College of Pharmacists of British Columbia

Board Meeting
November 23, 2018
Held at the College of Pharmacists of British Columbia
200-1765 West 8th Avenue, Vancouver, BC

MINUTES

Members Present:
Mona Kwong, District 1, Chair as noted in the minutes
Arden Barry, District 7, Vice Chair and Chair as noted in the minutes
Christine Antler, District 2, Vice Chair as noted in the minutes
Tara Oxford, District 3
Steven Hopp, District 4
Frank Lucarelli, District 5
Anca Cvaci, District 6
Bal Dhillon, District 8
Tracey Hagkull, Government Appointee
Justin Thind, Government Appointee
Jeremy Walden, Government Appointee

Absent:
Ryan Hoag, Government Appointee

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 and Licensure
Christine Paramonczyk, Director of Policy and Legislation
Gillian Vrooman, Director of Communications and Engagement
Jon Chen, Communications Project Officer
Stephanie Kwok, Executive Assistant

Guests:
Sam Chu, UBC Pharmacy Undergraduate Society President

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1. **WELCOME & CALL TO ORDER**
   Chair Kwong called the meeting to order at 8:45am on November 23, 2018.

College of Pharmacists of British Columbia

2. ELECTION OF CHAIR

In accordance with HPA bylaw 12(2) Board members at the November Board meeting must elect a Chair.

Registrar Nakagawa called for nominations.

- Arden Barry was nominated.

After no further nominations were made, Arden Barry was acclaimed as the new Board Chair for a one-year term to conclude at the start of the November 2019 Board meeting.

Arden Barry assumed the Board Chair position.

3. ELECTION OF VICE-CHAIR

Chair Barry called for nominations, the following three names were put forward for consideration:

- Christine Antler
- Bal Dhillon
- Steven Hopp

After 11 votes were electronically cast and tallied, Christine Antler was elected as the new Board Vice Chair for a one-year term to conclude at the start of the November 2019 Board meeting.

Christine Antler assumed the Vice Chair position.

4. CONSENT AGENDA

a) Items for further discussion

Item 4b.x. Governance Committee: Committee Member Appointments was placed onto the Regular Agenda after the Consent Agenda was approved.

b) Approval of Consent Items (Appendix 1)

It was moved and seconded that the Board:
Approve the Consent Agenda as circulated.

CARRIED

5. CONFIRMATION OF AGENDA (Appendix 2)

It was moved and seconded that the Board:
Approve the November 23, 2018 Draft Board Meeting Agenda as circulated.

CARRIED

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6. GOVERNANCE COMMITTEE (Appendix 3)

a) Committee Updates [Governance and Hospital Pharmacy Advisory]

Governance Committee
Arden Barry, Chair of the Governance committee reported that the committee last met on October 17 to discuss the composition of the committees.

Hospital Pharmacy Advisory Committee
Arden Barry, Chair of the Hospital Pharmacy Advisory Committee reported that the committee has not met since the last Board meeting.

b) Committee Member Appointments

Arden Barry, Chair of the Governance committee provided background to the proposed committee member appointments for decision in the consent agenda. The purpose of the appointments derived from results of the Board elections and recognition that two of the Board's government appointees' terms are ending at the end of this year.

c) Board Members as Chairs of Committees

It was moved and seconded that the Board:
Require that all committees of the College of Pharmacists of British Columbia, except the following committees, must have a Board member as Chair:

- *Application Committee*
- *Discipline Committee*
- *Drug Administration Committee*
- *Inquiry Committee*
- *Registration Committee*
- *Quality Assurance Committee*

CARRIED

d) Amalgamation of Committees

Arden Barry, Chair of the Governance Committee reported that the Governance Committee will be proposing that the advisory committees be amalgamated into one, as these individual committees are only called upon to meet when member's expertise are needed on very specific topics. Given that these committees do not meet often, the amalgamation of the committees will address these concerns and allow for more engagement of the committee members. This item will be placed on the February board agenda for consideration and decision.

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7. COMMITTEE UPDATES

a) Governance Committee

Arden Barry, Chair of the Governance Committee, provided an update under item 6a of the regular agenda.

b) Hospital Pharmacy Advisory Committee

Arden Barry, Chair of the Governance Committee, provided an update under item 6a of the regular agenda.

c) Application Committee

Mona Kwong, on behalf of the Application Committee reported that Application Committee meetings are held via teleconference at least 2 times per month to review both pharmacy files that do not renew within the required renewal timeline and those that do not meet the eligibility criteria. To-date, approximately 20% of pharmacy licence renewals are late. Depending on the number of pharmacy licence renewals for a particular month, the numbers may vary as follows:

- September 2018 – 98 direct owners (20% late = 20 pharmacies)
- October 2018 – 209 direct owners (20% late = 42 pharmacies)
- November 2018- 62 direct (20% late = 12 pharmacies).

d) Ethics Advisory Committee

Mona Kwong, on behalf of the committee reported that the committee has not met since the last Board meeting.

e) Inquiry Committee

Mona Kwong, on behalf of the Inquiry committee reported that for the period of August to September 2018, the committee has met once in person and 8 times via teleconferences. A total of 25 files were reviewed and 18 new formal complaints were received. This number has doubled from the same period last year, where only 7 were received. Also, the staff received 116 calls and tips for the 2 months. On average, the College receives about 12 complaints during the months of August and September. The year to date statistics from January to September include:

- 5 in-person meetings
- 33 teleconferences
- Reviewed 159 cases
- Received 582 calls/tips
- Received 94 formal complaints
    - Breakdown of the types/categories of complaints:
        - 47 medication related
        - 3 privacy breaches
        - 24 professional misconduct
        - 27 competency and practice issues
        - 3 medication reviews

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- 15 fitness to practice
- 4 unauthorized practice
- 4 unlawful activity
- 8 methadone
- 4 other **Note: some complaints have fall into more than one category

f) Jurisprudence Examination Subcommittee

Mona Kwong, on behalf of the committee reported that the committee met on November 21 to review the results of the Jurisprudence Examination as well as to review comments provided by pharmacists and pharmacy technicians on the exam questions and determine whether any adjustments should be made to the scoring metrics.

g) Residential care Advisory Committee

Mona Kwong, on behalf of the committee reported that the committee has not met since the last Board meeting.

h) Practice Review Committee

Tracey Hagkull, Chair of the Practice Review Committee reported that the committee met on October 16 via teleconference to discuss about how to manage the data and results from the Practice Review Program (PRP) Registrant Feedback Survey going forward and will continue this discussion at their next meeting. The committee approved a change in the PRP policies in relation to the recent PODSA changes to clarify that the PRP report will be delivered to the pharmacy manager and not to the pharmacy owner. The committee also approved a change in the requirement of the committee to meet 5 times per year to 4 times a year, 2 in person and in 2 via teleconference.

i) Audit and Finance Committee

Frank Lucarelli, Vice-Chair of the Audit and Finance Committee, reported that the committee has not met since the last Board meeting.

j) Quality Assurance Committee

Frank Lucarelli, Chair of the Quality Assurance Committee, reported that the committee met on November 21. The committee is on track with completing the 400 audits of the incoming learning records that registrants have been submitting via the Professional Development and Assessment Program (PDAP) portal. The committee will continue to collect and analyze the incoming data and explore the possibility of utilizing the portal for other things.

k) Community Pharmacy Advisory Committee

Tara Oxford, Chair of the Community Pharmacy Advisory Committee reported that the committee has not met since the last Board meeting.

l) Discipline Committee

Jeremy Walden, Chair of the Discipline Committee, provided an update under item 11a of the regular agenda.

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m) Legislation Review Committee

Jeremy Walden, Chair of the Legislation Review Committee, provided an update under item 11a of the regular agenda.

n) Registration Committee

Jeremy Walden, Chair of the Registration Committee, provided an update under item 11a of the regular agenda.

o) Drug Administration Committee

Doreen Leong, staff resource to the Drug Administration Committee reported that the committee met on October 23 to discuss about broadening the scope of practice for pharmacist in terms of injection authority, essentially to remove the restrictions on injection authority. The next meeting is scheduled for December and the committee will make recommendations to the Board for consideration and approval at the February 2019 Board meeting.

8. POTENTIAL ALTERNATIVES TO THE COLLEGE'S EXISITNG QUALITY AND MANAGEMENT PROGRAM (Appendix 4)

Ashifa Keshavji, Director of Practice Reviews and Quality Assurance provided a follow-up presentation on Melissa Sheldrick's request for the College to consider the implementation of mandatory medication error reporting. Several options were provided to the Board for consideration.

It was moved and seconded that the Board:
Direct the Registrar to explore implementation of mandatory medication error reporting to an independent third party.

CARRIED

9. UPDATE: ACTIONADE SOFTWARE AND RESEARCH PROGRAM (Appendix 5)

Katherin Badke, Clinical Pharmacy Specialist and Ellen Balka, Professor in Simon Fraser University's School of Communication provided an overview of the ActionADE Research Program as well as a demonstration of the software. This software and program was built with funding from the College of Pharmacists of BC and other researchers.

10. BCPHA OPIOID AGONIST TREATMENT COMPLIANCE AND MANAGEMENT PROGRAM FOR PHARMACY (OAT-CAMPP) (Appendix 6)

Bryce Wong, Director of Special Projects for the BC Pharmacy Association (BCPhA) provided an overview of the development of the BC Pharmacy Association's new Opioid Agonist Treatment Compliance and Management Program for Pharmacy (OAT-CAMPP) in response to the amendments of Professional Practice Policy-66. The BCPhA, in conjunction with the Ministry of Health, developed the OAT-CAMPP training program as a tool to help registrants address the province's current opioid crisis. The training program aligns with PPP-66 and will replace the College's current MMT training program.

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11. LEGISLATION REVIEW COMMITTEE

Jeremy Walden, Chair of the Legislation Review Committee presented on items 11a to 11c.

a) Committee Update

Registration Committee

Jeremy Walden, Chair of the Registration Committee, reported that the committee met on October 10 via teleconference to review registration cases.

Discipline Committee

Jeremy Walden, Chair of the Discipline Committee, reported that there are three ongoing files being reviewed by the committee.

Legislation Review Committee (Appendix 7)

Jeremy Walden, Chair of the Legislation Review Committee provided an update on the activities of the Legislation Review Committee in his presentation.

b) Drug Schedules Regulation: Scheduling by Reference

It was moved and seconded that the Board:

Direct the Registrar to pursue drug scheduling by reference to federal legislation and the National Drug Schedules established by the National Association of Pharmacy Regulatory Authorities (NAPRA), with respect to the Drug Schedules Regulation.

CARRIED

c) Professional Practice Policy-66: Amendment to Training Requirements

It was moved and seconded that the Board:

(1) *Approve amendments to Professional Practice Policy-66 Opioid Agonist Treatment (PPP-66) to align with a new opioid agonist treatment training program for pharmacy, as circulated.*

(2) *Amend the following policy guides to incorporate consequential and housekeeping amendments, as circulated:*

- *PPP-66 Policy Guide – Methadone Maintenance Treatment (2013)*
- *PPP-66 Policy Guide – Buprenorphine/Naloxone Maintenance Treatment (2018),*
- *PPP-66 Policy Guide – Slow Release Oral Morphine Maintenance Treatment (2018)*

CARRIED

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12. DEVELOPING A PHARMACY PROFESSIONAL MASTER'S DEGREE PROGRAM IN A CHANGING EDUCATIONAL LANDSCAPE (Appendix 8)

Dr. Patricia Gerber, Director of Degree Programs for Pharmacist at the University of British Columbia provided an overview of the current efforts to develop a new Pharmacy Professional Master's degree program at UBC in response to the evolving landscape of Pharmacy education, expansion of Pharmacists roles and the advancement of practice.

13. HEALTH CANADA'S PROBLEMATIC PRESENTATION PRESCRIPTION DRUG USE INITIATIVE (Appendix 9)

Angela Lina, Compliance and Enforcement Officer and Acting Team Lead of the Western Region Problematic Prescription Drug Use (PPDU), Controlled Substances Program of Health Canada presented on the PPDU initiative and provided an overview of the Community Pharmacy inspections process.

14. PHARMACIST PROVIDING ANTI-PSYCHOTIC DEPOT INJECTIONS (Appendix 10)

Registrar Nakagawa presented on a recent request to delegate the authority to administer anti-psychotic depot injections from a medical practitioner to pharmacists from Pro-Health Pharmacy in Chilliwack B.C in response to addressing a gap in the mental health care in the Chilliwack area.

It was moved and seconded that the Board:
Approve the delegation request to authorize pharmacists from Pro-Health Pharmacy to administer anti-psychotic depot injections.

CARRIED

15. CLEAR REGULATORY EXCELLENCE AWARD – COLLEGE OF PHARMACISTS OF BC (Appendix 11)

Registrar Nakagawa provided an overview of the mission and mandate of the Council on Licensure, Enforcement & Regulation (CLEAR). The College of Pharmacists of BC was presented the 2018 Regulatory Excellence Award in recognition of work our pharmacy security regulations.

16. ITEMS BROUGHT FORWARD FROM CONSENT AGENDA

Item 4b.x. Governance Committee: Committee Member Appointments
To correct the motion to remove Jeremy Walden as a member of the Discipline Committee as he would like to remain on the Discipline Committee and there is an ongoing Discipline file requiring his involvement.

It was moved and seconded that the Board:
Appoint Jeremy Walden as member of the Discipline Committee.

CARRIED

ADJOURNMENT

Chair Barry adjourned the meeting at 3:12pm on November 23, 2018.

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4. 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. Compliance Certificate
    b. Risk Register November 2018
    c. Current Strategic Plan Update
    d. Action Items & Business Arising
iii. September 14, 2018 Draft Board Meeting Minutes
iv. Committee Updates
v. Audit and Finance Committee: Finance Report: September Financials
vi. Practice Review Committee: Phase 1 and 2 Update
vii. Legislation Review Committee
    a. Telepharmacy Licence Requirements – Removal of Schedules "C" and "E" **[DECISION]**
    b. Drug Schedules Regulation – Housekeeping Amendment **[DECISION]**
    c. Drug Schedules Regulation – Cannabinoids **[DECISION]**
viii. Approval of September 13, 2018 Committee of the Whole Meeting Minutes **[DECISION]**
ix. Approval of 2019 Board Meeting Schedule **[DECISION]**
x. Governance Committee: Committee Member Appointments **[DECISION]**

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4.b.i. Chair's Report

INFORMATION ONLY

Chair's Report of Activities

This will be my final report as Board Chair for the term Nov 2017 to Nov 2018. Thank you for the opportunity - it has truly been a privilege to serve in this capacity. I will be finishing the final year of my election term by serving on committees in 2019.

Since the previous Board Meeting report (Sept 2018), I have been involved in the following activities as Board Chair:

General Administration

- Communications for Board Strategic Planning Session (planning)
- Communications for On-boarding of new board (planning for Nov changeover of board and for training on topics such as governance for future boards)
- Communications with IT for board portal design and access for future boards (planning)
- Public Board Reappointment Report sent (for Public Members finishing terms)
- Attended regular meetings with Registrar, Deputy Registrar, Vice-Chair on general Board related items, on CPBC related items, and on AGM planning
- Reviewed agendas and minutes
- Election call-out messaging

Conference/Meetings/AGM on behalf of CPBC

- BC Health Regulators Fall Symposium
- Pharmasave Regional Meeting – Presented an Update on College Activities
- College of Pharmacists of BC AGM (to be completed on Nov 22nd)

Committee/Group Involvement

- Governance Committee
- Legislation Review Committee
- Registrar Evaluation Task Group and Process Rollout (Completion of one cycle and planning and rollout of next cycle)

Registrant/Public Engagement Understanding

- Answered general questions from registrants and public and other BCHR members including newly elected CPBC board members (phone and in person) about roles of committee members, what are the roles of board members, what occurs in planning for public, linked individuals to departmental emails to answer questions

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Compliance Certificate

We have reviewed the College's official records and financial reports and we certify that the College has met its legal obligations with respect to the following:

Annual Report - Filed June 29, 2018

Non-profit Tax Return – Mailed August 30, 2018

Non-profit Information Return – Filed August 30, 2018

Employee statutory payroll deductions – remitted to Canada Revenue Agency – all remittances are current.

Employee pension plan remittances – all remittances are current.

WorkSafeBC BC assessments – all remittances are current.

Sales Taxes – all remittances are current.

Investments – invested as per policy.

Bank signing authority documents – current as per policy.

Insurance – all insurance policies are up to date.

Business Licence – current.

Signed by:

Bob Nakayama
Registrar

M. O'Callaghan
Chief Operating Officer

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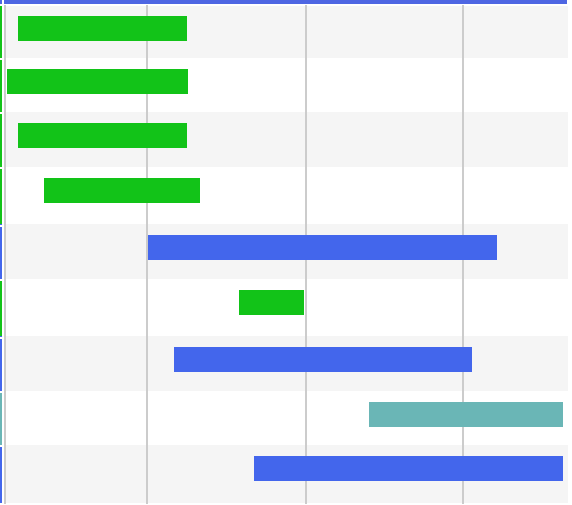
39
ACTION ITEMS

69%
ACTION ITEM COMPLETION

COLLEGE OF BC PHARMACISTS PLAN

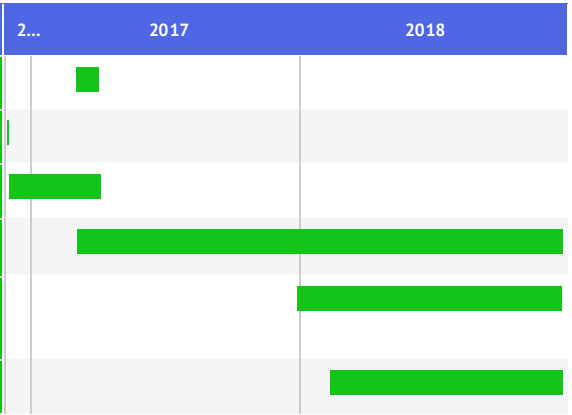
LEGISLATIVE STANDARDS & MODERNIZATION

Action Item	Owner	Current Completion
Implement PODSA ownership changes (Phase 1) by 1st Apr 2018	Director of Registration, Licensure & Pharmanet	100% -
→ Implement revised bylaw by 1st Apr 2018	Director of Policy and Legislation	100% -
→ Streamline business processes by 1st Apr 2018	Director of Registration, Licensure & Pharmanet	100% -
→ Complete communications and engagement activities by 30th Apr 2018	Director of Communications	100% -
Implement PODSA Modernization (Phase 2) by 31st Mar 2020	Director of Registration, Licensure & Pharmanet	10% 5% ahead
→ Update and re-scope entire PODSA Phase 2 project by 31st Dec 2018	Director of Registration, Licensure & Pharmanet	100% -
→ Implement revised bylaw (POSDA Phase2) by 31st Jan 2020	Director of Policy and Legislation	35% 2% behind
→ Streamline business processes by 31st Aug 2020	Chief Operating Officer	0% -
→ Complete communications and engagement activities (PODSA 2) by 31st Aug 2020	Director of Communications	30% 20% ahead



PROFESSIONAL EXCELLENCE

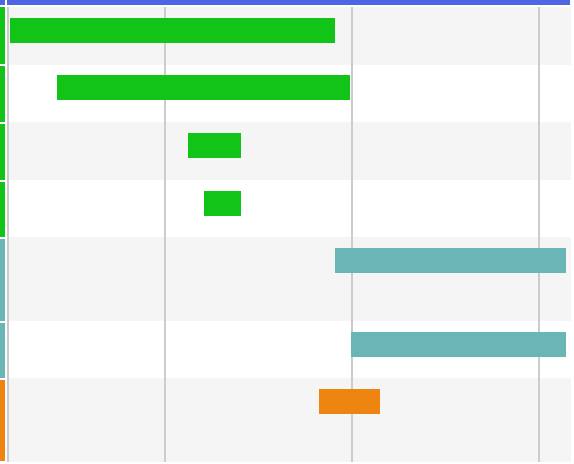
Action Item	Owner	Current Completion
Implement Hospital PRP by 1st Apr 2017	Director PR & QA	100% -
→ Develop Hospital PRP program by 26th Nov 2016	Director PR & QA	100% -
→ Launch Hospital PRP program by 3rd Apr 2017	Director PR & QA	100% -
Complete Implementation of Methadone Action Plan by 31st Dec 2018	Deputy Registrar	100% -
→ Provide recommendations to the board based on findings of MMT inspections and undercover operations. by 31st Dec 2018	Deputy Registrar	100% -
→ Complete legal elements by 31st Dec 2018	Director of Policy and Legislation	100% -



Manage inspections by 31st Dec 2018	Deputy Registrar	100% -

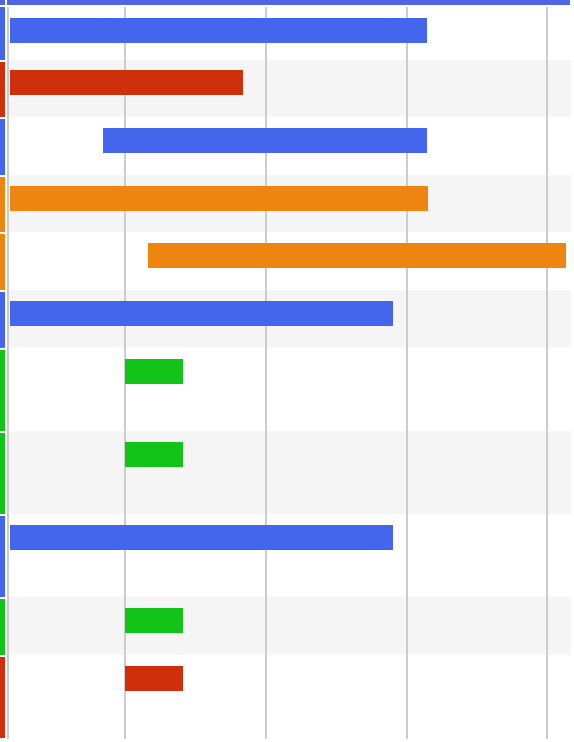
DRUG THERAPY ACCESS & MONITORING

Action Item	Owner	Current Completion
Recommend to the Minister of Health that pharmacists be granted the authority to prescribe by 30th Nov 2018	Director of Registration, Licensure & Pharmanet	100% -
Develop framework/proposal for pharmacist prescribing for submission to the Minister of Health by 31st Dec 2018	Director of Registration, Licensure & Pharmanet	100% -
Complete communication and engagement activities by 31st May 2018	Director of Communications	100% -
Submit Proposal for Pharmacist Prescribing to Minister of Health by 31st May 2018	Director of Registration, Licensure & Pharmanet	100% -
Seek greater access to patient lab values to enhance pharmacists' ability to provide quality, timely service to patients by 29th Feb 2020	Director of Registration, Licensure & Pharmanet	0% -
Complete communications and engagement activities by 29th Feb 2020	Director of Communications	0% -
Develop and submit framework/proposal document outlining a strategy for how to create access to Patient Lab Values by 28th Feb 2019	Director of Registration, Licensure & Pharmanet	0% 11% behind



ORGANIZATIONAL EXCELLENCE

Action Item	Owner	Current Completion
Update IT infrastructure by 28th Feb 2020	Chief Operating Officer	54% 3% behind
Implement IT updates required by PODSA Modernization (Phase 1) by 31st Oct 2018	Chief Operating Officer	90% 10% behind
Implement IT Department organization, processes and procedures by 29th Feb 2020	Chief Operating Officer	80% 36% ahead
Implement Enterprise Content Management system by 29th Feb 2020	Chief Operating Officer	35% 22% behind
Enhance public safety through ensuring Practice Review Program systems needs are addressed by 28th Feb 2021	Chief Operating Officer	10% 14% behind
Enhance organizational best practices to obtain silver certification from Excellence Canada by 29th Nov 2019	Chief Operating Officer	80% 18% ahead
Develop human resources / wellness policies and procedures (plans or guidelines) required to attain Silver certification by 1st Jun 2018	Chief Operating Officer	100% -
Develop Governance and Leadership policies and success indicators required to attain Silver certification by 1st Jun 2018	Chief Operating Officer	100% -
Develop organizational policies and procedures (plans or guidelines) required to attain Silver certification by 29th Nov 2019	Chief Operating Officer	90% 28% ahead
Define customer segments and develop a customer experience plan, including key partners by 1st Jun 2018	Chief Operating Officer	100% -
Develop a methodology for regularly identifying and capturing key processes, including Project Management, Change Management and Procurement by 1st Jun 2018	Chief Operating Officer	90% 10% behind



Register with Excellence Canada for official verification by 31st Jan 2019	Chief Operating Officer	0% -	
Review gap analysis and assign secondary action plan projects to teams by 30th Jun 2018	Chief Operating Officer	100% -	
Complete secondary projects by 1st Sep 2018	Chief Operating Officer	100% -	
Facilitate Excellence Canada verification team visits and focus groups by 31st May 2019	Chief Operating Officer	0% -	
Receive Silver Certification from Excellence Canada by 29th Nov 2019	Chief Operating Officer	0% -	

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4.b.ii. Registrar's Update
d) Action Items & Business Arising

INFORMATION ONLY

	MOTIONS/ACTION ITEMS	RELEVANT BOARD MEETING	STATUS UPDATE
1.	Motion: 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. **Status: Recommended implementation plan has been communicated to registrants. College staff will bring forward a proposed motion for the Board's consideration, to officially adopt the Standards, closer to the May 2021 effective date.**	04-2017	IN PROGRESS
2.	Motion: Direct the Registrar to develop bylaws and/or practice standards for Medication Reviews and require mandatory training for pharmacists who wish to conduct them. To be prioritized by the Legislation Review Committee for implementation. **Status: Research and analysis has begun, in accordance with the College's Legislation Operational Plan.**	06-2017	IN PROGRESS
3.	Motion: Direct the Registrar to explore potential alternatives to the College's existing quality management requirements, including mandatory medication error reporting to an independent third party. **Status: Research and analysis has completed; item added to the November 2018 Board meeting agenda.**	11-2017	IN PROGRESS
4.	Motion #1: Direct the Registrar to explore the development of new requirements for the security of information in local pharmacy computer systems; **Status: This issue has been identified and Policy & Legislation Department is aware. We have addressed some of the issues in the new electronic record keeping PPP.**	02-2018	IN PROGRESS

	MOTIONS/ACTION ITEMS	RELEVANT BOARD MEETING	STATUS UPDATE
	Motion #2: If new requirements are deemed necessary, direct the Registrar to propose that the Ministry of Health consider amending their PharmaNet Professional and Software Compliance Standards document to enhance the software security requirements of the local pharmacy computer systems." **Status: David Pavan has had discussions with the Ministry on updating the SCS document. He has been informed, during a meeting, that this update is underway. In addition, the Ministry is implementing the PRIME project.**		
5.	Motion: Direct the Registrar to proceed with engagement on the Strategic Plan Themes developed by the Strategic Plan Working Group. **Status: The College's Communications and Engagement Department is reviewing all the content provided by the Board and developing the survey for the public, registrants and other stakeholders which will be completed by the end of 2018.**	09-2018	IN PROGRESS

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4.b.iii. September 14, 2018 Draft Board Meeting Minutes

DECISION REQUIRED

Recommended Board Motion:

Approve the September 14, 2018 Draft Board Meeting Minutes as circulated.

Appendix	
1	http://library.bcpharmacists.org/2_About_Us/2-1_Board/Board_Meeting_Minutes-20180914.pdf

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4.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.

For confidentiality purposes, the Discipline Committee and Inquiry Committee have provided summaries of their meetings, but will not be submitting minutes.

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

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4.b.v. Audit and Finance Committee – Finance Report – September Financials

INFORMATION ONLY

Purpose

To report on the highlights of the September 2018 financial reports.

