the chair to the Board annually or as required by the Board.

## Membership

- At least six full pharmacists or pharmacy technicians appointed by the Board who are practicing in the area of residential care (there must be representation from both groups of registrants).

## Term of appointment

- Appointments are determined by the Board and will not exceed 2 years. Appointees are eligible for reappointment by the Board but may not serve more than 6 consecutive years.
- A registrant appointed to the committee ceases to be a member if they are no longer a full pharmacist or pharmacy technician in good standing or if they become a College employee.
- Any committee member may resign upon written notification to the registrar. Committee members who are absent for more than three committee meetings per year automatically forfeit membership on the committee. The chair has the discretion to approve, in advance, an extended absence of any committee member.

## Committee officers

Board appoints a committee chair and vice-chair from among the members of the committee.

## Voting rights

Each committee member is entitled to one vote on all matters coming before the committee.

## Meeting procedures

| | |
|---|---|
| *Schedule:* | As required to fulfill its mandate and responsibilities. |
| *Format:* | In person, by teleconference or by videoconference. |
| *Agenda:* | Developed by College staff in consultation with the committee chair with input from committee members. |
| *Attendees:* | Only Residential Care Pharmacy Advisory Committee members and College staff are entitled to attend committee meetings, with the exception of invited guests. |
| *Quorum:* | A majority of the committee. |
| *Minutes:* | Drafted by College staff for review and approval at next committee meeting; filed at the College office. |
| *Secretariat Support:* | Provided by the College, including meeting coordination, preparation and distribution of materials and drafting meeting minutes. |

## Conflict of interest disclosure

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## Remuneration

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## Reporting relationship

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## Membership

- At least six full pharmacists or pharmacy technicians appointed by the Board who are practicing in the area of residential care (there must be representation from both groups of registrants).

## Term of appointment

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