Background

The September 2018 financial reports reflect **seven 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 with a balance of approximately $1,305,000. Cash is in our Operating Bank account with excess transferred to a Premium Savings account. Investments totalled more than $5.7 million. Payables and accruals amount to just over $540,000; so, we are well-funded by the cash balance.

Revenue

Licensure revenues are right on budget. *Other revenues* (administrative fees, etc.) are over budget but most of the overage is in flow-through funds; so, this is not significant to the operation. Grant revenue is under budget as the one provincial grant anticipated has not been received yet. In total, revenues are over budget by approximately $83,000.

Expenses

Total Year to Date actual expenditures are under budget by $76,580. See the variance analysis which follows for details.

Variance analysis by department:

Department	Budget	Actual	Comment
Board & Registrar's Office	434,646	493,061	Primarily due to timing of events and unbudgeted consulting.
Finance and Administration	2,153,338	2,108,542	
Grant distribution	90,000	127,395	Timing
Registration & Licensure	495,007	573,351	Primarily due to the flow-through funds (off-setting the revenue) and Application Committee meetings.
Quality Assurance	33,705	26,925	Timing
Practice Review	931,288	822,265	Timing and gapping in staffing
Complaints Resolution	959,175	925,391	A large legal invoice re a discipline case received after year-end. Auditors may select to treat as a prior period adjustment.
Policy and Legislation	281,101	257,971	Some of the projects' expenditures will be reallocated here at year-end.
Public Engagement	254,894	219,011	Some activities delayed due to other priorities
Projects	126,400	115,124	Timing
Amortization	231,110	195,118	Timing of development projects
Total Expenses	5,990,664	5,864,154	

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 at September 30, 2018

ASSETS	
Cash and Cash Equivalents	1,305,345
Investments	5,722,777
Receivables	23,154
Prepaid Expense and Deposits	176,261
Current Assets	7,227,536
Investments in College Place Joint Venture	1,575,220
Development Costs	403,759
Property & Equipment	566,707
Non-current Assets	2,545,687
Total Assets	**9,773,223**

LIABILITIES AND NET ASSETS	
Payables and Accruals	540,675
Deferred Revenue	5,065,372
Deferred Contributions	80,711
Total Current Liabilities	5,686,759
Total Net Assets	4,086,464
Total Liabilites and Net Assets	**9,773,223**

College of Pharmacists of BC

Statement of Revenue and Expenses

For the 7 months ended September 30, 2018

	Budget YTD 2018/19	Actual YTD 2018/19	Variance ($) (Budget vs. Actual)	Variance (%) (Budget vs. Actual)
Revenue				
Licensure revenue	4,733,603	4,744,402	10,799	0%
Non-licensure revenue	419,491	491,644	72,153	17%
Transfer from Balance Sheet	644,827	644,827	-	0%
Total Revenue	**5,797,921**	**5,880,873**	**82,951**	1%
Total Expenses Before Amortization	5,759,555	5,669,036	90,519	2%
Amortization	231,110	195,118	35,991	16%
Total Expenses Including Amortization	**5,990,664**	**5,864,154**	**126,510**	2%
Net Surplus/(Deficit) of revenue over expenses	**(192,743)**	**16,718**	**209,461**	

College of Pharmacists of BC

Statement of Revenue

For the 7 months ended September 30, 2018

	Budget YTD 2018/19	Actual YTD 2018/19	Variance ($) (Budget vs. Actual)	Variance (%) (Budget vs. Actual)
Revenue				
Pharmacy fees	1,852,046	1,884,149	32,103	2%
Pharmacists fees	2,428,785	2,445,039	16,253	1%
Technician fees	452,772	415,214	(37,557)	(8%)
Licensure revenue	4,733,603	4,744,402	10,799	0%
Other revenue	101,435	184,931	83,497	82%
Grant Revenue	102,223	90,000	(12,223)	(12%)
Investment income	61,250	76,713	15,463	25%
College Place joint venture income	154,583	140,000	(14,583)	(9%)
Non-licensure revenue	419,491	491,644	72,153	17%
Transfer from Balance Sheet	644,827	644,827	-	0%
Total Revenue	**5,797,921**	**5,880,873**	**82,951**	1%

College of Pharmacists of BC

Statement of Expenses

For the 7 months ended September 30, 2018

	Budget YTD 2018/19	Actual YTD 2018/19	Variance ($) (Budget vs. Actual)	Variance (%) (Budget vs. Actual)
Expenses				
Board and Registrar's Office	434,646	493,061	(58,415)	(13%)
Finance and Administration	2,153,338	2,108,542	44,796	2%
Grant Distribution	90,000	127,395	(37,395)	(42%)
Registration, Licensure and Pharmanet	495,007	573,351	(78,345)	(16%)
Quality Assurance	33,705	26,925	6,781	20%
Practice Reviews	931,288	822,265	109,023	12%
Complaints Resolution	959,175	925,391	33,784	4%
Policy and Legislation	281,101	257,971	23,130	8%
Public Engagement	254,894	219,011	35,883	14%
Projects	126,400	115,124	11,276	9%
Total Expenses Before Amortization	5,759,555	5,669,036	90,519	2%
Amortization	231,110	195,118	35,991	16%
Total Expenses Including Amortization	**5,990,664**	**5,864,154**	**126,510**	2%

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

4.b.vi. Practice Review Committee – Phase 1 and 2 Update

INFORMATION ONLY

Purpose

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

Background

The Practice Review Program is an in-person review of a pharmacy professional's practice and the pharmacy where they work. The program aims to protect public safety by improving compliance with College Bylaws and Professional Practice Policies and ensuring consistent delivery of pharmacy services across British Columbia.

Every pharmacy and pharmacy professional will be reviewed to ensure they meet College standards. The Program's multi-year time frame allows for all pharmacies and pharmacy professionals currently practicing in British Columbia to be reviewed on a cyclical basis. In some cases reviews may occur more frequently in order to address areas of concern.

Transparency is an important element of the Practice Review Program. The results of the Pharmacy Review are shared with the pharmacy manager, and results of all Pharmacy Professionals Reviews are shared confidentially with each individual pharmacist and pharmacy technician.

The Practice Review Program first began in February 2015 and started with reviews in community pharmacy practice settings. The program expanded to include hospital pharmacy practice settings with reviews beginning in April 2017.

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

Practice Review Program Update

OPERATIONS	
Update	**Next Steps**

General
• 2017-18 fiscal year reports
  ○ Investigate potential options for an analyst or statistician to review PRP data
• Determined impact of the new Pharmacy Operations and Drug Scheduling Act (PODSA) on PRP
• Monitoring the Risk Register and updating as needed
	General
	• 2017-18 fiscal year reports
	  ○ Work with an analyst or statistician to review PRP data and develop reports
	• Amend program policies to reflect impact of the new PODSA on PRP
	• Continue to monitor the Risk Register and make updates as needed

Community Practice • Conducted September and October reviews (Appendix 1) • Scheduled November and December reviews • Integrate for implementation, review form for Residential Care services ○ IT fixing Question Bank module to enable addition of review services	Community Practice • Schedule pharmacies for January reviews • Implement review form for Residential Care services once IT fix of Question Bank module is complete • Develop review forms for other services: telepharmacy, central fill, packaging, compounding and other services based on Board direction and resources

Hospital Practice
• Conducted September and October reviews (Appendix 2)
• Scheduled November and December reviews
• Selected pharmacies for January and February reviews
• Pharmacist Compliance Officer Resignation
  ○ Cancelled Pharmacist Reviews scheduled in hospital pharmacies from August – September
  ○ Posted position, interviewed applicants and hired a pharmacist to start December 3rd, 2018
	Hospital Practice
	• Schedule pharmacies for January and February reviews
	• Train new pharmacist Compliance Officer
	• Continue to monitor and adjust policies and processes as needed

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

COMMUNICATIONS & ENGAGEMENT	
Update	**Next Steps**
Community Practice • Drafting new PRP Insights articles	Community Practice • Continue to draft and release PRP Insights articles based on findings from reviews (Appendix 3)
Hospital Practice • Drafted new PRP Insights article ○ Scheduling FAQ for Pharmacy Managers	Hospital Practice • Continue to draft and release PRP Insights articles based on findings from reviews

POLICY & LEGISLATION	
Update	**Next Steps**

General
• Provided feedback on legislation based on findings from reviews
• Provided subject matter expertise (SME) for
  ○ National working group on the National Association of Pharmacy Regulatory Authorities' (NAPRA) Model Standards for Pharmacy Compounding of Non-Sterile Preparations
  ○ Internal working group for Pharmacy Operations and Drug Scheduling Act (PODSA) Modernization
  ○ Medication Error Reporting
	General
	• Continue to provide feedback on legislation based on findings from review
	• Continue to provide SME:
	  ○ Meet with other Provincial Regulatory Authorities (PRA) on the NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations
	  ○ Regular internal working group meetings for PODSA Modernization
	  ○ Medication Error Reporting

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

COMPLAINTS & INVESTIGATIONS	
Update	**Next Steps**
General • Prioritizing pharmacies/registrants for reviews as per requests from the Complaints and Investigations department • Working with the Complaints and Investigations department to review selected pharmacies (to prevent overlap) • Sharing PRP Information as needed	General • Continue to prioritize pharmacies/ registrants for reviews as per requests from the Complaints and Investigations department • Continue to work with Complaints and Investigations Department to review selected pharmacies (to prevent overlap) • Continue to share PRP information as needed

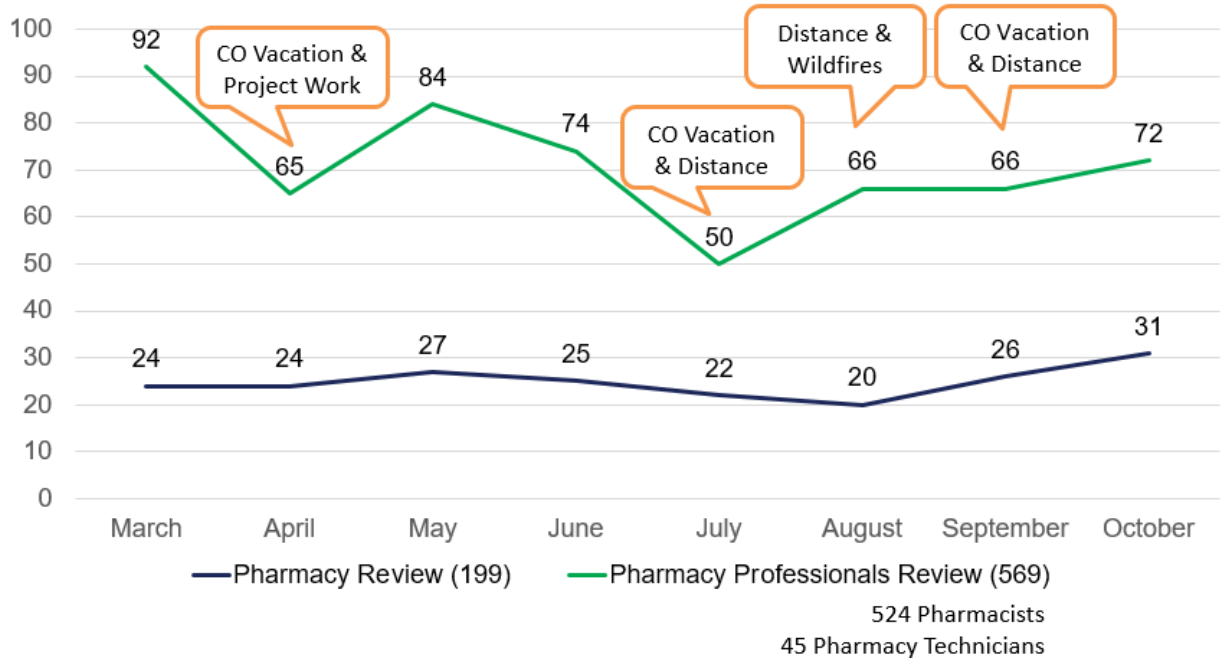
INFORMATION TECHNOLOGY	
Update	**Next Steps**
Community Practice • Fixing Question Bank module in PRP Application ○ Enable addition of review services	Community Practice • User acceptance testing of Question Bank module
Hospital Practice • Provide support as needed	Hospital Practice • Provide support as needed

Appendix	
1	Community Practice Operational Statistics
2	Hospital Practice Operational Statistics
3	PRP Insights Articles for ReadLinks

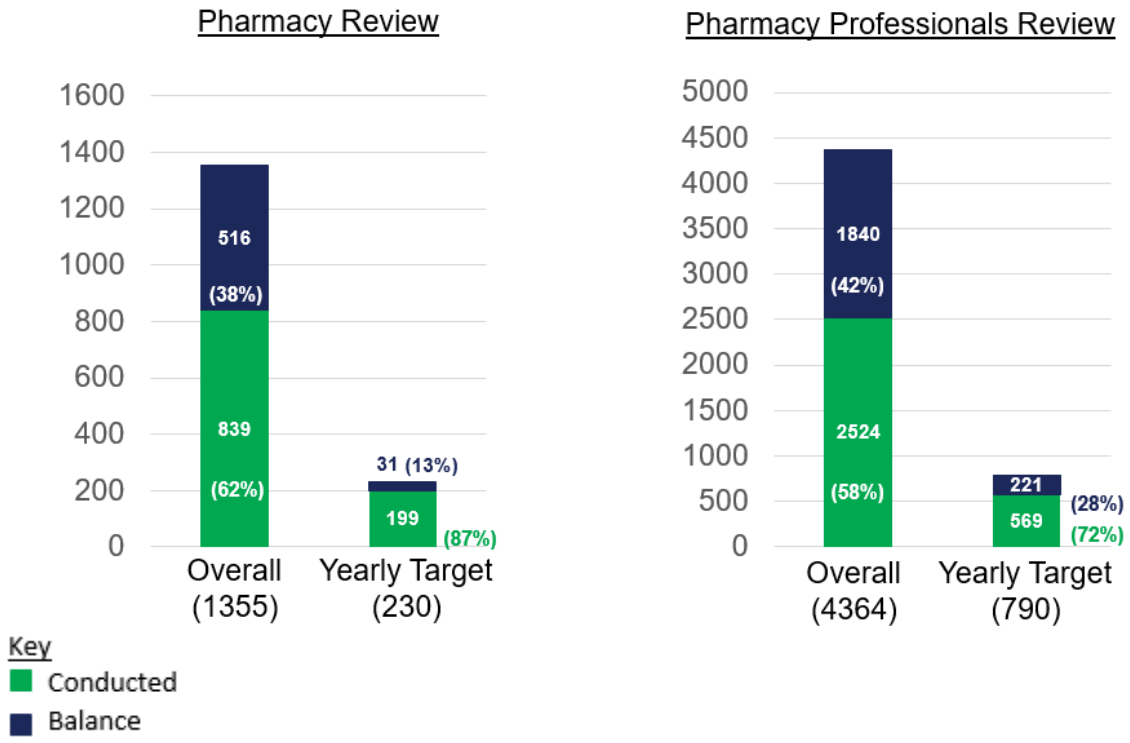
Appendix 1

PRP: Community Practice Operational Statistics
2018-19 Fiscal Year Progress: March 1st, 2018 – October 31st, 2018

Fiscal Year:



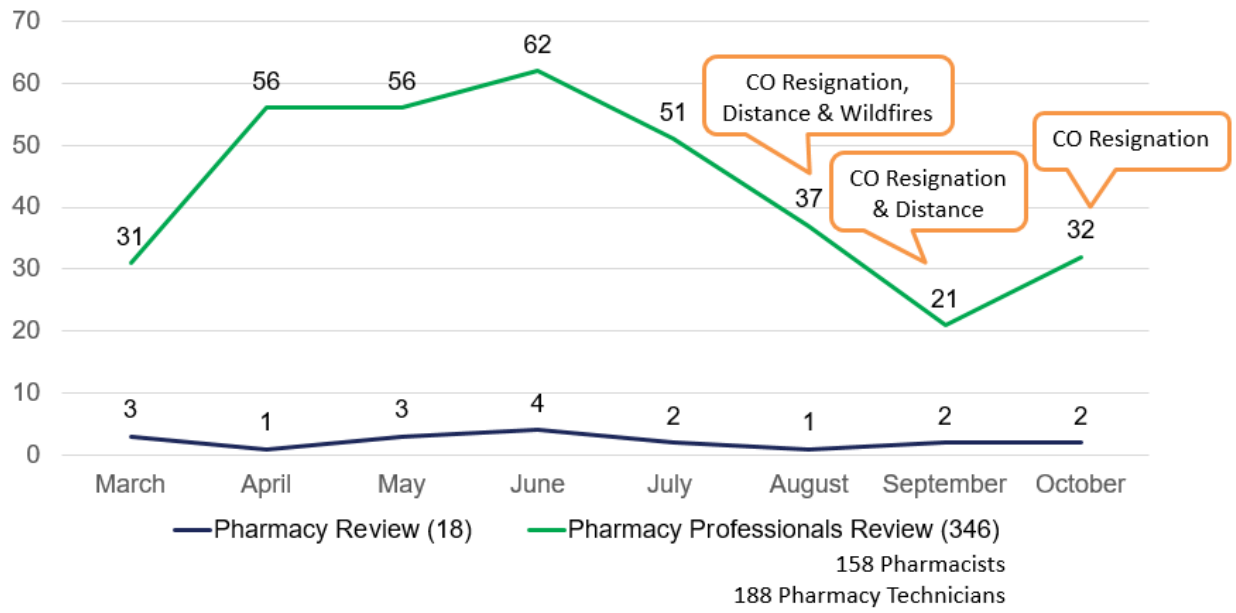
Overall and Fiscal Year:



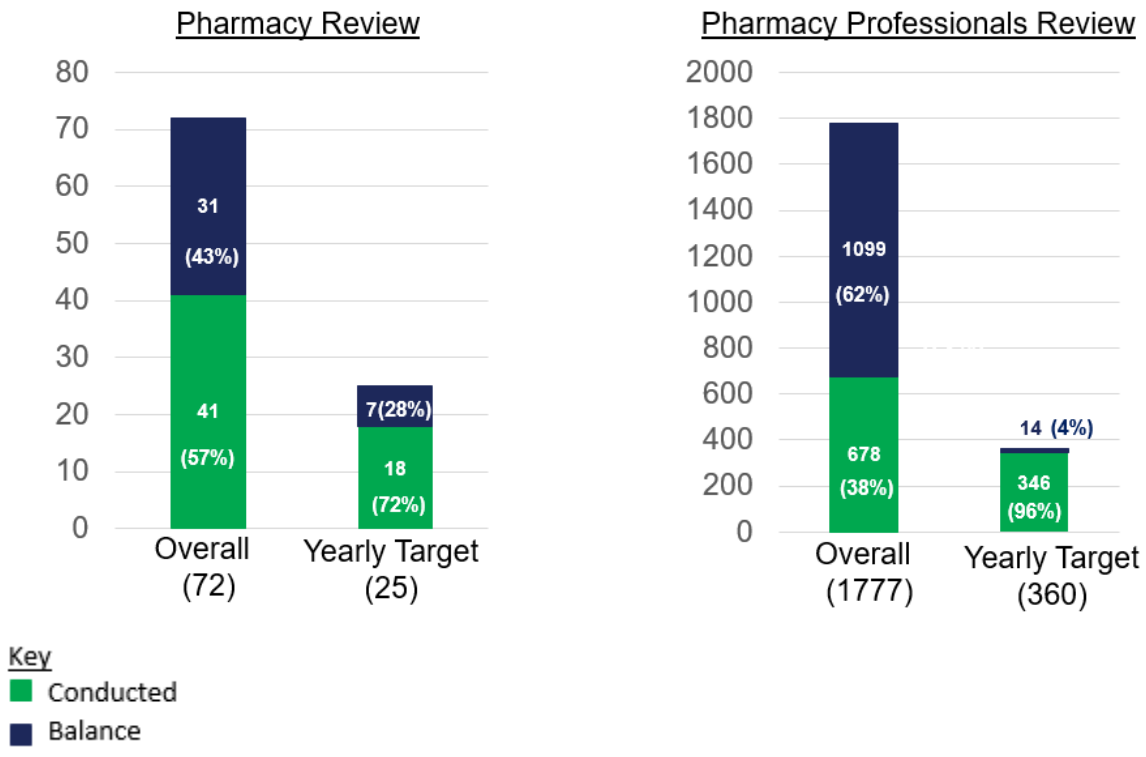
Appendix 2

PRP: Hospital Practice Operational Statistics
2018-19 Fiscal Year Progress: March 1st, 2018 – October 31st, 2018

Fiscal Year:



Overall and Fiscal Year:



PRP: Insights Articles

July 2018 Article: Documentation Requirements for Emergency Prescription Refills

PRP INSIGHTS

Helping Patients Receive Safe and Effective Drug Therapy through Therapeutic Substitutions

PRP INSIGHTS: DOCUMENTATION REQUIREMENTS FOR EMERGENCY PRESCRIPTION REFILLS

In our Practice Review Program, Compliance Officers have come across questions from pharmacists regarding documentation requirements for emergency prescription refills ("emergency supplies"). As per Professional Practice Policy 31: Emergency Prescription Refills:

- *Pharmacists must use their CPBC pharmacist registration numbers in the PharmaNet practitioner ID field to identify the responsible decision-maker when providing an emergency supply of a drug to a patient*
- *Pharmacists must document in the client's record any emergency refill of the prescription, the rationale for the decision, and any appropriate follow-up plan*

Confusion has occurred around what is sufficient documentation for a **rationale** and **follow-up plan**:

Rationale: This refers to the reasoning behind your decision. Simply stating "continuity of care" alone is insufficient because that is already an assumed requirement of an emergency prescription refill and does not give any additional information about the scenario or why you made the decision. Every scenario is different and the details affect whether it's appropriate to provide an emergency supply at all, and if so how much to give. For example, the patient may have run out of medication, or the patient goes to the pharmacy for an authorized refill of a valid prescription but PharmaNet returns the message "101 Prescriber not found".

> *Example of rationale documentation: *"Patient ran out of medication, her doctor is away this weekend. The dose is stable and the drug is currently effective with no issues"*

Follow-up plan: This refers to the need of documenting what happens after the emergency supply is used up. Lacking a documented follow-up plan leaves the situation open-ended, where there's no resolution or plan of action for patient care and continuity of therapy. For example, is the patient going to see the doctor for a new prescription? Does the patient have an appointment with the doctor or knows to make one before the emergency supply is used up? Or is the patient expecting the pharmacy to contact the doctor for a refill? Documentation of a follow-up plan removes ambiguity and serves to reinforce the rationale and appropriate course of action.

> *Example of follow-up plan documentation: *"Patient will make an appointment to see her doctor next week for a new prescription"*

*The above documentation examples are for illustrative purposes only. The level of detail expected varies with each scenario and is based on professional judgement.

Previous Articles:

May 2018 Article: Scheduling and Preparing for your Practice Review in Community Pharmacies

December 2017 Articles: Patient ID in Community Pharmacy , Profile Check in Community Pharmacy , Counseling in Community Pharmacy, Documentation in Community Pharmacy

November 2017: New PRP Focus Areas

July 2017: New PRP Focus Areas for Pharmacy Technicians in Community Practice Coming Soon

May 2017: Prepare for Your Next Practice Review with the New PRP Support Tools!

April 2017: Advice from our Compliance Officers on your next review

March 2017: Compliance Officers offer individual perspectives on practice reviews

February 2017: Meet our Compliance Officers

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
November 23, 2018

4b.vii. Legislation Review Committee
a) Telepharmacy Licence Requirements – Removal of Schedules "C" and "E"

DECISION REQUIRED

Recommended Motion:

Approve the following resolution:

"RESOLVED THAT, in accordance with the authority established in section 21(1) of the Pharmacy Operations and Drug Scheduling Act, and subject to the requirements in section 21(8) of the Pharmacy Operations and Drug Scheduling Act, the Board of the College of Pharmacists of BC approves the proposed draft bylaws of the College of Pharmacists of British Columbia relating to telepharmacy licence requirements and the removal of Schedules "C" and "E" for public posting, as circulated."

Purpose

To consider approval of the following for public posting purposes:

- Amending the *Pharmacy Operations and Drug Scheduling Act* (PODSA) Bylaws to replace references to Schedules "C" and "E" with a reference to physical requirements; and,
- Repeal Schedules "C" and "E" under the PODSA Bylaws.

Background

The PODSA Bylaws outline requirements for pharmacy licensure, including telepharmacies. As part of the licensure process, an applicant for a new telepharmacy licence must provide a diagram, photos and videos of the proposed site to demonstrate that it complies with the physical requirements for a telepharmacy as outlined in the College's Bylaws and policies. This is consistent with the process for a new community pharmacy licence.

Currently, s.12(c) and (e) of the PODSA Bylaws requires that new telepharmacy applications include diagrams, photos and videos confirming compliance with Schedules "C" and "E", where appropriate, under the PODSA Bylaws. Schedules "C" and "E" are lists of all existing relevant physical requirements for telepharmacies throughout the College's Bylaws and policies.

There are no similar Schedules for applicants for new community pharmacies. Instead, s.3(2)(c) and (e) under the PODSA Bylaws requires that new community pharmacy applications include diagrams, photos and videos "…demonstrating compliance with the physical requirements in the bylaws and applicable policies". Detailed information on how to submit a community pharmacy application is outlined on the College website[1].

Discussion

The use of Schedules "C" and "E" in the PODSA Bylaws pose the following key issues:

- When telepharmacy physical requirements are amended, the Schedules must also be consequentially amended. This requires public posting and filing with the Ministry of Health every time a relevant amendment is made.
- The use of Schedules "C" and "E" for telepharmacy applications is not consistent with the process for community pharmacies.

Proposed Amendments

The proposed amendments involve repealing Schedules "C" and "E" and replacing references to them in the PODSA Bylaws (i.e., s.12(c) and (e)) with a requirement that applicants demonstrate compliance with the physical requirements in the bylaws and applicable policies. This is consistent with the approach for community pharmacy licence applicants.

For telepharmacy applicant convenience, a checklist can be created comprised of all relevant physical requirements in the Bylaws and policies. This checklist tool could be updated quickly, as it would not require public posting and filing should physical requirements change.

Recommendation

That the Board approve the proposed bylaws for public posting, as presented.

[1] See: http://www.bcpharmacists.org/community-pharmacy

Next Steps

If the Board approves the proposed bylaws for public posting, the approved amendments would then be publicly posted on the College's website for 90 days. If no substantive revisions are made to the draft bylaws, then at the April 2019 Board meeting, the College would propose that the draft bylaws be filed with the Ministry of Health.

If the bylaw amendments are approved for filing at the April 2019 Board meeting, the amended bylaws would come into force in June 2019. The College would inform its registrants of the changes via communications tools, such as ReadLinks articles and Frequently Asked Questions articles on the College's website.

Appendix	
1	PODSA Bylaws (proposed amendments in track changes)
2	Schedules "C" and "E" (proposed to be repealed)

Pharmacy Operations and Drug Scheduling Act - BYLAWS

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~~Schedule "C" – Telepharmacy Diagram and Photos/Videos~~

Schedule "D" – Hospital Pharmacy Diagram

~~Schedule "E" – Telepharmacy Additional Photos/Videos~~

Schedule "F" – Telepharmacy/Community Licenced Sites

Schedule "G" – Telepharmacy Staff Exempted Sites

Schedule "H" – Telepharmacy Rural and Remote Communities

FORMS

1A. Application for New Pharmacy Licence – Community

1C. Application for New Pharmacy Licence – Hospital

1E. Application for Hospital Satellite

1F. Application for New Pharmacy Licence – Pharmacy Education Site

2. Application for New Telepharmacy Licence - Community

2A. Application for Pharmacy Licence Renewal – Community

2C. Application for Pharmacy Licence Renewal – Hospital

2F. Application for Pharmacy Licence Renewal – Pharmacy Education Site

3A. Application for Pharmacy Licence Reinstatement – Community

3C. Application for Pharmacy Licence Reinstatement – Hospital

Commented [A1]: Schedule "C" is proposed to be removed, and replaced by amended language outlined in section 12 of the PODSA Bylaws.

Commented [A2]: Schedule "E" is proposed to be removed, and replaced by amended language outlined in section 12 of the PODSA Bylaws.

3F. Application for Pharmacy Licence Reinstatement – Pharmacy Education Site
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12. Application for Telepharmacy Licence Renewal - Community

Definitions

1. In these bylaws:

"*Act*" means the *Pharmacy Operations and Drug Scheduling Act*;

"attestation" means the attestation referred to in section 2(2)(d)(ii) of the *Act*;

"British Columbia Company Summary" means a summary issued by the BC Corporate Registry Services;

"central pharmacy" means a community pharmacy that holds one or more telepharmacy licences;

"Central Securities Register" means the register maintained under section 111(1) of the *Business Corporations Act* [SBC 2002] C.57 as amended from time to time;

"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;

"criminal record history" means the results of a criminal record search of Royal Canadian Mounted Police and local police databases, in the form approved by the board from time to time;

"direct owner" has the same meaning as in section 1 of the *Act*;

"**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 18(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 *Act*;

"electronic signature" means

(a) information in electronic form that a person has created or adopted in order to sign a record, other than with respect to a prescription signed by a full pharmacist

for the purpose of prescribing, that is in, attached to or associated with a record, is secure and is only reproducible and used by that person; and,

(b) with respect to a prescription signed by a full pharmacist for the purpose of prescribing, the electronic signature must meet the requirements of paragraph (a) and must be a unique mark personally applied by that pharmacist;

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

"health authority" includes

(a) a regional health board designated under the *Health Authorities Act*,
(b) the Provincial Health Services Authority,
(c) First Nations Health Authority, and
(d) Providence Health Care Society.

"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;*

"indirect owner" has the same meaning as in section 1 of the *Act*;

"manager" has the same meaning as in section 1 of the *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 Professions Act*;

"pharmacy" has the same meaning as in section 1 of the *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;

"record" has the same meaning as the definition of record in Schedule 1 of the *Freedom of Information and Protection of Privacy Act*;

"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 set out in Schedule "H";

"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*;

"signature" on a record means either a handwritten signature in ink or an electronic signature;

"support person" has the same meaning as in the *Act* except that it does not include a pharmacy technician;

"telepharmacy" means a pharmacy located in a rural and remote community that is licenced to provide pharmacy services;

"**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.

PART I – Pharmacy Licences

Licence Types

2. (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.

New Community Pharmacy Licence

3 (1) Applicants for a new community pharmacy licence must submit an application consistent with the type of ownership under section 5(2) of the *Act*.

(2) A direct owner may apply for a new community pharmacy licence by submitting:

(a) an application in Form 1A;

(b) the fee(s) 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 pharmacy, demonstrating compliance with the physical requirements in the bylaws and applicable policies;

(d) Form 10;

(e) photographs or video demonstrating compliance with the physical requirements in the bylaws and applicable policies; and

(f) a copy of the pharmacy's current business licence issued by the jurisdiction, if applicable.

(3) In addition to the requirements in subsection (2), a direct owner described in section 5(2)(b) or (c) of the *Act* must submit:

(a) Form 7;

(b) a copy of the power(s) of attorney, if applicable;

(c) a copy of the Certificate of Incorporation, and

(d) a copy of the Notice of Articles, or

(e) a copy of the British Columbia Company Summary, whichever is current;

(f) a certified true copy of the Central Securities Register if a direct owner is or includes a corporation that is not traded publicly; and

(g) a certified true copy of the Central Securities Register for a parent corporation if a direct owner is a subsidiary corporation.

(4) If an indirect owner is a company incorporated under the *Company Act* or the *Business Corporations Act* that is not traded publicly, the following must be submitted for that company:

(a) a copy of the power(s) of attorney, if applicable;

(b) a copy of the Certificate of Incorporation, and

(c) a copy of the Notice of Articles, or

(d) a copy of the British Columbia Company Summary, whichever is current; and

(e) a certified true copy of the Central Securities Register.

(5) Proof of eligibility in Form 5 and a criminal record history in accordance with section 14 must be submitted by the following:

(a) any pharmacist who is a direct owner described in section 5(2)(a) of the *Act*;

(b) indirect owner(s); and

(c) the manager.

Community Pharmacy Licence Renewal

4. (1) A direct owner may apply to renew a community pharmacy licence no later than 30 days prior to the expiry of the existing pharmacy licence by submitting:

(a) an application in Form 2A;

(b) the fee(s) specified in Schedule "A";

(c) a copy of the pharmacy's current business licence issued by the jurisdiction, if applicable; and

(d) a copy of the current British Columbia Company Summary, if a direct owner is or includes a corporation.

(2) At the time of the renewal application, an attestation in Form 5 must be submitted by:

(a) any pharmacist who is a direct owner described in section 5(2)(a) of the *Act*;

(b) indirect owner(s); and

(c) the manager.

(3) An application submitted later than 30 days prior to the expiry of the pharmacy licence is subject to the fee(s) specified in Schedule "A".

4.1. The first application to renew an existing licence, submitted after the *Pharmacy Operations and Drug Scheduling Amendment Act 2016* comes into force, is an application for a new community pharmacy licence under section 3 but the requirements in subsections 3(2)(c),(d) and (e) do not apply.

Community Pharmacy Licence Reinstatement

5. (1) A direct owner may apply to reinstate a community pharmacy licence that has been expired for 90 days or less by submitting:

(a) an application in Form 3A;

(b) the fee(s) specified in Schedule "A";

(c) a copy of the pharmacy's current business licence issued by the jurisdiction, if applicable; and

(d) a copy of the current British Columbia Company Summary, if the direct owner is or includes a corporation.

(2) At the time of the reinstatement application, an attestation in Form 5 must be submitted by:

(a) any pharmacist who is a direct owner described in section 5(2)(a) of the *Act*;

(b) indirect owner(s); and

(c) the manager.

5.1. The first application to reinstate an existing licence, submitted after the *Pharmacy Operations and Drug Scheduling Amendment Act 2016* comes into force, is an application for a new community pharmacy licence under section 3 but the requirements in subsections 3(2)(c),(d) and (e) do not apply.

New Hospital Pharmacy Licence

6. (1) Applicants for a new hospital pharmacy licence must submit an application consistent with the type of ownership under section 5(2) of the *Act*.

(2) A direct owner may apply for a new hospital pharmacy licence by submitting:

(a) an application in Form 1C;

(b) the fee(s) specified in Schedule "A"; and

(c) a diagram professionally drawn to a scale of ¼ inch equals 1 foot, including the measurements and entrances of the pharmacy, confirming compliance with Schedule "D".

(3) The manager must submit an attestation in Form 5 and a criminal record history in accordance with section 14.

(4) 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.

Hospital Pharmacy Licence Renewal

7. (1) A direct owner may apply to renew a hospital pharmacy licence no later than 30 days prior to the expiry of the existing pharmacy licence by submitting:

(a) an application in Form 2C; and

(b) the fee(s) specified in Schedule "A".

(2) At the time of the renewal application, the manager must submit an attestation in Form 5.

(3) An application submitted later than 30 days prior to the expiry of the pharmacy licence is subject to the fee(s) specified in Schedule "A".

7.1. The first application to renew an existing hospital licence, submitted after the *Pharmacy Operations and Drug Scheduling Amendment Act 2016* comes into force, is an application for a new hospital pharmacy licence under section 6 but the requirement in subsection 6(2)(c) does not apply.

Hospital Pharmacy Licence Reinstatement

8. (1) A direct owner may apply to reinstate a pharmacy licence that has been expired for 90 days or less by submitting:

(a) an application in Form 3C; and

(b) the fee(s) specified in Schedule "A".

(2) At the time of the reinstatement application, the manager must submit an attestation in Form 5.

8.1. The first application to reinstate an existing licence, submitted after the *Pharmacy Operations and Drug Scheduling Amendment Act* 2016 comes into force, is an application for a new hospital pharmacy licence under section 6 but the requirement in subsection 6(2)(c) does not apply.

New Pharmacy Education Site Licence

9. (1) Applicants for a new pharmacy education site licence must submit an application consistent with the type of ownership under section 5(2) of the *Act*.

(2) A direct owner may apply for a new pharmacy education site licence by submitting:

(a) an application in Form 1F; and

(b) the fee(s) specified in Schedule "A".

(3) The manager must submit an attestation in Form 5 and a criminal record history in accordance with section 14.

Pharmacy Education Site Licence Renewal

10. (1) A direct owner may apply to renew a pharmacy education licence no later than 30 days prior to the expiry of the existing pharmacy licence by submitting:

(a) an application in Form 2F; and

(b) the fee(s) specified in Schedule "A".

(2) At the time of the renewal application, the manager must submit an attestation in Form 5.

(3) An application submitted later than 30 days prior to the expiry of the pharmacy licence is subject to the fee(s) specified in Schedule "A".

10.1. The first application to renew an existing licence, submitted after the *Pharmacy Operations and Drug Scheduling Amendment Act* 2016 comes into force, is an application for a new pharmacy education site licence under section 9.

Pharmacy Education Site Licence Reinstatement

11. (1) A direct owner may apply to reinstate a pharmacy education site licence that has been expired for 90 days or less by submitting:

(a) an application in Form 3F; and

(b) the fee(s) specified in Schedule "A".

(2) At the time of the reinstatement application, the manager must submit an attestation in Form 5.

11.1. The first application to reinstate an existing licence, submitted after the *Pharmacy Operations and Drug Scheduling Amendment Act* 2016 comes into force, is an application for a new pharmacy education site licence under section 9.

New Telepharmacy Licence

12. A direct owner of a community pharmacy may apply for a new telepharmacy licence by submitting:

(a) an application in Form 2;

(b) the fee(s) 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, demonstrating

Commented [A3]: Proposed that Schedule "C" be removed and this requirement be amended to be more similar to s.3(2)(c) of the PODSA Bylaws. A checklist tool is be developed to help applicants understand what the applicable physical requirements are.

compliance with the physical requirements in the bylaws and applicable policies~~confirming compliance with Schedule "C"~~;

(d) Form 11;

(e) photographs or video demonstrating compliance with the physical requirements in the bylaws and applicable policies~~confirming compliance with Schedules "C" and "E"~~; and

(f) if applicable, a copy of the telepharmacy's business licence issued by the jurisdiction in which the telepharmacy is located.

Commented [A4]: Proposed that Schedules "C" and "E" be removed and this requirement be amended to be more similar to s.3(2)(e) of the PODSA Bylaws. A checklist tool is be developed to help applicants understand what the applicable physical requirements are.

Telepharmacy Licence Renewal

13. A direct owner may apply to renew a telepharmacy licence no later than 30 days prior to the expiry of the existing telepharmacy licence by submitting:

(a) an application in Form 12;

(b) the fee(s) specified 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.

Criminal Record History of Direct Owner, Indirect Owner(s) and Manager

14. A direct owner, indirect owner(s) and a manager must submit a criminal record history pursuant to section 5.1 of the *Act*, in the form approved by the board from time to time.

Unlawful Operation

15. (1) Pursuant to section 7(1) of the *Act*, persons listed in Schedule "B" are authorized under this bylaw to store, dispense or sell drugs or devices to the public.

(2) Pursuant to section 7(3) of the *Act*, the registrar may authorize the direct owner, indirect owner(s) or manager of an unlicensed pharmacy, or a full pharmacist to continue the operation of the pharmacy for a period not exceeding 90 days, for the limited purpose of transferring drugs and personal health information on the premises to another licenced pharmacy.

(3) On receiving a referral under section 16(6), the application committee may consider whether to authorize the operation of the pharmacy pursuant to section 7(3) of the *Act* pending a determination under section 4(4)(b) of the *Act* as to relevance or risk to the public.

PART II - All Pharmacies

Change in Direct Owner, Indirect Owner(s) or Manager

16. (1) If a direct owner changes, the registrar may issue a new pharmacy licence upon receipt of the following from the new direct owner:

(a) Form 8A;

(b) the fee(s) specified in Schedule "A";

(c) a copy of the pharmacy's current business licence issued by the jurisdiction, if applicable; and

(d) the documents listed in sections 3(3), 3(4) and 3(5) as applicable.

(2) If there is a change of indirect owner(s) the following must be submitted:

(a) Form 8B;

(b) the fee(s) specified in Schedule "A";

(c) a Notice of Change of Directors, if applicable;

(d) a certified true copy of the Central Securities Register, if there is a change of shareholder(s) of a non-publicly traded corporation; and

(e) the documents listed in sections 3(3), 3(4) and 3(5), as applicable.

(3) If the change in subsection (2) includes a new indirect owner(s), proof of eligibility in Form 5 and a criminal record history in accordance with section 14 must be submitted by the new indirect owner(s).

(4) If there is a change of manager, the registrar may issue a new pharmacy licence upon receipt of:

(a) Form 8C submitted by the direct owner;

(b) the fee(s) specified in Schedule "A"; and

(c) proof of eligibility in Form 5 and a criminal record history in accordance with section 14 submitted by the new manager.

(5) In the event that a direct owner, indirect owner(s) or manager is no longer eligible under section 3 of the *Act*, the direct owner, indirect owner(s) or manager must submit a notice in Form 6.

(6) On receipt of a Form 6 under subsection (5), the Registrar must refer the matter to the application committee who may act under sections 4(3), 4(4), 4(5) of the *Act*.

Changes to the Pharmacy Premises and Name

17. (1) If there is a change in the name of a corporation that is a direct owner the following must be submitted:

(a) Form 8D;

(b) the fee(s) specified in Schedule "A";

(c) a copy of the pharmacy's current business licence issued by the jurisdiction, if applicable; and

(d) a copy of the Alteration to the Notice of Articles.

(2) If there is a change in the name of a corporation that is an indirect owner, the following must be submitted:

(a) Form 8D;

(b) the fee(s) specified in Schedule "A"; and

(c) a copy of the Alteration to the Notice of Articles.

(3) If there is a change in the operating name of the pharmacy, the following must be submitted:

(a) Form 8E;

(b) the fee(s) specified in Schedule "A"; and

(c) a copy of the pharmacy's current business licence issued by the jurisdiction, if applicable.

(4) If there is a change in location of the pharmacy, the registrar may issue a new pharmacy licence upon receipt of the following from the direct owner:

(a) Form 8F;

(b) the fee(s) specified in Schedule "A"; and

(c) the requirements in section 3(2)(c), (d) and (e) for a community pharmacy, or

(d) the requirements in section 6(2)(c) for a hospital pharmacy; and

(e) a copy of the pharmacy's current business licence issued by the jurisdiction, if applicable.

(5) If there is a change in layout of the pharmacy, the direct owner must submit the following:

(a) Form 8G;

(b) the fee(s) specified in Schedule "A"; and

(c) a diagram, photographs or video to demonstrate the changes in layout in accordance with section 3(2)(c),(d) and (e) for a community pharmacy, or

(d) a diagram to demonstrate the changes in layout in accordance with section 6(2)(c) for a hospital pharmacy.

Responsibilities of Manager, Direct Owners, Directors, Officers and Shareholders

18. (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,

(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, and

(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;

(j.1) ensure that pharmacy records containing personal information about patients are secure from unauthorized access, use, disclosure, modification and destruction;

(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) provide for the safe transfer and appropriate storage of all Schedule I, II, and III drugs and controlled drug substances,

(ii) advise the registrar in writing of the disposition of all drugs and prescription records at the time of a closure,

(iii) 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,

(iv) 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

(v) remove all signs and advertisements from the closed pharmacy premises;

(u) in the event that a pharmacy will be closed temporarily for up to 14 consecutive days,

(i) notify patients and the public of the temporary closure at least 30 days prior to the start of the temporary closure, and

(ii) make arrangements for emergency access to the pharmacy's hard copy patient records.

(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 anyone 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) provide the registrar with access to the pharmacy premises in cases where a pharmacy licence has been cancelled or suspended due to loss of eligibility under section 3 of the *Act*;

(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 a direct owner and indirect owner(s) with their obligations under the bylaws to the *Act*; and

(cc) notify the registrar of any change of telephone number, fax number, electronic mail address or any other information previously provided to the registrar.

(3) Subsection (2)(p) does not apply to a hospital pharmacy, hospital pharmacy satellite, telepharmacy or a pharmacy education site.

(4) For the purpose of subsection (2)(t), a pharmacy closure includes a suspension of the pharmacy licence for a period of more than 30 days, unless otherwise directed by the registrar.

(5) Subsection (2)(aa) does not prevent a manager, direct owner or indirect owner(s) 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.

(6) 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.

(7) A pharmacy education site's manager must ensure that only registrants and instructors are present in the pharmacy education site and must also comply with subsections (2)(a), (d), (h), (o), (r) and (t)(i) and (ii).

(8) A direct owner, directors and officers must do all of the following:

(a) ensure compliance with subsections 2(d), (e), (g), (j), (k), (p), (p.1), (q), (z) and (aa);

(b) ensure that the requirements to hold a pharmacy licence under the Act are met at all times;

(c) notify the registrar of any change of name, address, telephone number, electronic mail address or any other information previously provided to the registrar; and

(d) in the event of a pharmacy closure under subsection 2(t), notify the registrar in writing at least thirty days before the effective date of proposed closure in Form 4.

(9) Shareholders must comply with subsections 2(d) and 8(c).

Sale and Disposal of Drugs

19. (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

20. (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

21. 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

22. 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

23. (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) Despite subsection (1), a registrant must not destroy prescriptions, patient records, invoices and documentation as described in subsection (1) until the completion of any audit or investigation for which the registrant has received notice.

(3) Registrants, support persons, managers, direct owners, and indirect 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.

23.1. (1) All records required to be kept under bylaws of the college or other legislation that regulates the practice of pharmacy shall be readable, complete, filed systematically and maintained in a manner that is secure, auditable and allows for easy retrieval.

(2) Notwithstanding subsection (1), a prescription record that is valid must be retrievable immediately.

(3) For purposes of subsection (2):

(a) prescriptions for oral contraceptives are valid for a period of up to two years from the prescribing date; and

(b) prescriptions other than for oral contraceptives are valid for a period of up to one year from the prescribing date.

(4) With respect to prescriptions for drugs included in the controlled prescription program, the original prescription form must be retained, regardless of whether or not such prescription form has also been stored electronically.

(5) Prescriptions stored electronically must accurately reflect the original prescription, including the original colour composition of that prescription.

23.2. (1) A pharmacy manager must ensure that a policy is in place that:

(a) describes the pharmacy's records filing system, the records format and the method and system for storing records,

(b) is compliant with the sections 23.1, 23.2 and 23.3 requirements; and

(c) is readily accessible to and understood by pharmacy staff.

(2) With respect to electronic records, the policy must include a description of the process for the preservation, storage and backing up of records that is compliant with section 23.3 requirements.

23.3. (1) A pharmacy may maintain electronic records containing personal health information if the pharmacy has the equipment, software and systems necessary for the input, storage, use, protection and retrieval of records that are required to be kept under bylaws of the college or other legislation that regulates the practice of pharmacy.

(2) For purposes of subsection (1), the equipment, software and systems must:

(a) be capable of storing the electronic records for the periods required by applicable law;

(b) keep the records secure from unauthorized access, use, disclosure, modification and destruction;

(c) for audit purposes, be capable of uniquely identifying each time an electronic record is accessed and modified;

(d) be capable of restricting the functions that may be used by an authorized person;

(e) be capable of tracing alterations to records by identifying the original entry, the identity of the individual who made the alteration and the date of the alteration;

(f) be capable of searching and sorting electronic prescription records chronologically, and by drug name, drug strength, patient, prescriber, prescription number and transaction number;

(g) ensure that electronic records can be stored, backed up and recovered in accordance with subsection (3); and,

(h) provide for a deliberate and auditable procedure to be carried out by the pharmacy manager or by an authorized person prior to the destruction of any electronic record that includes information identifying the pharmacy manager or authorized person who destroyed the record and the date, time and reason for its destruction.

(3) A pharmacy manager must ensure that electronic records are preserved and backed up at least once daily and that such electronically preserved and backed up records are stored:

(a) in a location resistant to environment perils including but not limited to fires and floods;

(b) so that they are secure from unauthorized access, use, modification, destruction and disclosure; and,

(c) in a manner that would enable the backed up records, once restored, to be compliant with section 23.1(1) requirements.

(4) Notwithstanding subsections (1), (2) and (3), a pharmacy that presently stores electronic records has six months from the date this section comes into effect to bring itself into full compliance with the requirements of subsections (1), (2) and (3).

PART III – Community Pharmacies

Community Pharmacy's Manager – Quality Management

24. (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

25. (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 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), 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,

(f) contain an adequate stock of drugs to provide full dispensing services, and

(g) contain a refrigerator.

(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.

(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.

(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

26. (1) A community pharmacy or telepharmacy must:

(a) 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) 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) 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 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 26(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 manager, direct owner or indirect owner(s) 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.

(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

27. (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 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; and

(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

28. (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 IV – Hospital Pharmacies

Hospital Pharmacy's Manager – Quality Management

29. (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

30. (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 V – Telepharmacy

Telepharmacy Licence

31. (1) The registrar must not issue a telepharmacy licence to a central pharmacy unless

(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 operating name of the telepharmacy includes the word "telepharmacy",

(d) except for a pharmacy located at an address listed in Schedule “F”, the proposed telepharmacy does not have a licence as a community pharmacy,

(e) the central pharmacy applicant and the telepharmacy will have the same direct 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 stated on the telepharmacy licence.

Telepharmacy Operation

31.1 (1) A telepharmacy must not remain open and prescriptions must not be dispensed without a full pharmacist physically present on duty at the telepharmacy, 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 located at an address 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 located at an address 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) All transactions in PharmaNet must be distinguishable between the central pharmacy and telepharmacy.

PART VI – PharmaNet

Application of Part

32. This Part applies to every pharmacy that connects to PharmaNet.

Definitions

33. 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

34. 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

35. (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

36. 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.

PART VII – College

Forms

37. The Registrar may establish forms for the purposes of the *Act*.

Use, Disclosure and Retention of Criminal Record History Information

38. (1) The College may disclose criminal record history information only for the purpose of licensing pharmacies or for the purpose of regulating registrants (including for the discipline of registrants).

(2) The College must retain criminal record history information only for so long as is permitted by the applicable College records retention and disposal provisions established by the College.

College of Pharmacists of B.C.

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.18(2)(p)** The manager must 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. **Telepharmacy: *PODSA Bylaws* s.18(2)(p.1)** 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. **Telepharmacy: *PODSA Bylaws* s.31(1)(c)** The registrar must not issue a telepharmacy licence to a central pharmacy unless the proposed operating name of the telepharmacy includes the word "telepharmacy".	(Entrance to the pharmacy)	✓
	Hours of operation sign	***PODSA Bylaws* s.27(2)(f)** 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(2)** Schedule III drugs may be sold by a pharmacist to any person from the self-selection Professional Products Area of a licensed pharmacy. ***PODSA Bylaws* s.25(1)(a)** 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 and is visually distinctive from the remaining areas of the premises by signage. ***PODSA Bylaws* s.18(2)(j)** 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 pharmacist present.	✓	✓
	Signage at 25 feet from dispensary OR N/A	***PODSA Bylaws* s.25(1)(a)** 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 and is visually distinctive from the remaining areas of the premises by signage.	✓	✓
	"Medication Information" Sign **OR N/A**	***PODSA Bylaws* s.25(1)(b)** 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 full pharmacist's advice.	✓	✓
Dispensary	**Dispensary area**	***PODSA Bylaws* s.25(2)(a)** The dispensary area of a community pharmacy or a telepharmacy must be at least 160 square feet. **Telepharmacy: *PODSA Bylaws* s.25(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.		✓
	Gate/door at the entrance into the dispensary	***PODSA Bylaws* s.25(2)(b)** 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)** The manager must display the licence issued under subsection (1) 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)** 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)	✓
	Patient consultation area	***PODSA Bylaws* s.25(4)** In all new and renovated community pharmacies or telepharmacies, an appropriate area must be provided for patient consultation that	✓	✓

Category	Item	Reference & Requirements	Diagram	Photo/Video
		(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.		
	Dispensing counter and service counter	***PODSA Bylaws* s.25(2)(c)** 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. **Telepharmacy: *PODSA Bylaws* s.25(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.	✓	✓
	Computer terminals for prescription processing	***PODSA Bylaws* s.34(b)** 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 (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.	✓	✓
	Shelving	***PODSA Bylaws* s.25(1)(d)** The dispensary area of a community pharmacy or a telepharmacy must contain adequate shelf and storage space.	✓	✓
Security	**Secure storage space**	***PODSA Bylaws* s.25(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.	✓	✓
	Locked Metal Safe **OR** **Safe Declaration**	***PODSA Bylaws* s.26(1)(a)** 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. ***PPP-74 Policy Statement #4*** 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. ***PODSA Bylaws* s.26(4)** The manager, direct owner or indirect owners (s) of a community pharmacy or a telepharmacy that does not stock IA drugs must complete a declaration attesting that Schedule IA drugs are never stored on the premises.	✓	✓
	Security camera system AND Surveillance signage	***PODSA Bylaws* s.26(1)(b)** A community pharmacy or telepharmacy must 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. ***PPP-74 Policy Statement #4*** 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.26(1)(c)** A community pharmacy or telepharmacy must install and maintain motion sensors in the dispensary.		✓
	Monitored alarm OR N/A	***PODSA Bylaws* s.26(2)(a)** When no full pharmacist is present and the premise is accessible to non-registrants, the dispensary area must be secured by a monitored alarm. ***PPP-74 Policy Statement #4*** Independent alarms for the dispensary are optional, when a full pharmacist is present at all times and the premise is accessible by non-registrants.		✓
		Telepharmacy (in addition to the above): ***PODSA Bylaws* s.26(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. ***PODSA Bylaws* s.31.1(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.		
	Physical barriers OR N/A	***PODSA Bylaws* s.26(2)(b)** When no full pharmacist is present and the premise is accessible to non-registrants, subject to subsection 2.1,schedule I and II drugs, controlled drug substances and personal health information, are secured by physical barriers. ***PPP-74 Policy Statement #4*** Physical barriers provide an additional layer of security and deter: 1. Unauthorized access to drugs, including but not limited to: • All Schedule I, and II and, controlled drug substances and personal health information. 2. Unauthorized access to personal health information, including but not limited to:	✓	✓

Category	Item	Reference & Requirements	Diagram	Photo/Video
		• Hard copies of prescriptions, • Filled prescriptions waiting to be picked up, and/or • Labels, patient profiles, and any other personal health information documents waiting for disposal. 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. When a full pharmacist is present at all times, physical barriers are optional.		
		Telepharmacy (in addition to the above): ***PODSA Bylaws* s.26(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. ***PODSA Bylaws* s.31.1(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.		
Equipment & Reference	**Double stainless steel sink**	***PODSA Bylaws* s.25(2)(e)** The dispensary area of a community pharmacy or a telepharmacy must contain a double stainless steel sink with hot and cold running water. ***PPP-59* Policy Statement #1** The dispensary of all community pharmacies at a minimum must have the following equipment as per PODSA Bylaw 18(2)(w): (n) double sink with running hot and cold water;	✓	✓
	Equipment (basic): 1. **Telephone** 2. **Refrigerator** 3. **Rx filing supplies** 4. **Rx balance** 5. **Metric weights** 6. **Glass graduates** 7. **Mortar** 8. **Pestle** 9. **Spatulas** 10. **Funnels** 11. **Stirring rods** 12. **Ointment slab/ parchment paper** 13. **Counting tray** 14. **Disposable drinking cups** 15. **Soap dispenser** 16. **Paper towel dispenser** 17. **Plastic/metal garbage containers** 18. **Plastic lining** 19. **Fax machine**	***PODSA Bylaws* s.18(2)(w)** The manager must ensure the pharmacy contains the reference material and equipment approved by the board from time to time. ***PPP-59* Policy Statement #1**; The dispensary of all community pharmacies at a minimum must have the following equipment as per PODSA Bylaw 18(2)(w): (a) telephone; (b) refrigerator; (c) prescription filing supplies; ***PPP-12* Policy Statement #3** 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. (d) prescription balance having a sensitivity rating of 0.01; (e) metric weights (10 mg to 50 g) for balances requiring weights or instruments with equivalent capability; (f) metric scale glass graduates (a selection, including 100 mL size); (g) mortar and pestle; (h) Spatulas (metal and nonmetallic); (i) funnels (glass or plastic); (j) stirring rods (glass or plastic); (k) ointment slab or parchment paper; (l) counting tray; (m) disposable drinking cups; (o) soap dispenser and paper towel dispenser; (p) plastic or metal garbage containers to be used with plastic liners; (q) fax machine ***HPA Bylaws Schedule F Part 1 s. 7(1)(b)*** The facsimile equipment is located within a secure area to protect the confidentiality of the prescription information	✓ Fridge only	✓
	Equipment (Cold Chain) 1. **Thermometer** 2. **Temperature log**	***PPP-68* Policy Statement:** 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. ***Communicable Disease Control Immunization Program Section VI – Management of Biologicals (2015)* s.3.3.2** 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. At the start and end of each work day, record the minimum and maximum temperatures reached since the last monitoring, on the Temperature Form. 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.		✓
	Equipment (Methadone) 1. **Calibrated device** 2. **Auxiliary labels** 3. **Containers for daily dose**	***PPP-66 Policy Guide MMT (2013)* Principle 3.3.1** Methadone doses must be accurately measured in a calibrated device that minimizes the error rate to no greater than 0.1 ml. ***PPP-66 Policy Guide MMT (2013)* Principle 3.3.1 Guidelines** 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.		✓

Category	Item	Reference & Requirements	Diagram	Photo/Video
	4. Patient/Rx Log **OR N/A**	***PPP-66 Policy Guide MMT (2013)* Principle 4.1.6** 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. ***PPP-66 Policy Guide MMT (2013)* Principle 4.1.6 Guidelines** Each dose must be dispensed in an individual, appropriately sized, child-resistant container. ***PPP-66 Policy Guide MMT (2013)* Principle 4.1.3** Prior to releasing a methadone prescription the patient and pharmacist must acknowledge receipt by signing a patient/ prescription-specific log.		
	References (CPBC) **1. BC Pharmacy Practice Manual** **2. ReadLinks**	***PODSA Bylaws* s.18(2)(w)** The manager must ensure the pharmacy contains the reference material and equipment approved by the board from time to time. ***PPP-3* Electronic Database References** 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. ***PPP-3* Policy Statement 1st Paragraph** All community pharmacies are required to have the most current versions of the BC Pharmacy Practice Manual. The CPBC Read Links is an exception, as only the most recent three years must be retained.		✓
	References (General) **1. Compendium** **2. Complementary/ Alternative** **3. Dispensatory** **4. Drug Interactions** **5. Nonprescription Medication (2x)** **6. Medical Dictionary** **7. Pregnancy and Lactation** **8. Pediatrics** **9. Therapeutics**	***PODSA Bylaws* s.18(2)(w)** The manager must ensure the pharmacy contains the reference material and equipment approved by the board from time to time. ***PPP-3* Electronic Database References** 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. ***PPP-3* Page 2** 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 18(2)(w). [which are: 1. Compendium (current year); 2. Complementary/Alternative (within the last 4 years); 3. Dispensatory (within last 3 years); 4. Drug Interactions (in its entirety every 2 years, or continual updates); 5. Nonprescription Medication (most current issue of BOTH references required); 6. Medical Dictionary (within the last 15 years); 7. Pregnancy and Lactation (within the last 3 years); 8. Pediatrics (within the last 4 years); 9. Therapeutics (within last 4 years)]		✓
	References (if applicable) • **Veterinary** • **Psychiatric** • **Geriatric** • **Specialty compounding** • **Methadone** ○ **PPP-66** ○ **CSPBC** ○ **CAMH** ○ **Monograph** **OR N/A**	***PODSA Bylaws* s.18(2)(w)** The manager must ensure the pharmacy contains the reference material and equipment approved by the board from time to time. ***PPP-3* Electronic Database References** 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. ***PPP-3* Page 2** In addition to the above list, pharmacies must be equipped with references relevant to their practices (e.g. Veterinary, Psychiatric, Geriatric). ***PPP-66* Required References** 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: (1) CPBC Methadone Maintenance Treatment Policy Guide (2013) and subsequent revisions, (2) most recent version of the CPSBC Methadone and Buprenorphine: Clinical Practice Guideline for Opioid Use Disorder, (3) most current edition of Opioid Agonist Maintenance Treatment: A Pharmacist's Guide to Methadone and Buprenorphine for Opioid Use Disorders, and (4) product monographs for the commercially available 10mg/ml methadone oral preparations.		✓
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)*** At the time of dispensing, a prescription must include the following additional information: (a) the address of the patient; (b) the identification number from the practitioner's regulatory college; (c) the prescription number; (d) the date on which the prescription was dispensed; (e) the manufacturer's drug identification number or the brand name of the product dispensed; (f) the quantity dispensed.		✓

Category	Item	Reference & Requirements	Diagram	Photo/Video
		Telepharmacy (in addition to the above): ***PODSA Bylaws* s.31.1(4)** Prescriptions and labels relating to prescriptions dispensed at a telepharmacy must identify the prescription as having been dispensed at that telepharmacy. ***PODSA Bylaws* s.31.1(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.		
Confidentiality	**Shredder OR** **Contract with a Document Destruction Company**	***HPA Bylaws* s.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 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. ***HPA Bylaws* s.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.		✓
	Offsite Storage Contract **OR N/A**	***HPA Bylaws* s.74(b)** 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.20(3)** All drug shipments must be delivered unopened to the pharmacy or a secure storage area.	✓	✓
	Drugs	***PODSA Bylaws* s.5(2)(f)** 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.20(4)** 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** **1. Single entity product** **2. Multiple-entity product**	***HPA Bylaws Schedule F Part 1* s.9(2)** The label for all prescription drugs must include (a) the name, address and telephone number of the pharmacy, (b) the prescription number and dispensing date, (c) the full name of the patient, (d) the name of the practitioner, (e) the quantity and strength of the drug, (f) the practitioner's directions for use, and (g) any other information required by good pharmacy practice. ***HPA Bylaws Schedule F Part 1* s.9(3)** For a single-entity product, the label must include (a) the generic name, and (b) at least one of (i) the brand name, (ii) the manufacturer's name, or (iii) the drug identification number (DIN). ***HPA Bylaws Schedule F Part 1* s.9(4)** For a multiple-entity product, the label must include (a) the brand name, or (b) all active ingredients and at least one of (i) the manufacturer's name or (ii) the drug identification number (DIN).		✓
		Telepharmacy (in addition to the above): ***PODSA Bylaws* s.31.1(4)** Prescriptions and labels relating to prescriptions dispensed at a telepharmacy must identify the prescription as having been dispensed at that telepharmacy. ***PODSA Bylaws* s.31.1(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.		
	Filling supplies (e.g. vials and bottles including caps)	***HPA Bylaws Schedule F Part 1* s.10(4)** All drugs must be dispensed in a container that is certified as child-resistant unless….		✓

Category	Item	Reference & Requirements	Diagram	Photo/Video
Pharmacy Manager's Responsibilities	**Name Badge**	***PODSA Bylaws* s.18(2)(m)** 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.18(2)(g)** A manager must establish policies and procedures to specify the duties to be performed by registrants and support persons. ***PODSA Bylaws* s.18(2)(h)** A manager must establish procedures for (i) inventory management, (ii) product selection, and (iii) proper destruction of unusable drugs and devices. ***PODSA Bylaws* s.18(2)(k)** A manager must ensure there is a written drug recall procedure in place for pharmacy inventory. ***PODSA Bylaws* s.18(2)(q)** A manager must establish and maintain policies and procedures respecting pharmacy security. ***PPP-74 Policy Statement #1*** 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: • Training, • Pharmacy security equipment, • Emergency responses, • Incident review, and • Pharmacy security evaluation ***PPP-74 Policy Statement #5*** 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. ***PODSA Bylaws* s.24(1)(c)** 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 ***HPA Bylaws* s.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.		✓ (or document file)
		Telepharmacy (in addition to the above): ***PODSA Bylaws* s.31.1(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.		

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	**Marked prescription (sample)**	***HPA Bylaws Schedule F Part 6 s.5(2)*** An original physical prescription may be submitted to a telepharmacy and, upon receipt, must be marked with the date of receipt and the name of the telepharmacy.
Central Pharmacy	**Tool/technology enabling direct supervision on dispensary activities**	***PODSA Bylaws* s.31.1(1)(a)** A telepharmacy must not remain open and prescriptions must not be dispensed without a full pharmacist physically present on duty at a telepharmacy, unless a full pharmacist at the central pharmacy is engaged in direct supervision of the telepharmacy in accordance with the *Telepharmacy Standards of Practice*. ***PODSA Bylaws Definitions*** "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 18(2). ***HPA Bylaws Schedule F Part 6* s.3** "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. ***HPA Bylaws Schedule F Part 6* s.4(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.
	Tool/technology used for transmitting prescription and personal health information between sites	***HPA Bylaws Schedule F Part 6* s.6(2)** 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)** All prescription processing must occur at the central pharmacy unless a full pharmacist is physically present on duty at the telepharmacy. ***HPA Bylaws Schedule F Part 6* s.6(2)** 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.31.1(1)(a)** A telepharmacy must not remain open and prescriptions must not be dispensed without a full pharmacist physically present on duty at the telepharmacy, unless a full pharmacist at the central pharmacy is engaged in direct supervision of the telepharmacy in accordance with the *Telepharmacy Standards of Practice*. ***HPA Bylaws Schedule F Part 6* s.3** "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. ***HPA Bylaws Schedule F Part 6* s.4(2)(a)** 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. ***HPA Bylaws Schedule F Part 6* s.4(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. ***HPA Bylaws Schedule F Part 6* s.4(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.
	Tool/technology enabling direct pharmacist/patient consultation	***HPA Bylaws Schedule F Part 6* s.3** "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. ***HPA Bylaws Schedule F Part 6* s.4(2)(b)** A supervising pharmacist must be readily available at all times when a telepharmacy is open to provide pharmacist/patient consultation. ***HPA Bylaws Schedule F Part 6* s.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*.
	Policy and procedure manual (document file acceptable)	***PODSA Bylaws* s.24(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.*

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

4b.vii. Legislation Review Committee
b) Drug Schedules Regulation – Amendments

DECISION REQUIRED

Recommended Board Motion:

Approve the following resolution to amend drug scheduling in the Drug Schedules Regulation:

RESOLVED THAT, in accordance with the authority established in section 22(1) of the *Pharmacy Operations and Drug Scheduling Act*, and subject to filing with the Minister as required by section 22(2) of the *Pharmacy Operations and Drug Scheduling Act*, the board amend the Drug Schedules Regulation, B.C. Reg. 9/98, as outlined in the schedule attached to this resolution.

Purpose

To seek Board approval to amend the Drug Schedules Regulation (DSR) under the *Pharmacy Operations and Drug Scheduling Act* (PODSA) in order to address a scheduling gap, improve alignment with the the Prescription Drug List made under the *Food and Drugs Act* (Canada) (FDA), and the Schedules to the *Controlled Drugs and Substances Act* (Canada).

Background

Health Canada determines whether a drug must be sold by prescription only or can be sold over the counter (non-prescription status). Provincial regulatory authorities can further restrict the conditions of sale of "non-prescription" products; however, they cannot be less stringent than the federal requirements. For example, a product that has not been federally designated as a prescription product could be assigned prescription status by a province or territory. However, a product that is regulated under the FDA with a prescription-only status cannot be given non-prescription status by a province or territory. Prescription drugs are classified as Schedule 1 or 1A on the DSR.

Typically, for those drugs determined by Health Canada to be non-prescription, most provincial regulatory authorities schedule by reference to recommendations made by National Association of Pharmacy Regulatory Authorities (NAPRA) in the National Drug Schedules. B.C. is one of the few provinces in Canada that maintains its own list of scheduled drugs in the DSR[1]. Nevertheless, most amendments to B.C.'s DSR are based on recommendations from NAPRA.

NAPRA created the National Drug Scheduling Advisory Committee (NDSAC) to recommend appropriate placement of non-prescription drugs within a three schedule national model[2] in the National Drug Schedules. "NDSAC members are chosen for their knowledge and expertise in such areas as pharmacotherapy, drug utilization, drug interactions and toxicology, pharmacy practice, academic research, the drug industry and pharmaceutical regulatory affairs at federal and provincial levels".[3] Their recommendations include an examination of the scientific evidence to support their rationale, along with allowing for public input through a public posting period.

Legislative Authority

The legislative authority for the Board to amend the DSR is outlined in section 22 of the PODSA:

> ***Regulations of the board***
> ***22*** *(1) Subject to the Food and Drugs Act (Canada), the board, by regulation, may make drug schedules specifying the terms and conditions of sale for drugs and devices.*
> *(2) A regulation under subsection (1) must be filed with the minister.*

B.C.'s process requires the College to complete an internal review of NDSAC's recommendations in order to assess any modifications for the context of BC's health sector. Next, the College submits the proposed amendments to the Ministry of Health, Professional Regulation & Oversight branch. The Ministry completes their review and if satisfied, forwards the request to Legislative Counsel for a legal review. If no issues are identified, Legislative Counsel provides the College with a tagged schedule of amendments. The tagged scheduled of amendments is then presented to the College's Board for approval.

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[1] In B.C., drugs are scheduled in the DSR as Schedule I, IA, II, III, and IV. The schedules are differentiated as follows:

- Schedule I (Prescription)
- Schedule IA (Prescription - Triplicate/Duplicate Prescription Program)
- Schedule II (Non-Prescription – Retained within the Professional Service Area)
- Schedule III (Non-Prescription – Available for self-selection in the Professional Products Area)
- Schedule IV (Prescription by Pharmacist)

[2] The National Drug Schedules categorize drugs as Schedule I, II, or III.

[3] http://napra.ca/committee-membership

Under the Nurses (Registered) and Nurse Practitioners Regulation made under the *Health Professions Act* (British Columbia), registered nurses and nurse practitioners may, under certain circumstances, prescribe drugs that are categorized as Schedule I, IA and II on the DSR. If a drug is not scheduled on the DSR, the Ministry has taken the position that registered nurses and nurse practitioners are not authorized to prescribe the drug (even if it is listed on the Prescription Drug List or on a Schedule to the *Controlled Drugs and Substances Act* (Canada)). Recently, the College has received a number of requests from the British Columbia College of Nursing Professionals (BCCNP) to add certain drugs to the DSR so that nurses can legally prescribe them.

Discussion

There are three proposed amendments to the DSR.

Codeine

Depending on its dosage form, codeine is currently scheduled on the DSR as a Schedule 1A or a Schedule II drug. However, these two categories do not capture the dosages of codeine found in Tylenol #2 and Tylenol #3. Therefore, it is proposed that a separate category, Schedule 1 codeine, be created to address the scheduling gap. Tylenol #2 and Tylenol #3 would fall under this new category. This change is being proposed at the request of BCCNP.

Lisdexamfetamine dimesylate

BCCNP has requested that lisdexamfetamine dimesylate be added to the DSR so that nurse practitioners will be able to prescribe this drug. This drug is a prescription drug that is currently listed on a Schedule to the *Controlled Drugs and Substances Act* (Canada). It is a drug often used to treat attention deficit hyperactivity disorder.

Nicotine

The nicotine qualifier in the DSR is proposed to be amended for alignment with recent changes to the PDL.

The proposed amendments would not result in significant changes to pharmacy practice.

Please refer Appendix 1 for the tagged schedule of DSR amendments. In addition, please refer to Appendix 2 for a chart setting out the current DSR entries, the proposed amendments and the reasons for the amendments.

Next Steps

If approved by the Board, the Board resolution will require a final approval by the Ministry. After receiving final approval from the Ministry, the College will deposit the tagged schedule with the Registrar of Regulations, at which time the amendments will come into force 60 days from the deposit date.

Recommendation

The Board approve the proposed amendments to the DSR as set out in Appendix 1.

Appendix	
1	Draft Schedule of Drug Schedules Regulation amendments
2	Table of Proposed Amendments

November 22, 2018 1124625

Mr. Bob Nakagawa, BSc (Pharm), RPEBC, FCSHP, ACPR
Registrar, College of Pharmacists of British Columbia
College of Pharmacists of British Columbia
200 – 1765 W 8th Ave
Vancouver BC V6J 5C6

Dear Mr. Nakagawa,

The Ministry of Health has reviewed the draft schedules of amendments for amending the Drug Schedules Regulation to improve alignment of drug scheduling with the federal Prescription Drug List and the Schedules to the *Controlled Drugs and Substances Act*, as attached to your email of October 24, 2018.

We understand this resolution is to be considered at the next meeting of the board of the College on November 23, 2018.

The Ministry of Health, being satisfied with the draft schedules, forwarded them to Legislative Counsel for review. Enclosed are the tagged schedules of amendments provided by Legislative Counsel.

Sincerely,

Meghan Thorneloe
Director, Regulatory Initiatives
Professional Regulation & Oversight
Ministry of Health

Enclosure

Ministry of Health
Health Human Resources and Labour Relations Division
Professional Regulation & Oversight Branch
3rd Floor, 1515 Blanshard St
PO Box 9649 STN PROV GOVT
Victoria BC V8W 9P4
Tel: 250-952-2292

OFFICE OF LEGISLATIVE COUNSEL

Examined by: Sherie Verhulst

YELLOW TAG

Order in Council ☐ Regulation ☑

Cautions/Comments:

I have reviewed the attached regulation and section 22 of the *Pharmacy Operations and Drug Scheduling Act*. It is my opinion that there is legislative authority for this regulation.

The statute requires that once enacted by the board of the College of Pharmacists, the regulation must be filed with the Minister of Health, and the board may deposit it with the registrar under the *Regulations Act* if the following conditions are met:

(a) the minister has not disallowed all or a portion of the regulation within the period prescribed by the minister under that section;

(b) the regulation is not deposited with the registrar until the prescribed period or another shorter period specified by order of the minister has expired.

Signed: Sherie Verhulst Date: November 21, 2018

R10286903

APPENDIX

1 The Drug Schedules Regulation, B.C. Reg. 9/98, is amended in the Schedules

(a) by striking out the following:

1 Nicotine and its salts, for human use, except
- (a) in natural substances;
- (b) in the form of a chewing gum containing 4 mg or less of nicotine per dosage unit;
- (c) in the form of a transdermal patch with a delivery rate of 22 mg or less of nicotine per day;
- (d) in a form to be administered orally by means of an inhalation device delivering 4 mg or less of nicotine per dosage unit; or
- (e) in the form of a lozenge containing 4 mg or less of nicotine per dosage unit**, *and***

(b) by adding the following:

1 Codeine, except
- (a) when prescribed as a single entity,
- (b) when included in a preparation containing 60 mg or more per dosage unit, or
- (c) in preparations exempted from the Regulations to the *Controlled Drugs and Substances Act* (Canada)

1 Lisdexamfetamine dimesylate

1 Nicotine and its salts for human use, except
- (a) in natural substances,
- (b) in the form of a chewing gum containing 4 mg or less of nicotine per dosage unit,
- (c) in the form of a transdermal patch with a delivery rate of 22 mg or less of nicotine per day,
- (d) in a form to be administered into the oral cavity by means of a non-active device (one that operates on energy generated by the human body or by gravity) that delivers 4 mg or less of nicotine per dose for buccal absorption, or
- (e) in the form of a lozenge containing 4 mg or less of nicotine per dosage unit.

Drug Schedules Regulation (DSR) - Draft Proposed Amendments

Current DSR Entry	Amended DSR Entry	Rationale for Amendment/ Comments	Consistent with NAPRA (Y/N)	Consistent with PDL/CDSA (Y/N)
None	1 Codeine (except when prescribed as a single entity, when included in a preparation containing 60 mg or more per dosage unit, or in preparations exempted from the Regulations to the Controlled Drugs and Substances Act (Canada))	Revised at the request of BCCNP to address the scheduling gap for the dosages of codeine found in Tylenol #2 and Tylenol #3. The DSR currently includes entries for Schedule 1A Codeine and Schedule II Codeine, but Tylenol #3 and Tylenol #3 do not fit within either of those categories.	N The DSR distinguishes between Schedule 1A and Schedule 1 codeine, whereas NAPRA does not	N The DSR distinguishes between Schedule 1A and Schedule 1 codeine, whereas federal legislation does not
None	1 Lisdexamfetamine dimesylate	Added at the request of BCCNP	Y (Included under the category of amphetamines)	Y (Included under the category of amphetamines)
1 Nicotine and its salts, for human use, except (a) in natural substances;	1 Nicotine or its salts, for human use, except (a) in natural substances;	Revised for consistency with PDL[1]	N The change to the description of nicotine on the PDL	Y (PDL)

[1] Health Canada Notice: Prescription Drug List (PDL): Nicotine Qualifier Clarification
https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/prescription-drug-list/notices-changes/notice-nicotine-salts.html

Current DSR Entry	Amended DSR Entry	Rationale for Amendment/ Comments	Consistent with NAPRA (Y/N)	Consistent with PDL/CDSA (Y/N)
(b) in the form of a chewing gum containing 4 mg or less of nicotine per dosage unit; (c) in the form of a transdermal patch with a delivery rate of 22 mg or less of nicotine per day; (d) in a form to be administered orally by means of an inhalation device delivering 4 mg or less of nicotine per dosage unit; or (e) in the form of a lozenge containing 4 mg or less of nicotine per dosage unit	(b) in the form of a chewing gum containing 4 milligrams or less of nicotine per dosage unit; (c) in the form of a transdermal patch with a delivery rate of 22 mg or less of nicotine per day; (d) in a form to be administered into the oral cavity by means of a non-active device (one that operates on energy generated by the human body or by gravity) that delivers 4 mg or less of nicotine per dose for buccal absorption; (e) in the form of a lozenge containing 4 mg or less of nicotine per dosage unit		became effective on August 23, 2018. NAPRA has not updated the nicotine entry on the National Drug Schedules since June 2006. NAPRA is not consistent with the PDL.	

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

4b.vii. Legislation Review Committee
c) Drug Schedules Regulation – Cannabinoids

DECISION REQUIRED

Recommended Board Motion:

Approve the following resolution to amend drug scheduling in the Drug Schedules Regulation for alignment with the Prescription Drug List established under the *Food and Drugs Act* (Canada) and the Schedules to the *Controlled Drugs and Substances Act* (Canada):

RESOLVED THAT, in accordance with the authority established in section 22(1) of the *Pharmacy Operations and Drug Scheduling Act*, and subject to filing with the Minister as required by section 22(2) of the *Pharmacy Operations and Drug Scheduling Act*, the board amend the Drug Schedules Regulation, B.C. Reg. 9/98, as outlined in the schedule attached to this resolution.

Purpose

To seek Board approval to amend the Drug Schedules Regulation (DSR) under the *Pharmacy Operations and Drug Scheduling Act* (PODSA) in order to improve alignment with the the Prescription Drug List (PDL) made under the *Food and Drugs Act* (Canada) (FDA), and the Schedules to the *Controlled Drugs and Substances Act* (Canada) (CDSA).

Background

Health Canada determines whether a drug must be sold by prescription only or can be sold over the counter (non-prescription status). Provincial regulatory authorities can further restrict the conditions of sale of "non-prescription" products; however, they cannot be less stringent than the federal requirements. For example, a product that has not been federally designated as a prescription product could be assigned prescription status by a province or territory. However, a product that is regulated under the FDA with a prescription-only status cannot be given non-prescription status by a province or territory. Prescription drugs are classified as Schedule 1 or 1A on the DSR.

Typically, for those drugs determined by Health Canada to be non-prescription, most provincial regulatory authorities schedule by reference to recommendations made by National Association of Pharmacy Regulatory Authorities (NAPRA) in the National Drug Schedules. B.C. is

one of the few provinces in Canada that maintains its own list of scheduled drugs in the DSR[1]. Nevertheless, most amendments to B.C.'s DSR are based on recommendations from NAPRA.

NAPRA created the National Drug Scheduling Advisory Committee (NDSAC) to recommend appropriate placement of non-prescription drugs within a three schedule national model[2] in the National Drug Schedules. "NDSAC members are chosen for their knowledge and expertise in such areas as pharmacotherapy, drug utilization, drug interactions and toxicology, pharmacy practice, academic research, the drug industry and pharmaceutical regulatory affairs at federal and provincial levels".[3] Their recommendations include an examination of the scientific evidence to support their rationale, along with allowing for public input through a public posting period.

Legislative Authority

The legislative authority for the Board to amend the DSR is outlined in section 22 of the PODSA:

> ***Regulations of the board***
> ***22*** *(1) Subject to the Food and Drugs Act (Canada), the board, by regulation, may make drug schedules specifying the terms and conditions of sale for drugs and devices.*
> *(2) A regulation under subsection (1) must be filed with the minister.*

B.C.'s process requires the College to complete an internal review of NDSAC's recommendations in order to assess any modifications for the context of BC's health sector. Next, the College submits the proposed amendments to the Ministry of Health, Professional Regulation & Oversight branch. The Ministry completes their review and if satisfied, forwards the request to Legislative Counsel for a legal review. If no issues are identified, Legislative Counsel provides the College with a tagged schedule of amendments. The tagged scheduled of amendments is then presented to the College's Board for approval.

Under the Nurses (Registered) and Nurse Practitioners Regulation made under the *Health Professions Act* (British Columbia), registered nurses and nurse practitioners may, under certain circumstances, prescribe drugs that are categorized as Schedule I, IA and II on the DSR. If a drug is not scheduled on the DSR, the Ministry has taken the position that registered nurses and nurse practitioners are not authorized to prescribe the drug (even if it is listed on the PDL or on a Schedule to the CDSA). Recently, the College has received a number of requests from the

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[1] In B.C., drugs are scheduled in the DSR as Schedule I, IA, II, III, and IV. The schedules are differentiated as follows:

- Schedule I (Prescription)
- Schedule IA (Prescription - Triplicate/Duplicate Prescription Program)
- Schedule II (Non-Prescription – Retained within the Professional Service Area)
- Schedule III (Non-Prescription – Available for self-selection in the Professional Products Area)
- Schedule IV (Prescription by Pharmacist)

[2] The National Drug Schedules categorize drugs as Schedule I, II, or III.

[3] http://napra.ca/committee-membership

British Columbia College of Nursing Professionals (BCCNP) to add certain drugs to the DSR so that nurses can legally prescribe them.

Discussion

BCCNP has requested two additions to the DSR to enable nurse practitioners to prescribe the following drugs: phytocannabinoids (e.g. Sativex) and synthetic cannabinoids (e.g. Nabilone).

The addition of cannabinoids to the DSR is also necessary for taxation purposes. The Provincial Sales Tax Exemption and Refund Regulation specifically excludes cannabis from all of the health-related PST exemptions, unless the drug is on Schedule 1 or 1A of the DSR. Therefore, by adding cannabinoids to the DSR in a manner consistent with the PDL, the tax treatment of (PST vs. GST/HST) of these drugs will be the same as that for other prescription drugs. If these drugs are not placed on either Schedule I or IA of the DSR, pharmacies dispensing these drugs would be not collect GST on the sales, but would be required to collect PST.

Phytocannabinoids
Following the coming into force of the *Cannabis Act* (Canada) on October 17, 2018, most cannabis products are now regulated under the *Cannabis Act*. However, drugs containing cannabis that are associated with health claims (e.g., to diagnose, treat, mitigate or prevent a disease) are regulated under the FDA as health products. Subject to certain exemptions[4], any new or existing health product containing cannabis will be captured under the description of phytocannabinoids in the PDL[5]. In other words, they are prescription drugs. This includes Sativex, a drug containing cannabis that has been approved by Health Canada and has a drug identification number.

It should be noted that the PDL only regulates the prescription status of health products containing cannabis and not other types of cannabis products such as cannabis for non-medical purposes.[6]

The addition of phytocannabinoids to the DSR is consistent with the PDL.

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[4] The phytocannabinoids qualifier in the PDL exempts hemp-like natural health products from requiring a prescription. These products can therefore be approved as natural health products instead of prescription drugs. This allows natural health products to contain cannabis from hemp or other non-viable seeds, stalks, fibre, roots as long as it contains less than 10 ppm THC and does not contain an isolated or concentrated phytocannabinoid.
[5] Health Canada Notice of Amendment: Prescription Drug List (PDL): Phytocannabinoids https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/prescription-drug-list/notice-prescription-drug-list-2018-10-17.html
[6] *Cannabis Exemption (Food and Drugs Act) Regulations* made under the *Food and Drugs Act (Canada)*

Synthetic Cannabinoids
Because Nabilone is a synthetic cannabinoid that does not exist in nature, it does not meet the definition of cannabis under the *Cannabis Act*. The definition of cannabis includes synthetic phytocannabinoids (i.e., synthetic versions of cannabinoids produced by the cannabis plant, such as THC), but does not include other synthetic cannabinoids. Therefore, Nabilone will remain regulated under the CDSA as a controlled substance accessible by prescription only.[7]

A separate entry for "synthetic cannabinoids" would need to be added to the DSR to capture Nabilone. The addition of "synthetic cannabinoids" is consistent with the CDSA and NAPRA's National Drug Schedules.

Implications
Sativex and Nabilone have been available as prescription drugs for some time, and as a result, the proposed amendments would not result in significant changes to pharmacy practice. The amendments would allow nurse practitioners to prescribe Sativex and Nabilone, as well as any new drugs with a drug identification number that are phytocannabinoids or synthetic cannabinoids. The amendments would also allow pharmacies to collect GST, rather than PST, on these drugs.

The Ministry has reviewed the draft schedule of amendments and has produced a tagged schedule of amendments. Please refer Appendix 1 for the tagged schedule of DSR amendments. In addition, please refer to Appendix 2 for a chart setting out the current DSR entries, the proposed amendments and the reasons for the amendments.

Next Steps

If approved by the Board, the College will deposit the tagged schedule with the Registrar of Regulations, at which time the amendments will come into force 60 days from the deposit date.

Recommendation

The Board approve the proposed amendments to the DSR as set out in Appendix 1.

Appendix	
1	Tagged Schedule of Drug Schedules Regulation amendments
2	Table of Proposed Amendments

[7] Email from Health Canada dated October 12, 2018.

November 22, 2018 1124625

Mr. Bob Nakagawa
Registrar
College of Pharmacists of British Columbia
200 – 1765 West 8th Avenue
Vancouver BC V6J 5C6

Dear Mr. Nakagawa,

The Ministry of Health has reviewed the draft schedules of amendments for amending the Drug Schedules Regulation to improve alignment of drug scheduling with the federal Prescription Drug List and the Schedules to the *Controlled Drugs and Substances Act* relating to phytocannabinoids and synthetic cannabinoid receptors, as attached to your email of October 24, 2018.

We understand this resolution is to be considered at the next meeting of the board of the College on November 23, 2018.

The Ministry of Health, being satisfied with the draft schedules, forwarded them to Legislative Counsel for review. Enclosed are the tagged schedules of amendments provided by Legislative Counsel.

Sincerely,

Meghan Thorneloe
Director, Regulatory Initiatives
Professional Regulation & Oversight
Ministry of Health

Enclosure

Ministry of Health
Health Human Resources and Labour Relations Division
Professional Regulation & Oversight Branch
3rd Floor, 1515 Blanshard St
PO Box 9649 STN PROV GOVT
Victoria BC V8W 9P4
Tel: 250-952-2292

OFFICE OF LEGISLATIVE COUNSEL

Examined by: Sherie Verhulst

YELLOW TAG

Order in Council FO RB Regulation FO FE

Cautions/Comments:

I have reviewed the attached regulation and section 22 of the *Pharmacy Operations and Drug Scheduling Act*. It is my opinion that there is legislative authority for this regulation.

The statute requires that once enacted by the board of the College of Pharmacists, the regulation must be filed with the Minister of Health, and the board may deposit it with the registrar under the *Regulations Act* if the following conditions are met:

(a) the minister has not disallowed all or a portion of the regulation within the period prescribed by the minister under that section;

(b) the regulation is not deposited with the registrar until the prescribed period or another shorter period specified by order of the minister has expired.

Signed: Sherie Verhulst Date: November 21, 2018

R10287503

APPENDIX

1 The Drug Schedules Regulation, B.C. Reg. 9/98, is amended in the Schedules by adding the following:

1 Phytocannabinoids produced by, or found in, the cannabis plant and substances that are duplicates of such phytocannabinoids, except

(a) derivatives of cannabis as defined in subsection 2 (1) of the Cannabis Act (Canada) that are exempt from the application of that Act under the Industrial Hemp Regulations (Canada) and that do not contain an isolated or concentrated phytocannabinoid or a synthetic duplicate of that phytocannabinoid,

(b) anything referred to in Schedule 2 to the Cannabis Act (Canada) that contains no more than 10 µg/g delta-9-tetrahydrocannabinol and that does not contain an isolated or concentrated phytocannabinoid or a synthetic duplicate of that phytocannabinoid, or

(c) anything referred to in the Cannabis Exemption (Food and Drugs Act) Regulations (Canada) that is exempt from the application of the Food and Drugs Act (Canada)

1 Synthetic cannabinoid receptor type-1 agonists, their salts, derivatives, isomers, and salts of derivatives and isomers, as listed in the schedules associated with the Controlled Drugs and Substances Act (Canada) and the Narcotic Control Regulations (Canada) .

Drug Schedules Regulation (DSR) - Draft Proposed Amendments

Current DSR Entry	Amended DSR Entry	Rationale for Amendment/ Comments	Consistent with NAPRA (Y/N)	Consistent with PDL/CDSA (Y/N)
None	1 Phytocannabinoids produced by, or found in, the cannabis plant and substances that are duplicates of such phytocannabinoids, except (a) derivatives of cannabis as defined in subsection 2(1) of the *Cannabis Act* (Canada) that are exempt from the application of the *Cannabis Act* (Canada) under the *Industrial Hemp Regulations* and that do not contain an isolated or concentrated phytocannabinoid or a synthetic duplicate of that phytocannabinoid, (b) anything referred to in Schedule 2 to the *Cannabis Act* (Canada) that contains no more than 10 µg/g delta-9-tetrahydrocannabinol and that does not contain an isolated or concentrated phytocannabinoid or a synthetic duplicate of that phytocannabinoid, or (c) anything referred to in the *Cannabis Exemption (Food and Drugs Act) Regulations* made under the *Food and Drugs Act* (Canada) that is	Added at the request of British Columbia College of Nursing Professionals (BCCNP) and Ministry of Health (MoH), and for consistency with Prescription Drug List (PDL)[2] Changes come into effect on Oct. 17, 2018	N/A The change does not come into effect until Oct. 17, 2018 National Association of Pharmacy Regulatory Authorities (NAPRA) has confirmed that they will incorporate this entry, but they have not published their proposed wording	Y, except for paragraph (c) (PDL)

[2] Health Canada Notice of intent to amend: Prescription Drug List (PDL): Phytocannabinoids
https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/prescription-drug-list/notices-changes/notice-intent-cannabis.html

Current DSR Entry	Amended DSR Entry	Rationale for Amendment/ Comments	Consistent with NAPRA (Y/N)	Consistent with PDL/CDSA (Y/N)
	exempt from the application of the *Food and Drugs Act* (Canada)[1]			
None	1 Synthetic cannabinoid receptor type-1 agonists, their salts, derivatives, isomers, and salts of derivatives and isomers with the exception of ((3S)-2,3-dihydro-5-methyl-3-(4 morpholinylmethyl)pyrrolo[1,2,3-de]-1,4-benzoxazin-6-yl)-1-naphthalenyl-methanone (WIN 55,212-3) and its salts, as listed in the schedules to the	Added at the request of BCCNP and MoH, and for consistency with NAPRA and the Controlled Drugs and Substances Act (CDSA) Includes Nabilone[3]	Y	Y (CDSA)

[1] The exemption in paragraph (c) is not included in the description of phytocannabinoids that will be added to the PDL. The *Cannabis Exemption (Food and Drugs Act) Regulations* made under the *Food and Drugs Act* (Canada) exempts recreational cannabis and medical cannabis that does not have a DIN from application of the *Food and Drugs Act*. As a result, those drugs will be excluded from the PDL. Since the College has not adopted federal legislation by reference, the exemptions in the *Cannabis Exemption (Food and Drugs Act) Regulations* will not apply to drugs listed on the DSR. Therefore, it is proposed that paragraph (c) be added to refer to, and incorporate, the exemptions in the *Cannabis Exemption (Food and Drugs Act) Regulations*. Without paragraph (c), the description of phytocannabinoids in the DSR could be interpreted to include recreational cannabis and medical cannabis that does not have a DIN, with the result that those products would require a prescription.
Cannabis Exemption (Food and Drugs Act) Regulations:
http://www.gazette.gc.ca/rp-pr/p2/2018/2018-07-11/html/sor-dors144-eng.html (amendments in force on October 17, 2018)

Health Canada provided the following explanation for the amendments to the *Cannabis Exemption (Food and Drugs Act) Regulations*: "The *Cannabis Exemption (Food and Drugs Act) Regulations* will exempt cannabis from the application of the *Food and Drugs Act*, except for cannabis that is represented with a health claim, such as a drug or a natural health product containing hemp seed derivatives that are compliant with the *Industrial Hemp Regulations*. Cannabis will also continue to be regulated under the FDA if it is an active pharmaceutical ingredient, a drug authorized for clinical trials, or a disinfectant. Also, food and cosmetics containing cannabis will not be exempt from the FDA if they are exempt from the Cannabis Act pursuant to the IHR 2018."

[3] According to Health Canada, because nabilone is a synthetic cannabinoid which does not exist in nature, it does not meet the definition of cannabis under the proposed Cannabis Act. The proposed definition of cannabis includes synthetic phytocannabinoids, i.e., synthetic versions of cannabinoids produced by the cannabis plant, such as THC, but does not include other synthetic cannabinoids. Therefore, nabilone will remain regulated under current Controlled Drugs and Substances Act controls (i.e., as a controlled substance accessible by prescription only).

Current DSR Entry	Amended DSR Entry	Rationale for Amendment/ Comments	Consistent with NAPRA (Y/N)	Consistent with PDL/CDSA (Y/N)
	Controlled Drugs and Substances Act (Canada) and the *Narcotic Control Regulations*			

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

4.b.viii. September 13, 2018 Draft Committee of the Whole Minutes

DECISION REQUIRED

Recommended Board Motion:

Approve the September 13, 2018 Draft Committee of the Whole Minutes as circulated.

Appendix	
1	September 13, 2018 Draft Committee of the Whole Minutes (and appendices)

College of Pharmacists of British Columbia

Committee of the Whole
Day 1 - September 13, 2018: 8:30AM – 4:30PM
Day 2 – September 14, 2018: 9:15AM – 10:15AM
Held at the College of Pharmacists of British Columbia
200-1765 West 8th Avenue, Vancouver, BC

MINUTES

Present:
Mona Kwong, Chair, District 1
Arden Barry, Vice-Chair, District 7
Ming Chang, District 2
Tara Oxford, District 3
Christopher Szeman, District 4
Frank Lucarelli, District 5
Anar Dossa, District 6
Sorell Wellon, District 8
Tracey Hagkull, Government Appointee
Justin Thind, Government Appointee
Jeremy Walden, Government Appointee (Absent on day 1)

Regrets:
Ryan Hoag, Government Appointee (Absent both days)

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 and Licensure
Christine Paramonczyk, Director of Policy and Legislation
Gillian Vrooman, Director of Communications and Engagement
Stephanie Kwok, Executive Assistant

Facilitator:
Ailsa Forsgren, Partner and Career Business Leader, Mercer Canada
Karen Graham, Owner, Panacea Canada Inc

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1. **IN-CAMERA SESSION – REGISTRAR REVIEW BY AILSA FORSGREN**

2. **SETTING THE CONTEXT FOR THE DAY BY KAREN GRAHAM (APPENDIX 1)**

3. **STRATEGIC PLANNING COMMITTEE WORKING GROUPS BY KAREN GRAHAM**

College of Pharmacists of British Columbia

4. GROUP DISCUSSION BY KARAN GRAHAM (APPENDIX 2)

WORKING GROUP 1: PRACTICE TRENDS

Members: Anar Dossa, Frank Lucarelli, Ryan Hoag (Absent)
Staff Resource: Doreen Leong, David Pavan

WORKING GROUP 2: PROFESSIONALISM IN PHARMACY

Members: Ming Chang, Justin Thind
Staff Resource: Mary O'Callaghan, Bob Nakagawa

WORKING GROUP 3: BEST PHARMACY PRACTICE

Members: Arden Barry, Christopher Szeman, Jeremy Walden (Absent), Sorell Wellon
Staff Resource: Gillian Vrooman

WORKING GROUP 4: HPA MODERNIZATION

Members: Tracey Hagkull, Mona Kwong, Tara Oxford
Staff Resource: Ashifa Keshavji, Christine Paramonczyk

5. PATIENT RELATIONS STANDARD BY CHRISTINE PARAMONCZYK (APPENDIX 3)

Sorell Wellon, Chair of Ethics Advisory Committee presented on the Patient Relations Standard. The Committee has recommended that the Standard be brought to the September Board meeting for approval of a 90 day public posting period.

6. COLLEGE COMMITTEE DISCUSSION BY VICE-CHAIR BARRY (APPENDIX 4)

Arden Barry, Chair of Governance Committee presented an overview of the current committee structure and composition. The Committee has recommended that this item be deferred back to the Governance Committee for further discussion. The discussion to include possibility of amalgamating the advisory committees and the Practice Review Committee with the Quality Assurance Committee and removing the word "advisory" from committee names to ensure consistency.

7. ANNUAL MEETING OF COMMITTEE OF CHAIRS AND VICE-CHAIRS DISCUSSION BY CHAIR KWONG (APPENDIX 5)

The Committee discussed about the benefits of having annual meetings of Committee Chairs and Vice Chairs and directed the Governance Committee to look into scheduling a meeting date in 2019.

8. GOVERNANCE TRAINING/EDUCATION OPPORTUNITIES (APPENDIX 6)

Chair Kwong presented on two potential governance training courses to take place in February 2019.

9. CANNABIS BY CHAIR KWONG (APPENDIX 7)

The Committee discussed about the limitations of a pharmacist's role in protecting the best interest of the public in relation to the upcoming federal legalization of non-medical cannabis. The Committee suggested that this topic will be revisited at a later meeting.

College of Pharmacists of British Columbia Strategic Plan 2020 – 2023

Theme Working Groups

September 2018

College of Pharmacists of British Columbia

Introduction

College of Pharmacists of British Columbia

Overall Objective for today

To finalize consultation focus for the four strategic themes

Theme Working Groups

1. Practice Trends
2. Professionalism in Pharmacy
3. Best Pharmacy Practice (Previously: Optimized Roles of Registrants)
4. HPA Modernization

Resource

- *Working Groups Report – Revised (Rev2) - June 14, 2018*

Session Objectives

College of Pharmacists of British Columbia

- Each theme working groups to finalize its consultation focus
  - Plenary discussion of each theme to further sharpen consultation focus
  - College Staff to ensure clarity and understanding in order to execute consultation
  - Staff to use in the 8-week consultation phase:
    - Engagement with stakeholders
    - Environment Scan
- Board will ratify the consultation focus at its meeting tomorrow

College of Pharmacists of British Columbia

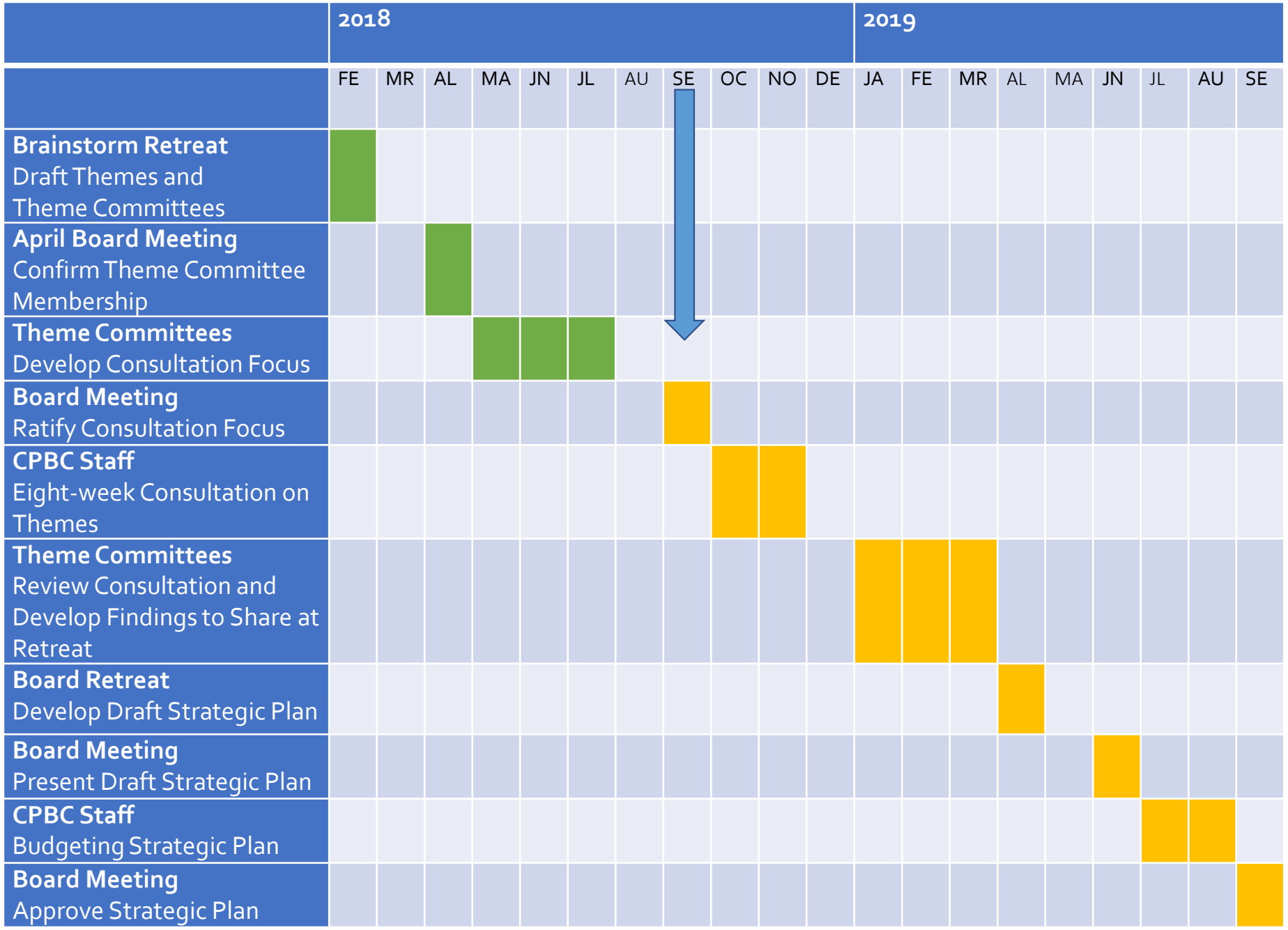
Context

- Strategic Planning Milestones
- Strategic Plan Timelines:

  Current Plan: March 1, 2017 – February 29, 2020

  Future Plan: 2020 – 2023: March 1, 2020 – February 28, 2023

2020 – 2023 Strategic Plan Project Milestones	2018		2019
Brainstorm Retreat: Draft Themes and Theme Committees	Feb	✓	
April Board Meeting: Confirm Theme Committee Membership	Apr	✓	
Theme Committees: Develop Consultation Focus	Apr to Aug	✓	
September Board Meeting: Ratify Consultation Focus	Sep		
CPBC Staff: Eight-week Consultation on Themes	Oct & Nov		
Theme Committees :Review Consultation and Develop Findings to Share at Retreat			Jan to Mar
Board Retreat: Develop Draft Strategic Plan			Apr
Board Meeting: Present Draft Strategic Plan			Jun
CPBC Staff: Budgeting Strategic Plan			Jul & Aug
Board Meeting: Approve Strategic Plan 2020 - 2023			Sep


2018
2019
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Brainstorm Retreat
Draft Themes and Theme Committees
April Board Meeting
Confirm Theme Committee Membership
Theme Committees
Develop Consultation Focus
Board Meeting
Ratify Consultation Focus
CPBC Staff
Eight-week Consultation on Themes
Theme Committees
Review Consultation and Develop Findings to Share at Retreat
Board Retreat
Develop Draft Strategic Plan
Board Meeting
Present Draft Strategic Plan
CPBC Staff
Budgeting Strategic Plan
Board Meeting
Approve Strategic Plan

Goals	Objectives	17/18	18/19	19/20	20/21	21/22	22/23
2017 - 2020	**ORGANIZATIONAL EXCELLENCE**						
Legislative Standards and Modernization	1. Recommend to MOH that Pharmacists be granted authority to prescribe						
	2. Implement comprehensive review and reform of legislative requirements under PODSA						
Professional Excellence	1. Extend practice review program into hospitals						
	2. Continue to implement 2015/18 Methadone Action Plan to ensure pharmacies providing methadone treatment to vulnerable populations meet required standards for professionalism and patient safety						
Drug Therapy Access and Monitoring	1. Recommend to MOH that Pharmacists be granted the authority to prescribe						
	2. Seek greater access to patient lab values to enhance pharmacists' ability to provide quality timely service to patients						
Organizational Excellence	1. Streamline licensure business process to improve its efficiency and effectiveness						
	2. Update the College's IT infrastructure to integrate and support the College's departments, programs and functions						
	3. Consider the Org Review recs which will inform a review of Board Policies and staffing levels and organization						
2020 - 2023	**RAISING THE BAR *(To be confirmed)***						
THEMES	**STRATEGIC GOALS**	**17/18**	**18/19**	**19/20**	**20/21**	**21/22**	**22/23**
Practice Trends	Strategic Goals to be Determined						
Professionalism in Pharmacy	Strategic Goals to be Determined						
Best Pharmacy Practice	Strategic Goals to be Determined						
HPA Modernization	Strategic Goals to be Determined						

Theme Working Groups' Consultation Focus

How your consultation focus will guide College staff

- Some consultation questions will be pursued in the *stakeholder engagement* by the College's Communications Team
  - Not necessarily verbatim
- Other questions are more amenable to an *environment scan*, to be undertaken in parallel.
  - For example, gathering information about practices in other provinces or countries

Focus Questions for Today

College of Pharmacists of British Columbia

❖ Theme Working Groups:

1. What, if any, **general changes** do you wish to make to the consultation focus you designed at the June 2018 Session?
2. Please fill in the following areas:
   a. If your listed stakeholders without any focus questions, *please add suggested questions*
   b. Where you suggested a multiple choice/list of options approach, *please suggest some options*
3. Brief overview to plenary from each working group
   - *Opportunity for Board and staff to clarify*

❖ Plenary Discussion:

1. What further revisions do you recommend for the eight-week consultation on each theme?
   - *Opportunity for Board and staff to clarify*

PANACEA
CANADA INC.

College of Pharmacists of British Columbia

Strategic Plan 2020 – 2023
Working Groups Revised Report
September 13, 2018

Karen Graham
September 18, 2018

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3. Best Pharmacy Practice 8
4. Standards of Practice Modernization: HPA Bylaws 11

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Participants

Board

Mona Kwong, Chair, District 1 – Metropolitan Vancouver
Arden Barry, Vice-Chair, District 7 – Community Hospitals
Ming Chang, District 2 – Fraser Valley
Tara Oxford, District 3 – Vancouver Island/Coastal
Christopher Szeman, District 4 – Kootenay/Okanagan
Frank Lucarelli, District 5 – Northern British Columbia
Anar Dossa, District 6 - Urban Hospitals
Sorell Wellon, District 8 – Pharmacy Technicians
Justin Thind, Government Appointee
Tracey Hagkull, Government Appointee

Regrets
Ryan Hoag, Government Appointee
Jeremy Walden, Government Appointee

Staff

Bob Nakagawa, Registrar
David Pavan, Deputy-Registrar
Mary O'Callaghan, Chief Operating Officer
Ashifa Keshavji, Director of Pharmacy Practice Reviews and Quality Assurance
Doreen Leong, Director of Registration and Licensure
Christine Paramonszyk, Director of Policy and Legislation
Gillian Vrooman, Director of Communications and Engagement

Introduction

At CPBC's February 2018 Strategic Planning Brainstorm Retreat, participants identified four themes for further elaboration. More detail is found in the report from that session: *Strategic Plan 2020 – 2023 Foundation Document.* A brief *Foundation Report Summary of Next Steps* is found in Appendix A.

Also appended (Appendix B) is an overview of planning project timelines as well as a high-level timeline that describes the current and future strategic plans.

Theme working groups include:

1. Practice Trends
2. Professionalism in Pharmacy
3. Best Pharmacy Practice
4. Standards of Practice Modernization: HPA Bylaws

Theme working groups convened working sessions on April 19, 2018 and June 14 2018. Summaries of their deliberations are found in (a) *Revised Report Theme Working Groups April 19, 2018* and (b) *Strategic Plan 2020 – 2023 Working Groups Report – Revised (Rev2) June 14, 2018*.

At this September working session, the theme working groups finalized theme focus, including consultation questions. The CPBC Board ratified the consultation focus at its September 14 2018 Board Meeting. The ratified consultation focus will guide College staff in two parallel efforts, culminating in information that the Board will need to create an effective draft strategic plan at its retreat in April 2019. The parallel efforts include:

- Consultation questions that will be pursued in a *stakeholder engagement* by the College's Communication ad Engagement Team. The questions suggested by the theme working groups will serve as guidance and will not necessarily be posed verbatim.
- Other questions will be explored through an *environment scan*, for example questions that seek to understand practices and experiences from other jurisdictions.

Questions that guided theme working group discussions included:

1. What, if any, general changes do you wish to make to the consultation focus you designed at the June 2018 session?
    a. If you listed stakeholders without any focus questions, please add suggested questions
    b. Where you suggested a multiple choice/list of options approach, please suggest some options

Each working group presented proposed changes for discussion in plenary. The following pages summarise the final consultation focus recommended by each working group, including specific insights from the September 13, 2019 working session.

Theme Working Group Reports – September 13, 2018

Following are the reports from each theme working group. Note that most of the content was generated at the April and June working sessions; discussion and changes that arose in the September 13, 2018 working session are included in blue.

1. Practice Trends

Members: Anar Dossa, Frank Lucarelli, Ryan Hoag (Absent)
Staff Resource: Doreen Leong, David Pavan

Finalized Theme Focus

Why is the theme important?

- Patient safety: identify gaps between central fill and Community Pharmacy

How does it relate to patient safety and providing better health through excellence in pharmacy?

- Are they both following the Community Pharmacy Standards of Practice (SOP)

Refined Theme Scope
Following four are all in-scope:

1. Interprovincial pharmacy services (Direct CPBC Impact)

    - Scope redefined as interprovincial pharmacy services, previously interjurisdictional pharmacy services and interjurisdictional pharmacy services
    - What is happening in other provinces? States?
    - What are their trends and their response to these trends?

2. Centralized Pharmacy Services (Direct CPBC Impact)

    - Include distribution, clinical and technical services
    - Centralized clinical services can impact a huge number of patients
    - Environmental scan of other PRAs:
        - What are they doing, what legislation do they have?
        - Site visits

3. Point of Care Testing (Indirect CPBC impact)

    - HealthTAB

4. New and emerging models of pharmacy service delivery (Direct CPBC Impact)

- How do patients want to get their services delivered?
- Ways of getting access to services
- Vending machines, drones etc.

Consultation Scope

- Environmental scans (What are they doing? What legislation do they have?)
- Other PRAs – national and international
    - Washington State Pharmacy Board
- Patients
- Prescribers – relationship with pharmacist
- Pharmacists/owners/directors
- Pharmacy technicians
- Government
- Advocacy groups
- Health Authorities
- Site Visits

Questions to Pose

Public:

- How do patients want to receive their pharmacy services: product and clinical services?
    - List of options and have them rate/rank the options 1-10
    - Options to include in-person, on-line, e-mail, text message and mix of these
    - Consider use of smart phones
    - Distinguish between services related to product and services related to counselling
- What services could be centralised?
- How do out of province patients like to receive their pharmacy services?
- What services would you like to receive that you currently don't receive?
    - For example, nutritional counselling, lab test ordering

Pharmacy Regulatory Authorities (PRAs):

- What service models do other PRAs have – national and international?
- What interprovincial pharmacy service models currently exist?
- What are other provincial jurisdictions doing re Point of Care testing and measuring outcomes?

Retailers:

- What business models are you currently using and what are you projecting?
- Compare across provinces

Discussion Points Removed from February Meeting:

- What are trends in Rx reimbursement?
- What will government cover via reimbursement?
- Integration of roles was referred to optimized roles of registrants group
- Opioids and cannabis for medical use:
    - is this a practice trend?
    - Work is underway on Opioids and Medical prescribing of Marijuana may already be in place by the time the next strategic plan is in place

Plenary Discussion Highlights

- Empowering the patient
- Pharmacists as the primary care provider
- Trust between patient and health care system
- Include demographics (age ranges and regions) to better understand responses
- Consider Interprovincial challenges, for example Alberta Pharmacists with prescribing privileges and impact on border community pharmacy practice; how National PharmaCare will influence pharmacy practice in BC

2. Professionalism in Pharmacy

Members: Ming Chang, Justin Thind
Staff Resource: Mary O'Callaghan, Bob Nakagawa

Finalized Theme Focus

- How would you describe your theme?
  - Enhancing stature, credibility and reputation of the pharmacy professional
- What background might be needed to understand the theme?
  - Survey key stakeholders as per question list
- Why is the theme important?
  - The public view pharmacists and technicians, i.e. the pharmacy profession as trusted expert.
  - Feedback/confidence
  - Holding accountable for making one non-credible to the point of complaints/harm to public

- What's in scope, or out of scope?
  - Right Touch legislation?
  - Nothing really out of scope

Consultation Scope:

- Patients / the public – no changes from April list
- Physicians (& Nurse Practitioners, etc.) – no changes from April list
- Business owners
- Registrants

Questions to Pose
Patients / the public

1. Is the interaction between you and your pharmacist is held in a confidential and private setting?
2. Do you feel the pharmacist spends enough time with you and your health/meds? Available for OTCs?
3. Do you feel the interaction is professional?
4. Do you view the Pharmacist as a professional?
5. How do you choose your pharmacy?
6. How to maintain a professional image of pharmacy – in marketing?
7. How do you think professionalism impacts you?
8. How do you define professionalism?
9. What are the barriers to professionalism?
10. Examples of professionalism: White coat, name tag, certificate

Physicians (& Nurse Practitioners, etc.)

1. Do you consider pharmacists to be peers? Drug therapy experts? Professionals?
2. How do you rate your interaction with pharmacists? Rate value of most recent interaction
3. List pharmacist roles and responsibilities: Did you know? Do you feel they are being done?
4. Do you contact Pharmacist for drug information? For other reasons?
5. Preference for/mode/method of communication? Any challenges?
6. What are the barriers to professionalism?

Business owners:

1. What are the barriers to professionalism for pharmacy professionals?
2. Does facility impact impression of professionalism?

Pharmacy Technicians:

1. Do you feel that you are being treated as a professional by pharmacists?
2. Do you have autonomy in doing your work?
3. What are the barriers to professionalism?
4. …. perhaps ask Pharmacy Technicians and pharmacists to find more questions….

UBC Faculty/Technician Colleges, include Professors and students:

1. What is important to convey about professionalism?
2. How is it conveyed?

Pharmacists:

1. Is your Practice environment professional?
2. Do you Consider MDs and Nurse practitioners as peers?
3. Examples of things that feel unprofessional, for example 'bad-mouthing' other pharmacists
4. What are the barriers to professionalism?

Managers:

1. Is your Practice environment professional?
2. Do you Consider MDs and Nurse practitioners as peers?
3. Examples of things that feel unprofessional, for example 'bad-mouthing' other pharmacists
4. What are the barriers to professionalism?

Plenary discussion highlights

- Patient care needs to be broader to include people seeking care in pharmacy who are not necessarily patients; consider public safety.
- Broadening understanding of our role and responsibilities.
- Identify any barriers in our current regulatory framework and legislation that prevent us going to where we want/need
- Promote the "aspirational" in our bylaws.
- Counselling on refills: the goal is to empower the patient to look at their health / lifestyle changes / etc.
- Look at relationship building, overall health, etc.
- Consider health objectives versus the "Product".
- Education about the role.
- Build bridges with other healthcare professions.
- Website videos about professionalism / professional interactions?
- University classes – discuss professionalism.
- Conference presentations at other healthcare professions' conferences.
- Include Cultural Humility?

Also consider

- Professionals' activities outside of work
- CPBC Compliance officers' views

3. Best Pharmacy Practice

Members: Arden Barry, Christopher Szeman, Sorell Wellon, Jeremy Walden (Absent)
Staff Resource: Gillian Vrooman

Finalized Theme Focus

Tentative Theme Title, from CPBC Mission: Promote best practices for the delivery of pharmacy care in BC

Summary Questions from September 13 Session

1. What is your vision of best practice in the delivery of pharmacy services?
2. How can pharmacists and registered pharmacy technicians be empowered to meet the future needs of patients and the public?
3. What barriers exist to pharmacists and registered pharmacy technicians providing public- and patient-centred care
4. How can the College "raise the bar"/ elevate/improve to ensure best pharmacy practice and patient safety?
5. How can the College best promote evidence-based practice and patient- and public-centred care?

Why is it important?

- Provides opportunities for pharmacists to provide more clinical services which results in better patient outcomes
- Results in better patient outcomes
- Making sure patients get the best out of their medications
- Pharmacy technicians, best practice, ensure accuracy and excellence in dispensing, allows
- Provide real life example of how Pharmacy technicians can support have a more clinical role, pharmacists more involved in counselling patients talk.
- Inspirational leaders TED talk, change happens when the patients ask for it, paint the picture of the future.
- Imagine X scenario of pharmacy in best practice
- Imagine a scenario where Pharmacy technicians are injecting

Description of theme should be developed based on these concepts:

- Aspirational
- Future of pharmacy
- Best Pharmacy Practice
- BC as a leader in pharmacy practice / patient care
- Elevating pharmacy care in BC
- Excellence in pharmacy (from our Vision)
- "Raising the bar"
    - raising the standards of practice
    - raising the bar in patient care through excellence in pharmacy
- Clinical care best practices
- Evidence-based practice; broad requirements for making evidence-based recommendations?
- Using scope to better meet patient care needs
- Maximizing registrants' full potential
- Enable registrants to meet the needs of patients
- Focus on the patient; patient centered care
- Imagine excellence in pharmacy where pharmacy professionals are able to raise the bar in patient care

- BC as a leader
- Raising the bar in patient care through excellence in pharmacy
- Promoting best practices for the delivery of pharmacy care in BC
- Elevating pharmacy care in BC: What are your ideas on how to implement “raising the bar”

Considerations

- How do we address payment / affordability concerns?
    - Out of our scope as a regulator, but impact what care could be possible
- Ensure best practices for both pharmacists (clinical) and pharmacy technicians (technical)
- Reflect different models of team-based care

Questions to Pose

Question concepts
In addition to questions considered in earlier sessions, consider, imagine X scenarios where we ask people to consider what the future of pharmacy practice should look like to meet the needs of patients.

- Provide examples of how techs can perform technical / dispensing roles and support pharmacists having a more clinical role
- Pharmacists more involved in counselling patients…
- Change happens when the patients ask for it, paint the picture of what the future could look like
- Look to inspirational leaders & TED talks for ideas

Question Ideas
What do we need to know more about on this topic from stakeholders?

- What is your vision of "best practice" or "excellence" in pharmacy practice?
- What should "best practice" or "excellence" in pharmacy practice look like in 2023?
- How can pharmacists be empowered to meet the future needs of patients?
- How can pharmacy technicians be empowered to meet the future needs of patients?
- What barriers exist to pharmacists practising to their full scope of practice?
- What barriers exist to pharmacy technicians practising to their full scope of practice?
- How can the College “raise the bar” to ensure best practice and patient safety?
- How can the College best promote evidence-based practice and patient-centered care?

Environmental Scan

- How are assistants used / restricted elsewhere?
- How are other provinces or international areas using Pharmacy Technicians?
- How are other regulators being aspirational or getting involved with best practices?

Stakeholders / Engagement Audience

- Pharmacy technicians
- Pharmacists
- Pharmacy Assistants
    - PTSBC and pharmacy managers may be best leads for these
- Pharmacy Owners

    - All directors / owners: College has on file as of October 2018
        - We have all pharmacist directors and are starting to collect all non-registrant indirect owners through pharmacy renewals under the new pharmacy ownership requirements
- Members of the public
- Patient groups (College has list of contacts)
- First Nations
    - FNHA
    - FN Health Council
- Pharmacy Education groups
    - UBC Pharmacy
        - Faculty
        - Students
        - Other Continuing Ed programs
        - Pharmacists Clinic
    - UBC other (other medical programs that may collaborate with pharmacy)
    - Pharmacy Technician schools
        - Obtain recommendations for specific organization from Sorell Wellon – to enhance traction
- Other healthcare professionals (who prescribe)
    - Physicians
        - General Practitioners
        - Specialists
    - Nurses and Nurse Practitioners
    - Dentists (since they can prescribe)
    - Veterinarians (since Veterinarians and Pharmacists sometimes collaborate and may need to collaborate more with anticipated further compounding requirements from Health Canada)
- Other (non-health) professionals?
    - This may be too out of scope for the online engagement, we'd need to be clear about what kind of questions we want to ask, but may work as part of an environmental scan

Risks

- Will this work seem to advocacy focused?
- Will best practice requirements be ignored by registrants?

Plenary Discussion from September 13, 2018

4. Standards of Practice Modernization: HPA Bylaws

Members: Tracey Hagkull, Mona Kwong, Tara Oxford
Staff Resource: Ashifa Keshavji, Christine Paramonczyk

Finalized Theme Focus

The HPA is an 'umbrella' statute that provides a common regulatory framework for health professions in BC.

The regulatory colleges have been delegated the authority under provincial legislation to govern the practice of their registrants in the public interest. Their mandate at all times is to serve and protect the public.

Our job is to protect the public 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. The College receives its authority from and is responsible for administering provincial pharmacy legislation.

(The primary function of the colleges with respect to the HPA is to ensure their registrants are qualified, competent and following clearly defined standards of practice and ethics).

Since the standards directly impact the care that a patient receives, it is critical that updates must reflect current day practice to enhance/keep at forthright the public and patient safety.

As practice changes or evolves, the standards of practice need to reflect current day practice (reviewed and updated to reflect current practice; rapidly evolving health system to provide best care)

Finalized theme focus

- The HPA governs the practice of regulated health professionals in BC.
- The CPBC Bylaws under the HPA define the expectations of the practice of pharmacy by pharmacists and pharmacy technicians with the aim of protecting the public interest.
- In general, the Bylaws under PODSA govern the requirements of the pharmacy site; whereas, the Bylaws under HPA govern the practice of pharmacy.
- The Standards of Practice under the College's HPA Bylaws are primarily divided into three main areas: community pharmacy, hospital pharmacy, and residential care facilities and homes, which define practice specific requirements in those settings.

Out of Scope

- Business interests and related matters (e.g. billing, etc.) are not within the College jurisdiction
- Board administration
- Pharmacist prescribing
- Federal requirements and rules

Our Scope:
To focus priority on modernization of the standards of practice (community, hospital, residential care) under the HPA bylaws

Questions to Pose

1. What are you hoping to learn through the input you receive?
   - Are they current and appropriate and required and are there gaps or missing information? What is mis-interpreted? What is misunderstood? Will this be relevant in the next five-ten years?
2. What are you looking for ideas on?
   - What is too much? Too little?
   - Relevancy to practice, current, clear?
   - "Sticky" topics?
   - Anything that blocks ability to practice? What is prohibitive to patient care?
   - Hybrid model/practice – emerging models
   - Primary Care – practitioners not attached to a hospital, community or RC
   - HA – ambulatory care; satellites (patient consent, emergency fill, ID verification, privacy – Freedom of Information and Privacy)
   - Forward looking – practice trends

3. Questions must keep in mind the community, hospital and residential care

   1. Impact of rules, indirectly, how does it impact you - e.g., why does a pharmacist have to counsel?
   2. How do the HPA Bylaws impact physicians and nurses and their relationship with pharmacists? Health Authorities?
   3. Community Care and Assisted Living Act – group homes, Plan B – whoever guides this in the Ministry, Foster care

Stakeholders:

- Government?
- Patient groups – Patient Voices Network, BC Quality Council; CLBC, CCALA, HA Directors, HA – ambulatory pharmacy
- All groups noted in the backgrounder: CPBC staff: PRP, Investigations, Policy team; BCPHA, Neighbourhood Pharmacy Association, CSHP, Pharmacy Technicians Society of BC, CRNBC, CPSBC
- UBC
- Chain Drug Stores

Also keep in mind:

- Impact of centralization/consolidation
- Interprovincial Services:
  - Telehealth
  - Production Centres

Plenary Discussion

September 13, 2018 Plenary Discussion Highlights

- Focus on patients rather than pharmacists or technicians, to avoid straying into territory of advocacy
- Include Public and Patients
- Consider that pharmacy professionals are the most accessible; need to reflect what's reasonable or in scope
- How might we stay positive?
    - Regulatory body focuses on negatives- what not to do, errors
    - The "what went wrong" approach is reactionary; opportunity is to be proactive and positive
- Need to consider that evidence is evolving:
    - Recalls and questions to pharmacists - "why did I receive this drug if it causes cancer?
    - How do pharmacists respond to this? E.g. Valsartan example
- Framing the survey is important
    - Past survey responses (for example how to increase uptake of pharmacy technicians in community pharmacies) were focused mostly on business models which are out of scope for the College
    - Need to clarify context at the outset of the engagement: explain CPBC's jurisdiction
    - Consider relevant frameworks from College of Physicians of BC and College of Nurses of BC
- Rather than enumerating all of the various practice sites, call it "Pharmacy Practice"

Following are the key points made in the June 2018 plenary discussion, for consideration in CPBC's strategic planning in general.

Patient Care versus Public Care

- Is the term *patient care* limiting?
- People can go to a pharmacy to ask questions but not necessarily be patients
- Maybe a better term would be *public care*?

Empowering Patients

- Counselling – Pharmacists should engage with their patients and empower them beyond prescription medication
- Empowerment - Giving them tools of knowledge to be successful
- Not just giving them instructions on how to take their medication but empowering the patients to make life changes
- Building a relationship with your patient – something your patient might not think is important, but you pick up as significant
- Optimizing role – fostering this kind of environment
- This is where health care needs to go

Trust and Credibility

- Idea of trust and building credibility
- Professionalism is trust
- Best practice and standards –meeting the standards and achieving best practice
- Work on engagement and relationship building with health care providers
- Trend – Trusting pharmacists to step in and be that person, be that better healthcare provider

Shift to Outcomes-based Care

- How do we shift health care to a more outcome based?
- Challenges – some medications sometimes take 30-40 years to work
- Pharmacists can't not get paid, outcomes might not be there

Other things to consider

- Healthy choice versus the easy choice.
- Why do we define site?
- Professionalism with whom: Registrant, Patient, MD?
- Practice trends – how do we define pharmacy services? Always tied to product.
- Do we have a role in prevention?

Appendix A: Foundation Report Summary for Board Next Steps (v3.1)

A well-founded strategic plan is critical to the success of any organization, allowing it to make intentional progress on its own agenda. CPBC's February 17, 2018 Brainstorm Retreat provided a springboard for its 2020-23 strategic plan. Participants came to consensus on several high-level themes for further development and consultation and Working Groups were established to lead next steps for each theme.

Developed to guide board members in leading next steps, the following is an overview of the four strategic themes including working groups, scope, preliminary work plan, approach and next steps envisioned at the retreat.

More detail is found in the Feb 23, 2018 *CPBC Strategic Plan 2020 – 2023 - Foundation Document.*

	1. Practice Trends	2. Professionalism in Pharmacy	3. Optimized Roles of Registrants	4. HPA Modernization
Working Group	Board Lead: Frank Board: Ryan, Staff: Doreen, David	Board Lead: Ming Board: Justin Staff: Bob, Mary	Board Lead: Chris Board: Arden, Sorrell, Jeremy, Anar Staff: Gillian	Board Lead: Tara Board: Mona, Tracey Staff: Ashifa, Christine
Possible Scope of Theme	Interjurisdictional practice Central fill technology Point of care testing Integration of roles New and emerging models of service delivery	Business versus profession E.g. quotas, incentives, Privilege of being a professional is earned Professionalism extends 24/7	Best clinical practice Evidence based care Best choice of drug for individual patients, including their informed consent Links to CPBC Vision: *Better Health through Pharmacy Excellence* Links to *Practice Trends Theme* Technician practice to full scope to enable pharmacist to practice to full scope Assistants' roles: may revisit previous work on this Uptake, use of full scopes; dependent on business and workflow	Links to all other themes Standalone because large piece of work Foundational – not just a support for contemporary or current practice Impact of PODSA and HPA together
Possible Scope of Engagement	Site Visits: McKesson, Safeway. Save-on Foods, London Drugs	Pharmacist, Technicians Academics Owners/head offices BCPhA CSHP BC Branch Pharmacy Technicians association of BC Patient groups: Seniors, First Nations	Pharmacists, Technicians, Hospital/Community Associations Other Health Care Professionals Other Board members Staff	Engage advisory committees including community, hospital, residential care Consider joint advisory committee

	1. Practice Trends	2. Professionalism in Pharmacy	3. Optimized Roles of Registrants	4. HPA Modernization
Work Plan	Monthly Teleconference on Wednesdays Doreen/David – Staff Support	Teleconferences PRN – biweekly – monthly SharePoint portal	Teleconferences as needed Shared on line space to build /share material	In person Meetings: at/around Board Meetings Teleconferences in between Board Meetings April Board Meeting: initial discussion June Board Meeting: Go through collated information and initial themes Upload information to SharePoint September Board Meeting present to the Board: what, who, how - *consulting*
Possible Approach	Environment Scan on emerging service delivery Focus groups/advisory committees Site Visits: McKesson, Safeway. Save-on Foods, London Drugs	April NS conference – members to attend conference Also, relevant work by Saskatchewan College of Pharmacy Professionals Review notes from previous discussions	Solidify theme Determine questions to ask Determine who to ask Identify research/resources	Historical and new information Linking data – enforcement, PRP
Next Steps	Agree to meeting schedule Staff resources to plan approach	First meeting 1st or 2nd week in March – when Ming is back Define and determine scope/draft TOR Conference Attendance – Nova Scotia and Saskatchewan	Expand working group to enhance capacity: include breadth of experience, practice sites invite guests: Board Members, staff, other	In person at April Board Meeting: initial discussion Internal staff to collate information initially

Two broad concerns were flagged:
(a) Composition of Group Three to be expanded to include adequate numbers and mix of backgrounds and practice experience; and
(b) Working Groups' efforts must be carefully aligned with overall Board direction.

Possible general next steps for working groups included:

Activities	Membership	Board Reporting
Define theme scope Develop Terms of Reference Develop key questions and target groups to submit for an eight-week online engagement in October and November After eight-week engagement, feedback to be shared with working groups for review	Working Groups can open to other people to supplement discussions e.g. guests: Board, staff Consider committee overload	Carve time at Board meetings to review progress Chair and Vice Chair to provide updates to Board Build in one-page updates at Board meetings

Appendix B: Strategic Planning Timelines

2020 – 2023 Strategic Plan Project Milestones	2018		2019
Brainstorm Retreat: Draft Themes and Theme Committees	Feb	✓	
April Board Meeting: Confirm Theme Committee Membership	Apr	✓	
Theme Committees: Develop Consultation Focus	Apr to Aug	✓	
September Board Meeting: Ratify Consultation Focus	Sep		
CPBC Staff: Eight-week Consultation on Themes	Oct & Nov		
Theme Committees :Review Consultation and Develop Findings to Share at Retreat			Jan to Mar
Board Retreat: Develop Draft Strategic Plan			Apr
Board Meeting: Present Draft Strategic Plan			Jun
CPBC Staff: Budgeting Strategic Plan			Jul & Aug
Board Meeting: Approve Strategic Plan 2020 - 2023			Sep

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Goals	Objectives	17/18	18/19	19/20	20/21	21/22	22/23
2017 - 2020	**ORGANIZATIONAL EXCELLENCE**						
Legislative Standards and Modernization	1. Recommend to MOH that Pharmacists be granted authority to prescribe						
	2. Implement comprehensive review and reform of legislative requirements under PODSA						
Professional Excellence	1. Extend practice review program into hospitals						
	2. Continue to implement 2015/18 Methadone Action Plan to ensure pharmacies providing methadone treatment to vulnerable populations meet required standards for professionalism and patient safety						
Drug Therapy Access and Monitoring	1. Recommend to MOH that Pharmacists be granted the authority to prescribe						
	2. Seek greater access to patient lab values to enhance pharmacists' ability to provide quality timely service to patients						
Organizational Excellence	1. Streamline licensure business process to improve its efficiency and effectiveness						
	2. Update the College's IT infrastructure to integrate and support the College's departments, programs and functions						
	3. Consider the Org Review recs which will inform a review of Board Policies and staffing levels and organization						
2020 - 2023	**RAISING THE BAR *(To be confirmed)***						
THEMES	**STRATEGIC GOALS**	**17/18**	**18/19**	**19/20**	**20/21**	**21/22**	**22/23**
Practice Trends	Strategic Goals to be Determined						
Professionalism in Pharmacy	Strategic Goals to be Determined						
Best Pharmacy Practice	Strategic Goals to be Determined						
HPA Modernization	Strategic Goals to be Determined						

College of Pharmacists of British Columbia

Committee of the Whole
September 13, 2018

5. Approval of the Patient Relations Program Standard

DECISION REQUIRED

Recommended Board Motion:

Approve the following resolution to amend the bylaws made under the *Health Professions Act*:
"RESOLVED THAT, in accordance with the authority established in section 19(1)(l) of the Health Professions Act ("HPA"), and subject to filing with the Minister as required by section 19(3) of the HPA, the Board of the College of Pharmacists of BC approves the proposed bylaws made under the HPA relating to patient relations for filing with the Minister of Health, as circulated."

Purpose

To seek Board approval on the proposed Patient Relations Program Standard, which would be incorporated into Schedule A – Code of Ethics of the *Health Professions Act* ("HPA") Bylaws, for filing with the Ministry of Health.

Background

The proposed Patient Relations Program Standard ("the Standard") outlines the responsibilities of registrants in relation to:

- Professional boundaries and dual relationships;
- Relationships with former patients; and,
- The duty to report sexual misconduct.

In addition, it also raises awareness of registrants' responsibility to educate themselves on professional ethics. See Appendix 1 for the proposed Standard.

Legislative Requirements for a Patient Relations Standard

The establishment of a patient relations program is a requirement for the College:

- It is requirement under s.16(2)(f) of the HPA[1]. Under the HPA, the purpose of a patient relations program is to seek to prevent professional misconduct of a sexual nature.
- It is also noted as a Board requirement under s. 84 of the HPA Bylaws[2].

[1] http://www.bclaws.ca/civix/document/id/lc/statreg/96183_01
[2] http://library.bcpharmacists.org/6_Resources/6-1_Provincial_Legislation/5076-HPA_Bylaws.pdf

- The College's current Code of Ethics references the "Patient Relations Program" as a companion document in Standard 7(b).[3]

The proposed Standard primarily addresses s. 84(2)(c) of the HPA Bylaw requirement (i.e. to "develop guidelines for the conduct of registrants with their patients"). The other two requirements for a Patient Relations Program under the HPA Bylaws (noted under s. 84(2)(a) and (b)), which regard setting procedures, and monitoring and evaluation of the program). It is proposed that those other requirements be addressed via a corresponding program information document to be adapted for the College's website (see Appendix 2). That information document is operational in nature and would not require filing; therefore, it is not the primary focus of this briefing note.

Development of the College's Patient Relations Program

In 2013, the BC Health Regulators (BCHR) established a working group (the "Working Group") to review programs dealing with patient-practitioner relationships and to make recommendations on a framework for a model patient-practitioner relationship program. The Working Group was comprised of registrars and compliance staff from ten different colleges. A key outcome was the development of a framework, to ensure that consistent principles and program elements are used in the development of each respective college's patient relations program (see the BCHR Framework in Appendix 3).

The Board approved the BCHR Framework at its September 2016 meeting. The College's Ethics Advisory Committee drafted a patient relations policy statement and program document, which has since been incorporated into the Standard and program information document (two separate documents). The Standard incorporates findings from cross jurisdictional research, and has been reviewed by legal counsel and College staff.

Discussion

The Standard provides guidance to registrants on maintaining proper professional boundaries with patients and former patients, and preventing professional misconduct of a sexual nature. These guidelines are based on an international review of professional standards on sexual misconduct, and are informed by legal counsel review. The Standard also outlines the statutory requirement of all registrants to report sexual misconduct under s. 32.4 of the HPA.

The Standard is intended to be read and understood in relation to its companion documents – the Code of Ethics and Conflict of Interest Standards. Collectively, these three documents address all key aspects of professional misconduct (see Appendix 4) and form a comprehensive suite of regulatory tools to enforce the College's patient relations program.

Alignment with the BCHR Framework

[3] http://library.bcpharmacists.org/6_Resources/6-1_Provincial_Legislation/5087-HPA_Bylaws_Code_of_Ethics.pdf

Careful consideration has been made to ensure that the College's patient relations program aligns with the BCHR Framework. The Standard addresses three program elements related to sexual misconduct and dual relationships, whereas the Code of Ethics and Conflict of Interest Standards address other aspects of professional misconduct (see Appendix 4). BCHR Framework elements which are not explicitly addressed via regulatory means – e.g. the use of social media – could be addressed through communications tools on the College's website.

Spousal Relationships and Sexual Misconduct

The Standard does not directly discuss the issue of providing pharmacy services to family members, including spouses. However, dispensing prescriptions to family members is generally prohibited under Standard 2(e) of the Conflict of Interest Standards[4]. This is consistent with the BCHR Framework, which requires all colleges to address "treatment of partners, spouses, or other family members" and "care of family members in emergency situations". Where further information is required on this matter, it is suggested that communications tools such as FAQs or Readlinks be employed.

Next Steps

Typically, upon Board approval, the Standard would undergo a 60 day filing period with the Ministry of Health, following which the Standard would come into force. (Note: The HPA does not require public posting for standards of professional ethics.) However, the Ministry has requested that Colleges refrain from filing new bylaw amendments at this time, due to a backlog. As such, the Standard would not be filed until the Ministry backlog is alleviated. In the meantime, College staff will finalize any applicable communications tools.

Recommendation

The Legislation Review Committee recommends that the Board approve the proposed Standard for filing with the Ministry of Health for a 60-day period, once the Ministry backlog is alleviated.

Appendix	
1	Patient Relations Program Standard
2	Patient Relations Program Information
3	BCHR Framework
4	CPBC Regulatory Tools for Non-Sexual Professional Misconduct

[4] http://library.bcpharmacists.org/6_Resources/6-1_Provincial_Legislation/5111-Code_of_Ethics_Conflict_of_Interest_Standards.pdf

Patient Relations Program Standard

Application

This standard applies to all registrants in all practice settings, and should be read in conjunction with Standard 7(b) of the Code of Ethics in Schedule "A" of the *Health Professions Act* Bylaws. It should also be read in connection with sections 32.2 and 32.4 of the *Health Professions Act*.

Definitions

In this standard:

"professional misconduct" has the same meaning as in s.26 of the Act*;*

"sexual misconduct" includes:

i. sexual intercourse or other forms of sexual relations between the registrant and the patient,

ii. touching of a sexual nature, of the patient by the registrant, or

iii. behaviour or remarks of a sexual nature, by the registrant towards the patient,

but does not include touching, behaviour or remarks by the registrant towards the patient that are of a clinical nature appropriate to the service being provided.

Purpose

This standard is to inform registrants and the public of the college's expectations for registrants to ensure that proper professional boundaries are observed and to prevent professional misconduct of a sexual nature.

Standards

(i) *Maintaining Professional Boundaries and Avoiding Dual Relationships*

It is important to ensure that there are clear professional boundaries between registrants and their patients. Professional boundaries are based on trust, respect and the appropriate use of power as there is a power imbalance between patients and registrants. Patients are entitled to rely on registrants to act in a professional and ethical manner and to never put their personal interests above those of their patients. Registrants have the responsibility to maintain appropriate professional boundaries at all times and should refrain from having dual relationships with patients.

The ways in which registrants must maintain appropriate professional boundaries include: (a) showing respect for the patient's privacy at all times; (b) avoiding physical contact outside of clinical necessity; (c) avoiding behaviour or remarks that may be interpreted as sexual or inappropriate by a patient; (d) refraining from asking personal information that is irrelevant to the professional services being provided; (e) refraining from sharing inappropriate personal information with the patient; and (f) showing sensitivity to the patient's cultural or religious background;

Forming a relationship with a patient outside the professional setting may place a registrant in an ethically compromising situation, and may result in the violation of a professional boundary which is a serious regulatory matter.

As a consequence, registrants should generally avoid dual relationships, even when the patient attempts to initiate the relationship or consents to enter into a personal relationship. The existence of a dual relationship may compromise the registrant's ability to provide objective and unbiased care which places the patient (and broader public) at risk.

(ii) *Relationships with Former Patients*

It is unethical for a registrant to terminate a professional relationship in order to initiate a personal or sexual relationship with a patient. Depending on the circumstances, it may be considered unethical and unprofessional conduct to form a relationship with a former patient. Registrants should have regard to the following considerations before considering a relationship with a former patient:

- The nature of the previous professional relationship and whether it involved a significant imbalance of power;
- Whether the former patient was, or is, vulnerable;
- Whether the registrant is using the knowledge or influence that the registrant gained through the professional relationship to develop or continue the personal relationship;
- Whether the registrant is already treating, or are likely to treat, any other members of the former patient's family;
- Whether the patient understands that the registrant-patient relationship has ended;
- Whether the patient is capable of consenting;

- Whether or not a reasonable interval of time has passed since the professional relationship ended with the patient.*

* Registrants should consider the following guidelines to self-assess whether a reasonable interval of time has passed:

- The nature, intensity and frequency of the former registrant-patient relationship, as well as the level of patient vulnerability and power imbalance should be taken into consideration.

- The relationship must not be a result of or appear to be a result of the use or exploitation of the trust, knowledge, influence, or emotions derived from the previous professional relationship.

- Registrants—not their clients—assume the full burden of demonstrating that the former client has not been exploited, coerced, or manipulated, intentionally or unintentionally.

(iii) *Duty to Report Sexual Misconduct*

Registrants have a statutory duty to report sexual misconduct under s. 32.4 of the *Health Professions Act*.

The college requires registrants who have reason to believe that a registrant of a health profession is engaging in sexual misconduct to promptly report that information to the college, and in any event no later than 30 days of reasonably concluding that such conduct is or has taken place. Any delay in filing a report may jeopardize public safety.

Guidelines

<u>Education on Professional Ethics</u>

Registrants have a responsibility to educate themselves on professional ethics and should be aware that the college has an online ethics program.

Patient Relations Program Information

In order to maintain professional boundaries between registrants and patients, and to prevent professional misconduct of a sexual nature, the College has established a patient relations program.

The College's patient relations program includes:

1. Procedures for dealing with complaints involving professional misconduct of a sexual nature;
2. Training to key College staff on how to appropriately handle complaints involving professional misconduct;
3. Requirements and guidelines for the conduct of registrants with their patients, outlined in the Patient Relations Program Standard, Conflict of Interest Standards, and Code of Ethics;
4. Education to registrants on professional boundaries and misconduct prevention;
5. Monitoring and evaluation of the patient relations program.

Establishing a Patient Relations Program is a requirement of all BC health regulators as stated in HPA s.16(2)(f):

> *(2) A college has the following objects:*
>
> > *(f)to establish, for a college designated under section 12 (2) (h), a patient relations program to seek to prevent professional misconduct of a sexual nature;*

<u>Role of the Ethics Advisory Committee</u>

To provide advice and guidance to the Board and the registrar on matters relating to the Patient Relations Program, and educational program proposals relating to ethics issues. The Ethics Advisory Committee also oversees the implementation of the Patient Relations Program.

1. Procedures for dealing with complaints involving professional misconduct

When a complaint involving professional misconduct is received by the College, it will follow the College's usual complaints process. The complaint is taken to the Inquiry Committee for "direction to investigate" the matter.

If the complainant wishes to meet with a College Investigator prior to formalizing their complaint, a meeting shall be arranged. The complainant will be advised, prior to the meeting that they may bring other persons of their choosing (e.g., a patient advocate, relative, friend or another support person) to the meeting if desired. They will also be advised that although all matters coming before the College are required to be kept in

confidence, all persons who could provide information concerning the complaint must be included in the formal complaint in the interest of fairness to both parties.

At the time of the meeting, the role of the College and its mandate, and the inquiry and disciplinary procedures will be explained prior to hearing the complaint. At the conclusion of the meeting, authorization will be sought from the complainant to proceed with an investigation, including providing the College with a formal complaint form and authorization for any other required information. The College Investigator shall assist the complainant to draft any submission required by the College's Inquiry Committee.

During the investigation phase, the Complaints Investigator gathers all relevant information from all parties involved. This step may, but is not limited to include telephone conversations, in-person interviews, and gathering of pharmacy records, PharmaNet patient profiles.

After the investigation is complete, the Inquiry Committee reviews the complaint and determines the appropriate actions needed to resolve the complaint. The Registrar may issue a citation for a Discipline Committee hearing in instances where the Inquiry Committee has determined an issue to be serious, a consensual agreement cannot be reached with the registrant, or the registrant has not responded to the complaint.

2. The College's guidelines on handling complaints regarding sexual abuse includes the following:

- Registrants and College staff must be educated about the nature of sexual abuse, the seriousness and magnitude of the problem and the range of problems suffered by victims of sexual abuse.
- Staff dealing with complaints regarding sexual abuse must be educated about barriers to disclosure and how to facilitate disclosure.
- Ensure reports taken by staff are received and processed in a competent, caring and sensitive manner.
- Ensure staff are appropriately trained on the proper procedures for the intake of complaints or reports of sexual abuse.
- Be aware of and able to refer complainants to treatment options for sexual abuse.
- Participate in and contribute to strategies for recognizing, confronting and treating abuse by colleagues and other healthcare professionals, and for reporting knowledge or suspicion of such abuse.

3. Guidelines for the conduct of registrants with their patients

Registrants demonstrate respect for patients by faithfully adhering to their professional Code of Ethics and behaving in the following ways:

- Respect the value, dignity and autonomy of patients,
- Respect patient vulnerability and maintain professional boundaries with patients,
- Do not exploit patients for personal advantage,
- Treat patients with sensitivity, caring, courtesy and respect,
- Utilize their professional judgment to serve the best interests of their patients.

4. Education to registrants on professional boundaries and sexual abuse prevention

The College's on-line ethics training program provides registrants with education and guidance regarding professional boundaries and sexual abuse prevention.

5. The Patient Relations Program will include a monitoring and evaluation strategy to measure the success of the program.

Framework for a Model Patient-Practitioner Relationship Program for BC Health Regulators

1. Legislative Framework

All Colleges regulated under the *Health Professions Act (HPA)* are required to establish a program to deal with patient-practitioner relationships:

> Section 16 (2) (f)
> … to establish, for a college designated under section 12 (2) (h), a patient relations program to seek to prevent professional misconduct of a sexual nature.

2. Program Position Statement

Health care practitioners regulated by Colleges of the BC Health Regulators provide health care that is built on a foundation of trust and respect. Patients trust their professional practitioner because they believe the practitioner has special knowledge, skills and abilities and uses these to provide safe, effective and ethical care. Practitioners demonstrate respect for patients by acknowledging their position of power and maintaining professional boundaries.

A Patient-Practitioner Relationship Program helps both patients and practitioners understand the need for boundaries in establishing the context and limits of care. The professional relationship between the professional and the patient exists for the patient's benefit. Setting boundaries requires the practitioner be a professional and to ensure that the autonomy and dignity of patients is maintained.

3. Key Concepts and Definitions

"Professional misconduct" is defined in the HPA (Part 3) to include "sexual misconduct, unethical conduct, infamous conduct and conduct unbecoming a member of the health profession".

"Dual relationships" in the health service context pertains to relationships in which the registered professional has more than one relationship with the service recipient. An example of a dual relationship is providing clinical services to a family member or friend.

"Conflict of Interest" arises where a reasonable person could form the view that a professional's ability and obligation to act in the patient's best interests may be affected or influenced by other competing interests. Such conflicts of interest can be real, potential or perceived. Conflicts of interest occur in a variety of circumstances including financial, non-financial, direct, and indirect transactions with patients and others.

"Informed consent" is defined in S. 7 of this Framework.

4. Principles for the Patient-Practitioner Relationship Program

a) Each program is developed in the context of the type of health care and the health care environment in which it is provided.
b) Each program must establish appropriate professional boundaries between the registrant and the patient, ensuring that:
   (i) the patient is able to provide full, free and informed consent;
   (ii) patient autonomy is maintained at all times; and
   (iii) the practitioner provides objective care to every patient.
c) Each program must have clear, concise and accessible information and materials for both registrants and the public.
d) Each program must provide training for College staff to support their understanding of the program and how it applies in practice.
e) The program is designed to enhance the registrant's capacity to understand and set boundaries and communicate those effectively to every patient.

5. Patient-Practitioner Relationship Program Elements

Each College's patient-practitioner relationship program must address the following areas:

a) romantic or sexual relationship with patients;
b) treatment of partners, spouses, or other family members;
c) relationships with former patients;
d) "bartering" or exchanging health care services for other services with a patient;
e) monetary gain from patients outside of the cost of the service/care provided;
f) use of social media;
g) non-trivial gifts from patients;
h) care of family members in emergency situations; and
i) guidance for practitioners working in small, rural or remote communities.

6. Shared Underlying Principles in the Patient-Practitioner Relationship

1. Avoidance, as much as possible, of any professional relationship with a patient when the professional's objectivity or competence could reasonably be expected to be impaired because of the professional's present or previous familial, social, sexual, emotional, financial, supervisory, political, administrative, or legal relationship with the patient or with another relevant person associated with or related to the patient.

2. If a dual relationship or conflict of interest is unavoidable, the professional should document the specific circumstance, an account of why the duality or conflict is unavoidable and document the informed consent of the patient(s) for all services.

3. Obtaining informed consent at the beginning of professional relationships and understanding that informed consent is an ongoing process, rather than a onetime event.

7. What Constitutes Informed Consent

The BC *Health Care (Consent) and Care Facility (Admission) Act* defines "*Informed Consent"* as follows:

4 Every adult who is capable of giving or refusing consent to health care has

(a) the right to give consent or to refuse consent on any grounds, including moral or religious grounds, even if the refusal will result in death,

(b) the right to select a particular form of available health care on any grounds, including moral or religious grounds,

(c) the right to revoke consent,

(d) the right to expect that a decision to give, refuse or revoke consent will be respected, and

(e) the right to be involved to the greatest degree possible in all case planning and decision making.

5 (1) A health care provider must not provide any health care to an adult without the adult's consent except under sections 11 to 15.

(2) A health care provider must not seek a decision about whether to give or refuse substitute consent to health care under section 11, 14 or 15 unless he or she has made every reasonable effort to obtain a decision from the adult.

6 An adult consents to health care if

(a) the consent relates to the proposed health care,

(b) the consent is given voluntarily,

(c) the consent is not obtained by fraud or misrepresentation,

(d) the adult is capable of making a decision about whether to give or refuse consent to the proposed health care,

(e) the health care provider gives the adult the information a reasonable person would require to understand the proposed health care and to make a decision, including information about

(i) the condition for which the health care is proposed,

(ii) the nature of the proposed health care,

(iii) the risks and benefits of the proposed health care that a reasonable person would expect to be told about, and

(iv) alternative courses of health care, and

(f) the adult has an opportunity to ask questions and receive answers about the proposed health care.

Appendix

CPBC Provisions for Professional Misconduct of a Non-Sexual Nature

Regulatory tool	Type of professional misconduct	Provision
Conflict of Interest Standards	Financial gain	Standard 1(a)(ii): Pharmacists must only adapt a prescription to optimize the patient's therapeutic outcome of treatment. In no instance should a pharmacist adapt a prescription in order to benefit financially or in kind.
Conflict of Interest Standards	Financial gain	Standard 1(a)(iii): Registrants must always provide/promote the drug or drug substitution that will best serve the patients needs. They must not provide/promote a particular drug or drug substitution simply in order to take advantage of a manufacturer's discount or other incentives.
Conflict of Interest Standards	Financial gain	Standard 1(a)(iv): Registrants must not dispense a smaller quantity than that required to serve the patient's best interests simply to accrue additional dispensing fees.
Conflict of Interest Standards	Financial gain	Standard 1(b): Registrants must not offer loyalty or incentive programs that are contrary to the patient's best interests.
Conflict of Interest Standards	Financial gain	Standard 2(b): Registrants must not ask for or accept any incentive, or gift which may affect or be seen to affect their commitment to their patient's best interests.

Appendix

CPBC Provisions for Professional Misconduct of a Non-Sexual Nature

Regulatory tool	Type of professional misconduct	Provision
Conflict of Interest Standards	Financial gain	Standard 2(c): Registrants must not accept cash payments or other incentives (excluding generally accepted ethical business practices) over and above remuneration for services provided to patients.
Conflict of Interest Standards	Financial gain	Standard 2(d): Registrants must not provide to or receive cash payments or other incentives from other registrants, other healthcare professionals or any other person or organization solely for the referral of patients.
Conflict of Interest Standards	Dual relationships with family members	Standard 2(e)(i,ii): e) Registrants must not dispense prescriptions for themselves or to their family members except; i. in an emergency situation, or ii. when another registrant is not readily available.
Conflict of Interest Standards	Financial gain	Standard 2(f): Registrants who have a financial interest in an organization, such as a pharmacy, pharmaceutical company, recovery home or clinic must not allow these interests to adversely affect the quality of patient care.
Code of Ethics	Professional boundaries	Standard 3(a): Registrants recognize the power imbalance inherent in professional relationships (registrant-patient relationship) and maintain appropriate professional boundaries.

Appendix

CPBC Provisions for Professional Misconduct of a Non-Sexual Nature

Regulatory tool	Type of professional misconduct	Provision
Code of Ethics	Professional boundaries	Standard 3(b): Registrants act in the best interests of their patients and do not exploit the professional relationship for any personal, physical, emotional, financial, social or sexual gain.
Code of Ethics	Discrimination	Standard 3(g): Registrants ensure that their personal beliefs and values do not prejudice patient care and do not engage in discrimination based on age, gender identity, race, ethnicity, culture, national origin, religion, sexual orientation, lifestyle, disability, socio-economic status or any basis proscribed by law.
Code of Ethics	Professional boundaries	Standard 6(f): Registrants ensure that they maintain appropriate professional boundaries in pharmacy student/instructor and supervisor/subordinate relationships.
Code of Ethics	Unethical conduct	Standard 7(e): Registrants do not justify unethical behavior by rationalizing that such behavior is not explicitly captured in a standard or guideline and therefore ethically permissible.
Code of Ethics	Professional integrity	Standard 7(f): Registrants shall resist any influence or interference that could undermine their professional integrity.
Code of Ethics	Professional integrity	Standard 7(m): Registrants enter only into relationships, contracts and agreements in which they can maintain their professional integrity and safeguard the interests of their patients.

Appendix

CPBC Provisions for Professional Misconduct of a Non-Sexual Nature

Regulatory tool	Type of professional misconduct	Provision
Code of Ethics	Dual relationships	Standard 8(d): Registrants avoid dual or multiple relationships and other situations which may present a conflict of interest and potentially reduce their ability to be objective and unbiased in their professional judgment.

College of Pharmacists of British Columbia

5. Patient Relations Standard

Sorell Wellon

Chair, Ethics Advisory Committee

College of Pharmacists of British Columbia

Background

Legislative Requirements for a Patient Relations Program:

HPA:

- Section 16 (2)(f) states that the board must: " …*establish…a patient relations program to seek to prevent professional misconduct of a sexual nature*."

College of Pharmacists of British Columbia

Background, continued

HPA Bylaws

- Section 84 requires that the patient relations program seek to prevent professional misconduct, including professional misconduct of a sexual nature.
- 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 (a), and
  c) develop guidelines for the conduct of registrants with their patients.

Code of Ethics

- The Patient Relations Program is noted as a companion document.

College of Pharmacists of British Columbia

CPBC Patient Relations Program

Development Timeline:

- **2013**: BCHR established a working group to review patient relations programs and develop a model framework.
- **2016**: CPBC Board approved the BCHR framework at their September Board meeting.
- **2018**: Ethics Advisory Committee and College staff developed a proposed Patient Relations Program standard.

College of Pharmacists of British Columbia

CPBC Patient Relations Program, continued

Proposed Patient Relations Program Document

- Key Topics Include:
  - Maintaining Professional Boundaries and Avoiding Dual Relationships;
  - Relationships with Former Patients;
  - Registrants' Statutory Requirement to Report Sexual Misconduct; and
  - Education on Professional Ethics (i.e., CPBC's online ethics program).

College of Pharmacists of British Columbia

Spousal Relationships and Sexual Misconduct

- The proposed Standard does not directly discuss the issue of providing pharmacy services to family members, including spouses.

- Dispensing prescriptions to family members is generally prohibited under Standard 2(e) of the Conflict of Interest Standards:

> *"Registrants must not dispense prescriptions for themselves or to their family members except;*
>
> *i. in an emergency situation, or*
>
> *ii. when another registrant is not readily available."*

College of Pharmacists of British Columbia

Next Steps

- Upon Board approval, the Standard would undergo public posting for a period of 90 days.
- Any comments received will be reviewed for possible amendments to the Standard.
- It is expected that the final Standard will be brought forward to the Board at their February 2019 meeting to decide on filing it with the Ministry of Health.
- After the 60-day filing period, the Standard would take effect.

College of Pharmacists of British Columbia

5. Patient Relations Standard

MOTION :

Approve the following resolution:

"RESOLVED THAT, in accordance with the authority established in section 19(1)(l) of the *Health Professions Act,* the board approve the proposed bylaws of the College of Pharmacists of British Columbia regarding a patient relations program standard, for public posting as circulated."

15 Board Committees

Legislated under the HPA

- Discipline (panels)
- Inquiry (panels)
- Registration (panels)
- Quality Assurance
- Patient Relations (under the Ethics Committee as a Program)

Legislated under the HPA Bylaws

- Drug Administration
- Practice Review

Legislated under the PODSA

- Application (panels)

Board

- Audit and Finance
- Governance
- Legislative Review
- Community Advisory
- Hospital Advisory
- Residential Care
- Jurisprudence Examination Subcommittee (reports to the Registration Committee)

Currently CPBC Board members are required to chair all committees **except** Discipline, Inquiry, Registration and Application (as of Nov/17)

	Mona	Arden	Ming	Tara	Chris	Frank	Anar	Sorell	Tracey	Ryan	Justin	Jeremy	**Meetings*** 2017-18
Application								Chair		Member	Member		**1**
Audit/Finance		Ex officio				Vice				Chair			**9**
Community				Chair									**0**
Discipline												Chair	**14**
Drug Admin													**0**
Ethics								Chair					**4**
Governance		Chair		Vice			Member	Member			Member		**4**
Hospital	Ex officio	Chair											**1**
Inquiry			Chair								Member		**78**
Jurisprudence					Chair								**6**
Legislation					Member			Member				Chair	**9**
Practice Rev									Chair				**7**
QA						Chair			Member				**5**
Registration												Chair	**10**
Res Care			Member					Chair					**1**
Total (15)		**3**	**2**	**2**	**2**	**2**	**1**	**5**	**2**	**2**	**3**	**3**	

* Number of meetings from January 2017 up to June 2018 Board meeting

Provincial Environmental Scan

Alberta (4): • Competence • Executive • Complaint Review • Nominating	Newfoundland & Labrador (6): • Complaints Authorization • Disciplinary • Expanded Practice • Finance and Audit • Structured Practice Experience • Professional Development Review
Saskatchewan (8): • Audit • Awards and Honours • Complaints • Discipline • Finance • Fitness to Practise • Professional Practice • Registration & Licensing Policies	Nova Scotia (8): • Executive • Audit • Governance • Nominating • Standards of Practice • Investigation • Hearing • Fitness to Practice
Manitoba (7): • Awards and Nominating • Executive • Extended Practice • Finance and Risk Management • Governance • Quality Assurance • Extended Practice Pharmacist	Prince Edward Island (7): • Investigation • Hearing • CE/Competence Assessment • Examinations • Pharmacy Endowment Fund • Practice Experience • Standards of Practice for Pharmacist Prescribing
Ontario (11): • Accreditation • Discipline • Executive • Fitness to Practise • Inquiries, Complaints and Reports • Patient Relations • Quality Assurance • Registration • Drug Preparation Premises • Elections • Finance & Audit	New Brunswick (9): • Governance • Nominating • Personnel • Finance • Registration • Continuous Professional Development • Complaints • Discipline & Fitness to Practise • Professional Practice

College of Pharmacists of British Columbia

Committee of the Whole
September 13, 2018

Chair Kwong Discussion for Committee as the Whole – September 2018

INFORMATION ONLY

As chair, I have been focussing on these points for the Board in the responsibility of the role:

- Leads the Board in reviewing and monitoring the strategic business plan, policy and directions of the College and the achievement of its objectives
- Fosters cohesion of direction and purpose at a policy and strategic level
- Ensures, with the assistance of the Registrar and the Governance Committee, that there is an orientation program for new Board members and an ongoing development program for existing Board members aimed at increasing the Board members' familiarity with the College and context

Thoughts to reflect upon and have a discussion as we move to the next year:

A) CPBC's strategic planning process

Significant Board member turnover is anticipated in the coming months, which may pose a risk to the strategic planning process currently underway. It's possible that only a few Board members who participated at the November 2017 brainstorm session will be present for the April 2019 retreat. While Board turnover is an inevitable reality in pharmacy regulatory authority governance, it will be important to ensure continuity and sustainability throughout CPBC's strategic planning process.

Such an approach could include the following:

1. Ensure that the incoming chair and vice chair are aligned with the planning cycle timing and elements, and well-versed in the work completed to date.
2. Create a strategy to engage new members:
    - Share planning materials with them;
    - Meet with them to brief them on progress to date; and
    - Offer teambuilding sessions like the one held in November 2017.

- Make use of the consultant as an objective, external, consistent champion of the planning process, elements and content as it evolves.

3. Ensure ongoing access to planning materials via the Board Portal.

4. Safeguard time in association with each Board meeting to ensure that there is adequate time for board members to discuss the plan as it evolves. (Especially important when there are new Board members).

5. Use time before the February 2019 Board meeting to ensure members are primed for the April 2019 retreat.

6. Inculcate the high-level view that CPBC's strategic plan is evolving from a focus on Foundational Elements (current plan) to Raising the Bar in Professional Practice.

7. Continue to support Board members in shifting from tactical thinking (how to/immediate problem solving) to strategic thinking (longer term direction/where do we want to be).

8. Take measures to ensure that all Board Members participate in discussions throughout the planning process.

B) Governance

1. Keep high level thinking throughout each board term by exploring a yearly formal education session (preliminary discussion of programs such as Watson).

2. Have an individual rate the board on high level thinking/strategic planning skills within our meetings to create self-awareness

3. Incorporate Succession Planning (preliminary discussion of chairs/vice-chair yearly meeting from each committee)

4. Board Assessment and Evaluation (preliminary discussion of incorporation into next cycle of evaluation now that the registrar evaluation cycle is almost completed in this first year)

College of Pharmacists of British Columbia

Committee of the Whole
September 13, 2018

8. Governance Training/Education Opportunities

INFORMATION ONLY

WATSON

Based in Vancouver, WATSON is Canada's largest governance consultancy. Established in 2005, WATSON has worked with hundreds of organizations across many industries on governance, board education and recruitment.

WATSON clients include private and public companies, public sector entities, major trade and professional associations and not-for-profit organizations.

For more information on WATSON, please access: https://www.watsoninc.ca/

Board Education

There are two Board courses that Watson offers:

1. Governing with Intention; and
2. The Intentional Board.

Key aspects of the above-noted courses are:

Course Name	Governing with Intention	The Intentional Board
General Description	• 2 day flagship course customized to your board • ~ $2100 per person, ~$1800 per person when enrolling 4 or more people • Course offered quarterly	• 1 day immersive program that focuses on the organisation's top 2-3 governance issues • Half day $18000, full day ~$20000 • For a Board – maximum 15 people • Date – flexible
Sample Curriculum	• Understand the principles of an intentional approach to governance • Identify directors duties and your legal foundation • Determine ways to maximize the contributions of key roles on the board and management team	**Morning Agenda** • Principles of an intentional approach to governance • WATSON's governance model • The legal foundation of your board • Director duties and responsibilities

Course Name	Governing with Intention	The Intentional Board
	• Consider how various changes to governance practices enhance the effectiveness of board and committee practices • Strengthen board culture by identifying and adopting practices specific to boards and the board/ management relationship • Apply WATSON's 'Managing the Line' method to help clarify the line between governance and management • Review five leading practices in leadership renewal to ensure your organization has the board and executive leaders it needs to achieve its goals over the next five years • Shift to a more strategic perspective	**Afternoon Agenda – 2 to 3 of the following modules** • Leadership in the Boardroom: The Chair-CEO Relationship • Evaluation: Enhancing board performance • Renewal and Diversity: Getting the board you need to succeed • The Line: Navigating the grey line between board and management • Dynamics: Creating the culture you want • Strategic Perspective: Elevating the board's contribution • Design Practices: Building the boardroom you need • Boardroom Roles: Maximizing your key roles

Please see Appendix 1 and 2 for the outlines for the "Governing with Intention" and "The Intentional Board" courses, respectively.

For more information about WATSON's courses for Boards, please access: https://www.watsoninc.ca/customized-board-courses/

Appendix	
1	Governing with Intention – Course Outline
2	Intentional Board – Course Outline

WATSON™

BRING YOUR ISSUES TO THE CLASSROOM. BRING SOLUTIONS BACK TO THE BOARDROOM.

Governing with Intention™

A Customized Approach for Your Board

Over the last decade, there has been an explosion of research and thinking on what constitutes good governance. Today, organizations can turn to a well-defined set of standards, structures and practices. Yet, governance continues to evolve. As directors across boardrooms can attest, each organization comes with its own challenges when it comes to governance.

WATSON is witnessing firsthand how boards are shifting their practices – from re-evaluating their size and composition to consciously reviewing their approach to governance for the benefit of the organization.

WATSON developed **Governing with Intention**™, our flagship education program, to help directors and management understand their responsibilities and how to navigate the unique governance challenges in their organization. Honed from years of advising organizations across all sectors, our Governance Academy program challenges traditional governance thinking. It is engaging, informative and practical. Participants learn how to shift the dialogue to the issues that matter, bridge the line between governance and management, elevate their personal contribution at the board table and design their board's culture.

Governing with Intention™ is tailored for boards to provide them with an in-depth and engaging learning experience. Our flagship course delivers practical tools and clear, relevant guidance to help boards and individual directors enhance their governance effectiveness.

In this two-day course, participants will:

- **Evaluate** the effectiveness of governance within their organization
- **Understand** the principles of an intentional approach to governance
- **Discuss** the practical application of directors' fiduciary responsibilities within their organization's framework
- **Determine** ways to maximize the contribution of key roles on the board and management team
- **Consider** how various changes to governance practices enhance the effectiveness of board and committee practices
- **Strengthen** board culture by identifying and adopting practices specific to boards and the board / management relationship
- **Apply** WATSON's 'Managing the Line' method to help clarify the grey line between governance and management
- **Review** leading renewal practices to ensure their organization has the board and executive leaders it needs to achieve its goals over the next five years
- **Shift** to a more strategic perspective
- **Come away** with a customized board action plan to enhance governance practices

WATSON™

Our Custom Approach

When you choose a custom **Governing with Intention**™ course, we work with you to ensure that the timing, the team, the process and the course are tailored to your specific needs. Working with your schedule we deliver a course that fits with the board's calendar. Prior to every customized course, WATSON embarks on a three-step process to ensure we fully understand the nuances of your organization, your board and your governance practices.

We start with a review
of your key governance documents such as your board manual, by-laws and most recent strategic plans.

Next, we seek stakeholder feedback
by surveying all directors and identified members of the management team to ensure we understand the issues you feel your board needs to address. We also interview two to three directors to get a sense of the cultural nuances around your board table.

Then, we tailor the program
by adjusting the agenda, the pace and the depth of specific topics to meet your board's needs. We handpick our facilitation team based on their experience working with similar organizations.

What Participants Receive

Governing with Intention™ Workbook
Explores governance in four key areas: Governing with Intention, Governance Design, Leadership and Renewal, and Strategic Perspective

WATSON Views
Articles on emerging governance issues

Room at a Glance
A snapshot of who's in the room – perceptions of individual and board's governance practices and performance

Action Plan
(post workshop)
An outline of key actions and ideas generated in the workshop that the board may wish to implement and further explore

PRE COURSE SURVEY

Each participant completes an online survey that assesses their board experience and perception of their personal and organization's governance practices and performance. Prior to the course, all participants receive a personalized **Room At a Glance** that outlines:

- The experience and contributions of current directors
- The key themes and opportunities the board feels it should address
- The board's perception of the importance of key stewardship activities and how they rate their current performance

WHO SHOULD ATTEND?

- All directors
- CEO or Executive Director
- Key members of management who closely support the board

WHAT PARTICIPANTS SAID

There was a visible shift in the participants' ability to grasp how to achieve a more strategic perspective

WATSON's lively and intelligent approach challenged us to look at all aspects of our governance and how we can improve

Loved how you surveyed and then tailored the training to our board

Very valuable for all directors and management to attend together and have a shared understanding

WATSON™

Sample Curriculum Highlights

UNDERSTAND the principles of an intentional approach to governance

- Purpose, Belief and Design – the three tenets of good governance in high performing boards
- The role of governance in an organization's success during changing times
- The unique characteristics of your organization's governance

IDENTIFY directors' legal responsibilities

- Fiduciary duty to the organization
- Practical application of the duty of care
- Reasonable reliance on management

DETERMINE ways to maximize the contributions of key roles on the board and management team

- Board versus operational committees
- Supporting the board – beyond the traditional corporate secretary role
- Laddering leadership and preparing incoming board and committee chairs for success
- The multi-faceted role of the board chair
- Strengthening the chair / CEO relationship

CONSIDER how various changes to governance practices enhance the effectiveness of board and committee practices

- Calculate your Governance Math – make the hours count
- Streamlining and refining board information packages
- Committee and task force responsibilities and practices
- The forward calendar and agenda as a strategic differentiator

STRENGTHEN board culture by identifying and adopting practices specific to boards and the board/ management relationship

- Importance and impact of board culture
- Attributes and behaviours that contribute to positive dynamics
- Techniques to enhance and maintain positive board culture
- How to individually contribute to your board's performance

APPLY WATSON's 'Managing the Line' method to clarify the grey line between governance and management

- The 'grey line' between management and governance
- The organizational stewardship spectrum
- Assessing the board's involvement in organizational stewardship

REVIEW five leading renewal practices to ensure your organization has the board and executive leaders it needs to achieve its goals over the next five years

- Active and creative recruitment in your organization
- Orientation beyond the board manual
- Tailoring education to the board, committees and individual directors
- Evaluation processes that enhance board, director and leadership performance
- Embedding renewal into board practices
- A CEO evaluation that is a positive, meaningful experience

SHIFT to a more strategic perspective

- Five ways for boards to elevate their strategic contribution
- Six steps for management to improve its support of the board
- Seven tips for individual directors to practice
- Asking strategic questions to keep the board out of the weeds

Walk into your next board meeting with a customized action plan.

ADDITIONAL EDUCATIONAL SUPPORT

After investing in a custom course for your board, you may opt to deliver additional governance education specific to your board's needs. Popular options include

New Director Orientation

Orient new or prospective directors at a **Governing with Intention**™ open course to ensure they share the same language and approach to governance as your directors who already have participated in the custom course. The open course is supported with a case-study approach to accommodate the variety of challenges facing different organizations. New directors engage with peers from other similar organizations; orientations can be hosted in your city or participants can attend an open session in Vancouver, BC.

The Intentional Board™

A one-day course for intact boards based on the principles of **Governing with Intention**™. **The Intentional Board**™ is perfect for augmenting your annual director education plans in alignment with your strategic priorities. Sample topics include:

Leadership in the Boardroom: The Chair-CEO Partnership
Evaluation: Enhancing board performance
Renewal and Diversity: Getting the board you need to succeed
The Line: Navigating the grey line between board and management
Dynamics: Creating the culture you want
Strategic Perspective: Elevating the board's contribution
Design Practices: Creating the boardroom you need
Boardroom Roles: Maximizing key roles

WATSON™

Bring your issues to the Classroom. **Bring solutions back to the boardroom.**

The Intentional Board™

A one-day course for your whole board based on the principles o**f Governing with Intention**™. **The Intentional Board**™ is tailored to address topics specific to your board and your organization. The day begins with WATSON's foundational principles of **Governing with Intention**™ followed by an afternoon of customized modules focusing on the governance topics most relevant to your organization.

Here's how we tailor the program to target the issues that matter to you most:

1. We start with a review

of your key governance documents such as your board manual, by-laws and most recent strategic plans.

2. Next, we seek stakeholder feedback

by surveying all directors and identified members of the management team to ensure we understand the issues you feel your board needs to address. We also interview two to three directors to get a sense of the cultural nuances around your board table.

3. Then, we tailor the program

by adjusting the agenda, the pace and the depth of specific topics to meet your board's needs. We handpick our facilitation team based on their experience working with similar organizations.

The agenda, materials, discussion and activities will help your board apply skills, practices and knowledge to specific issues it is facing while providing an in-depth and engaging learning experience.

WATSON™
Governance Academy

WATSON™

Syllabus Overview

PART ONE

Foundational Principles of Governing with Intention™

Overview of WATSON's Approach to Governance

- Governance is connected to purpose (the Board's and the organization's)
- Value governance because it leads to positive results
- Design accordingly (structure, committees, recruitment, etc.)
- Understand your personal contribution to the board
- The link between duty of care and reliance on management

The Fundamentals

- Legal foundation
- Board structure
- Roles and responsibilities of a not-for-profit Board and management
- Trends and "pressure points" in not-for-profit governance

Duty and Role of Board Members

- Board's role, Legal duties (fiduciary duty, duty of care)
- Board Member liability

PART TWO

Custom Modules

(2 or 3 of the following comprise the afternoon session)

1. **Leadership in the Boardroom**
   The Chair – CEO Partnership
2. **Evaluation**
   Enhancing board performance
3. **Renewal and Diversity**
   Getting the board you need to succeed
4. **"The Line"**
   Navigating the grey line between board and management
5. **Dynamics**
   Creating the culture you want
6. **Strategic Perspective**
   Elevating the board's contribution
7. **Designing Practices**
   Creating efficiencies, effectiveness and the processes you need
8. **Roles**
   Who does what and how to make the most of key roles

What Participants Receive

Governing with Intention™ Handbook

Explores governance in four key areas: Governing with Intention, Governance Design, Leadership and Renewal, and Strategic Perspective

WATSON Views

Articles on emerging governance issues

Room at a Glance

A snapshot of who's in the room – perceptions of individual and board governance practices and performance.

Summarized Takeaways (post workshop)

An outline of key actions and ideas generated in the workshop that the board may wish to implement and further explore.

Fees and Registration

Each session includes custom modules ensuring your directors have the tools and time to tackle specific challenge and develop action plans aligned with strategic priorities.

1 day session for your board and management team

$1,335 + tax/person (Min. 15 – Max. 20)

To register, call 604-569-2071
or email: register@watsoninc.ca

WATSON focuses exclusively on governance. Elizabeth Watson, QC founded WATSON on the belief that intentional governance helps organizations perform better. Since 2005 WATSON has helped hundreds of organizations establish and improve their approach to governance; conduct board, director and CEO evaluations; educate their boards and management team; plan for board and CEO succession; and connect with high performing directors and CEOs. WATSON's provides strategic support and advice to governments, public sector entities, private companies, major trade and professional associations and not-for-profit organizations.

WATSON™
Governance Academy

We help organizations perform better. | **www.watsoninc.ca** | **604 569 2071**

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

4.b.ix. Approval of 2019 Board Meeting Schedule

DECISION REQUIRED

Recommended Board Motion:

Approve the 2019 Board Meeting Schedule as circulated.

The Board Meeting Schedule for 2019 is:

Thursday, February 14, 2019
Friday, February 15, 2019

Thursday, April 11, 2019
Friday, April 12, 2019

Thursday, June 13, 2019
Friday, June 14, 2019

Thursday, September 12, 2019
Friday, September 13, 2019

Thursday, November 14 2019
Friday, November 15, 2019

CPBC Annual General Meeting
Thursday, November 14, 2019

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

4.b.x. Governance Committee: Committee Member Appointments

DECISION REQUIRED

Recommended Board Motion:

Approve College appointments of committee members for terms beginning on November 23, 2018, appointments of the Chair and Vice Chair of certain committees, and removal of certain committee members, as presented to the Board.

Purpose

To propose the appointment of new members to certain College committees, the appointment of the Chair and Vice Chair of certain committees, and the removal of certain committee members.

Background

The College committees are a vital resource to the Board that provide essential advice, expertise, and recommendations that ultimately help inform Board decisions.

Every year, two main processes are undertaken to fill anticipated vacancies on College committees:

- Current eligible Committee members are asked if they would like to be considered for re-appointment; and,
- The College issues a call for applications from pharmacists, pharmacy technicians and the public.

This process was most recently completed in May 2018.

Discussion

The Governance Committee has reviewed the current roster of committee members, and is proposing certain changes to committee membership. The proposed changes are due in part to the Board election in October 2018, and the expiry of the terms of certain government appointed Board members, which result in significant changes to Board composition.

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

The following changes to committee membership and positions are proposed:

Application Committee
- Appoint Christine Antler as Chair
- Appoint John Beever as Vice Chair
- Remove Ryan Hoag as a member
- Note: Sorell Wellon to remain as a member

Audit and Finance Committee
- Appoint Frank Lucarelli as Chair
- Appoint Board Vice Chair as Member
- Appoint Tracey Hagkull as a member and Vice Chair
- Remove Ryan Hoag as a member

Discipline Committee
- Appoint Derek Lee as Chair
- Appoint Heather Baxter as Vice Chair
- Appoint Justin Singh Thind as a member
- Remove Jeremy Walden as a member

Ethics Advisory Committee
- Appoint Bal Dhillon as Chair
- Remove Sorell Wellon as a member

Governance Committee
- Appoint Mona Kwong as a member and as Chair
- Appoint Board Vice-Chair as a member
- Remove Arden Barry as Chair
- Remove Sorell Wellon as a member

Hospital Advisory Committee
- Appoint Anca Cvaci as Chair

Inquiry Committee
- Appoint Mona Kwong as a member

Jurisprudence Examination Subcommittee
- Appoint Tara Oxford as a member and as Chair
- Note: Christopher Szeman to remain as a member

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

Legislation Review Committee

- Appoint Mona Kwong as Chair
- Appoint Justin Singh Thind as a member (required public Board member)
- Appoint Bal Dhillon as a member (required pharmacy technician Board member)
- Remove Christopher Szeman, Jeremy Walden, and Sorell Wellon as members

Registration Committee

- Appoint Maen Obeidat as Chair
- Appoint Dana Elliott as Vice Chair
- Appoint Tracey Hagkull as a member
- Remove Jeremy Walden as a member

Recommendation

The Governance Committee recommends that the Board approve the appointments of new members to certain College committees, the appointment of the Chair and Vice Chair of certain committees, and the removal of certain committee members, as outlined above.

All recommended appointments are for terms beginning on November 23, 2018 and ending at the next committee member selection cycle beginning in or around April 2018.

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

5. Confirmation of Agenda

DECISION REQUIRED

Recommended Board Motion:

Approve the November 23, 2018 Draft Board Meeting Agenda as circulated, or amended.

Appendix	
1	November 23, 2018 Draft Board Meeting Agenda

College of Pharmacists of British Columbia

Board Meeting
Friday, November 23, 2018
CPBC Office, 200-1765 West 8th Avenue, Vancouver

AGENDA

8:30am - 8:45am	15		Welcome & Swearing in of New Board Members	Chair Kwong Registrar Nakagawa
8:45am - 9:00am	15	**1.**	Call to Order *Land Acknowledgement*	Chair Kwong
		2.	Election of Chair **[DECISION]**	Registrar Nakagawa
		3.	Election of Vice Chair **[DECISION]**	Chair
		4.	Consent Agenda a) Items for Further Discussion b) Approval of Consent Items **[DECISION]**	Chair
		5.	Confirmation of Agenda **[DECISION]**	Chair
9:00am - 9:15am	15	**6.**	Governance Committee: a) Committee Updates [Governance & Hospital Pharmacy Advisory] b) Committee Member Appointments c) Board Members as Chairs of Committees **[DECISION]** d) Amalgamation of Committees	Arden Barry
9:15am - 9:30am	15	**7.**	Committee Updates: a) Governance Committee (update to be provided in item 6) b) Hospital Pharmacy Advisory Committee (update to be provided in item 6) c) Application Committee d) Ethics Advisory Committee e) Inquiry Committee f) Jurisprudence Examination Subcommittee g) Residential Care Advisory Commitee h) Practice Review Committee i) Audit and Finance Committee j) Quality Assurance Committee k) Community Pharmacy Advisory Committee l) Discipline Committee (update to be provided in item 11) m) Legislation Review Committee (update to be provided in item 11) n) Registration Committeee (update to be provided in item 11) o) Drug Administration Committee	Committee Chairs: Arden Barry Arden Barry Mona Kwong Mona Kwong Mona Kwong Mona Kwong Mona Kwong Tracey Hagkull Frank Lucarelli Frank Lucarelli Tara Oxford Jeremy Walden Jeremy Walden Jeremy Walden Doreen Leong
9:30am - 10:00am	30	**8.**	Potential Alternatives to the College's Existing Quality Management Program **[DECISION]**	Ashifa Keshavji
10:00am - 10:45am	45	**9.**	Update: ActionADE Software and Research Program	Katherin Badke Ellen Balka
10:45am - 11:00am	15		***BREAK***	
11:00am - 11:30am	30	**10.**	BCPhA Opioid Agonist Treatment Compliance and Management Program for Pharmacy (OAT-CaMPP)	Bryce Wong

College of Pharmacists of British Columbia

Board Meeting
Friday, November 23, 2018
CPBC Office, 200-1765 West 8th Avenue, Vancouver

AGENDA

11:30am - 12:00pm	30	**11.**	Legislation Review Committee: a) Committee Updates [Discipline, Registration & Legislation] b) Drug Schedules Regulation: Scheduling by Reference **[DECISION]** c) Professional Practice Policy-66: Amendment to Training Requirements **[DECISION]**	Jeremy Walden
12:00pm - 1:00pm	60		***LUNCH***	
1:00pm - 2:00pm	60	**12.**	Developing a Pharmacy Professional Master's Degree Program in a Changing Educational Landscape	Patricia Gerber
2:00pm - 2:45pm	45	**13.**	Health Canada's Problematic Prescription Drug Use Initiative	Angela Lina
2:45pm - 3:00pm	15	**14.**	Pharmacist Providing Anti-psychotic Depot Injections **[DECISION]**	Registrar Nakagawa
3:00pm - 3:05pm	5	**15.**	CLEAR Regulatory Excellence Award - College of Pharmacists of BC	Registrar Nakagawa
3:05pm - 3:15pm	10	**16.**	Items Brought Forward from Consent Agenda	Chair
			CLOSING COMMENTS AND ADJOURNMENT	

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

6. Governance Committee
a) Committee Update

INFORMATION ONLY

Purpose

For the Committee Chair to provide an update on the Governance Committee.

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

6. Governance Committee
b) Committee Member Appointments

INFORMATION ONLY

Purpose

To propose the appointment of new members to certain College committees, the appointment of the Chair and Vice Chair of certain committees, and the removal of certain committee members.

Background

The College committees are a vital resource to the Board that provide essential advice, expertise, and recommendations that ultimately help inform Board decisions.

Every year, two main processes are undertaken to fill anticipated vacancies on College committees:

- Current eligible Committee members are asked if they would like to be considered for re-appointment; and,
- The College issues a call for applications from pharmacists, pharmacy technicians and the public.

This process was most recently completed in May 2018.

Discussion

The Governance Committee has reviewed the current roster of committee members, and is proposing certain changes to committee membership. The proposed changes are due in part to the Board election in October 2018, and the expiry of the terms of certain government appointed Board members, which result in significant changes to Board composition.

The following changes to committee membership and positions are proposed:

<u>Application Committee</u>

- Appoint Christine Antler as Chair
- Appoint John Beever as Vice Chair
- Remove Ryan Hoag as a member
- Note: Sorell Wellon to remain as a member

Audit and Finance Committee

- Appoint Frank Lucarelli as Chair
- Appoint Board Vice Chair as Member
- Appoint Tracey Hagkull as a member and Vice Chair
- Remove Ryan Hoag as a member

Discipline Committee

- Appoint Derek Lee as Chair
- Appoint Heather Baxter as Vice Chair
- Appoint Justin Singh Thind as a member
- Remove Jeremy Walden as a member

Ethics Advisory Committee

- Appoint Bal Dhillon as Chair
- Remove Sorell Wellon as a member

Governance Committee

- Appoint Mona Kwong as a member and as Chair
- Appoint Board Vice-Chair as a member
- Remove Arden Barry as Chair
- Remove Sorell Wellon as a member

Hospital Advisory Committee

- Appoint Anca Cvaci as Chair

Inquiry Committee

- Appoint Mona Kwong as a member

Jurisprudence Examination Subcommittee

- Appoint Tara Oxford as a member and as Chair
- Note: Christopher Szeman to remain as a member

Legislation Review Committee

- Appoint Mona Kwong as Chair
- Appoint Justin Singh Thind as a member (required public Board member)
- Appoint Bal Dhillon as a member (required pharmacy technician Board member)
- Remove Christopher Szeman, Jeremy Walden, and Sorell Wellon as members

Registration Committee

- Appoint Maen Obeidat as Chair
- Appoint Dana Elliott as Vice Chair
- Appoint Tracey Hagkull as a member
- Remove Jeremy Walden as a member

Recommendation

The Governance Committee recommends that the Board approve the appointments of new members to certain College committees, the appointment of the Chair and Vice Chair of certain committees, and the removal of certain committee members, as outlined above.

All recommended appointments are for terms beginning on November 23, 2018 and ending at the next committee member selection cycle beginning in or around April 2018.

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

6. Governance Committee
c) Board Members as Chairs of Committees

DECISION REQUIRED

Recommended Board Motion:

Require that all committees of the College of Pharmacists of British Columbia, except the following committees, must have a Board member as Chair:

- *Application Committee*
- *Discipline Committee*
- *Drug Administration Committee*
- *Inquiry Committee*
- *Registration Committee*
- *Quality Assurance Committee*

Purpose

To clarify that certain College committees must have a Board member as Chair, while others do not.

Background

It is proposed that the following committees are required to have a Board member as Chair in order to ensure that there is a strong connection with the Board:

- Community Pharmacy Advisory Committee
- Ethics Advisory Committee
- Hospital Pharmacy Advisory Committee
- Jurisprudence Examination Subcommittee
- Practice Review Committee
- Residential Care Advisory Committee

It is proposed that the following committees would <u>not</u> be required to have a Board member as Chair:

- Application Committee
- Discipline Committee
- Drug Administration Committee

- Inquiry Committee
- Registration Committee
- Quality Assurance Committee

It is proposed that certain committees (i.e., the Application Committee, Discipline Committee, Drug Administration Committee, Inquiry Committee, Registration Committee and Quality Assurance Committee) would not require a Board member as Chair as they are statutory committees with independent decision making authority. They do not make recommendations, or report, to the Board.

Lastly, the following committees are comprised of only Board members, and therefore will have a Board member as Chair:

- Audit and Finance Committee
- Governance Committee
- Legislation Review Committee

Recommendation

The Governance Committee recommends that all committees of the College of Pharmacists of British Columbia, except the following committees, must have a Board member as Chair:

- Application Committee
- Discipline Committee
- Drug Administration Committee
- Inquiry Committee
- Registration Committee
- Quality Assurance Committee

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

6. Governance Committee
d) Amalgamation of Committees

INFORMATION ONLY

Purpose

To discuss the proposed amalgamation of the following committees into one committee named "Pharmacy Advisory Committee," effective April 2019:

- Community Pharmacy Advisory Committee
- Hospital Pharmacy Advisory Committee
- Residential Care Advisory Committee

Background

College committees are a vital resource to the Board that provide essential advice, expertise, and recommendations that ultimately help inform Board decisions.

The amalgamation of the committees (i.e., Community Pharmacy Advisory, Hospital Pharmacy Advisory, and Residential Care Advisory) is being proposed for the following reasons:

- It will enable the College to make more efficient use of its resources.
- The committees proposed for amalgamation have a similar role and are often asked to advise on issues that are common across all types of pharmacy practice.

The Governance Committee recommends that the Board proceed with the amalgamation of the Community Pharmacy Advisory Committee, Hospital Pharmacy Advisory Committee, and Residential Care Advisory Committee into one committee named the "Pharmacy Advisory Committee", effective in April 2019.

It is proposed that, at their February 2019 meeting, Board members will be asked to approve the amalgamation of the Advisory Committees, approve a new Terms of Reference for the new Committee, appoint Committee members, and appoint a Chair and Vice Chair of the Committee.

College of Pharmacists of British Columbia

6. Governance Committee

Arden Barry

Chair of Governance Committee

College of Pharmacists of British Columbia

6 a) Committee Update

College of Pharmacists of British Columbia

6 b) Committee Member Appointments

College of Pharmacists of British Columbia

Background

- Governance Committee has reviewed the current roster of committee members.
- Changes to committee membership and positions are proposed.
- Proposed changes are due in part to the following, which result in significant changes to Board composition:
  - Board member election in October 2018
  - Expiry of terms of certain government appointed Board members

College of Pharmacists of British Columbia

6 c) Board Members as Chairs of Committees

College of Pharmacists of British Columbia

Background

- Some College committees are required to have a Board member as Chair, while others do not.
- Clarify that certain College committees must have a Board member as Chair, while others do not.

College of Pharmacists of British Columbia

Committees that Require Board Chair

The Governance Committee recommends that the following committees would be required to have a Board member as Chair in order to ensure that there is a strong connection with the Board:

- Community Pharmacy Advisory Committee
- Ethics Advisory Committee
- Hospital Pharmacy Advisory Committee
- Jurisprudence Examination Subcommittee
- Practice Review Committee
- Residential Care Advisory Committee

College of Pharmacists of British Columbia

Committees that Do Not Require Board Chair

The Governance Committee recommends that the following committees would not be required to have a Board member as Chair because they are statutory committees with independent decision making authority - they do not make recommendations, or report, to the Board:

- Application Committee
- Discipline Committee
- Drug Administration Committee
- Inquiry Committee
- Registration Committee
- Quality Assurance Committee

College of Pharmacists of British Columbia

Committees Comprised of Board Members Only

The following committees are comprised of only Board members, and therefore will have a Board member as Chair:

- Audit and Finance Committee
- Governance Committee
- Legislation Review Committee

College of Pharmacists of British Columbia

6 c) Board Member as Chairs of Committees

MOTION :

Require that all committees of the College of Pharmacists of British Columbia, **except the following committees**, must have a Board member as Chair:

- Application Committee
- Discipline Committee
- Drug Administration Committee
- Inquiry Committee
- Registration Committee
- Quality Assurance Committee

College of Pharmacists of British Columbia

6 d) Amalgamation of Committees

College of Pharmacists of British Columbia

Proposal for Amalgamation

The Governance Committee recommends that the following committees amalgamate into one committee named “Pharmacy Advisory Committee”, effective April 2019:

- Community Pharmacy Advisory Committee
- Hospital Pharmacy Advisory Committee
- Residential Care Advisory Committee

College of Pharmacists of British Columbia

Reasons for Amalgamation

- Amalgamation will enable the College to make more efficient use of its resources.
- The committees proposed for amalgamation have a similar role and are often asked to advise on issues that are common across all types of pharmacy practice.

College of Pharmacists of British Columbia

Next Steps

It is proposed that, at the February 2019 Board meeting, Board members will be asked to:

- Approve the amalgamation of the Advisory Committees,
- Approve a new Terms of Reference for the new Committee,
- Appoint Committee members, and
- Appoint a Chair and Vice Chair of the Committee.

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

8. Potential Alternatives to the College's Existing Quality Management Program

DECISION REQUIRED

Recommended Board Motion:

Direct the Registrar to explore implementation of mandatory medication error reporting to a College-specified independent third party.

Purpose

To determine whether the College of Pharmacists of British Columbia (the "College") should explore implementation of mandatory medication error reporting to an independent third party.

Background

In July 2017, Melissa Sheldrick – a patient safety advocate whose son passed away due to a drug dispensing error in Ontario – requested that the College of Pharmacists of BC consider implementation of mandatory medication error reporting. She met with College Registrar Bob Nakagawa in August 2017, to discuss her work in advocating for all provinces to implement mandatory anonymous medication incident reporting programs. In particular, discussion was held on the importance of implementing a program in British Columbia to fulfill the College's mandate of protecting public safety.

The College Board reviewed briefing material on mandatory medication error reporting (see Appendix 1), including related complaints statistics and an incident reporting interjurisdictional scan at their November 2017 meeting. Melissa Sheldrick also presented to the Board at that meeting and shared how her 8 year old son, Andrew, died suddenly, as a result of a medication error. Ms. Sheldrick and emphasized the importance of having a mandatory anonymous medication error reporting system that allows learning to occur through data analysis of the errors reported.

Following a thorough discussion, the Board decided to move forward with exploring potential alternatives to the College's existing quality management requirements. The motion was:

> It was moved and seconded that the Board:
>
> Direct the Registrar to explore potential alternatives to the College's existing quality management requirements, including mandatory medication error reporting to an independent third party.

Discussion

Implementation of mandatory medication error reporting aligns with the College's duty to protect the public and the College's vision of "Better health through excellence in pharmacy":

> *Health Professions Act*, s. 16:
>
> 16 (1) It is the duty of a college at all times
>
> (a) to serve and protect the public, and
>
> (b) to exercise its powers and discharge its responsibilities under all enactments in the public interest.

Medication error reporting also aligns with the College's Code of Ethics which requires, among other things, commitments by registrants to "endeavor to advance the quality of pharmacy services and care provided to the public" (Standard 6d), "participate in continuous evaluations of their practice…" (Standard 10b), and "develop, promote and participate in quality assurance and accountability processes" (Standard 10e).[1]

[1] College of Pharmacists of BC Code of Ethics – Detailed
http://www.bcpharmacists.org/library/6_Resources/6-1_Provincial_Legislation/5019-Code_of_Ethics_Detailed.pdf

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

Public Safety

The most common complaints received by the College[2] are now related to medication dispensing errors by pharmacy professionals. In addition, since medication error reporting issues were first brought to the Board's attention in November 2017, additional cases of medication errors across Canada have gained notoriety and further highlighted the relationship between medication error reporting systems and public safety.[3]

Data analysis of medication errors has the potential to improve public safety nationally and provincially. Mandatory anonymous error reporting provides data that can be analyzed to help identify trends in errors that are occurring and provide opportunities to learn from mistakes, improve practice and better protect the public.

Current State

Sections 24(1) and 29(1) of the Bylaws made under the *Pharmacy Operations and Drug Scheduling Act* ("PODSA") requires pharmacy managers of community and hospital pharmacies to 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. The specific requirements of the program are left to the discretion of the pharmacy manager and the College does not assess the adequacy of the program.

The College has some oversight over quality management through its Practice Review Program, an in-person review of pharmacy professionals' practices and the pharmacies where they work. The Practice Review Program is comprised of two components: the Pharmacy Review and the Pharmacy Professionals Review. During a practice review, Compliance Officers adjudicate compliance with College Bylaws and Professional Practice Policies. Compliance Officers record and document areas of compliance and non-compliance while observing pharmacy professionals throughout the review process. For areas of noncompliance, action-items are assigned, if necessary. All pharmacies and pharmacy professionals will be reviewed under the Practice Review Program on a cyclical basis. Of the pharmacies reviewed in the 2017-18 fiscal year, approximately 10% of pharmacies did not develop, document or implement an ongoing

[2] College of Pharmacists of BC 2016/17 Annual Report http://annualreport.bcpharmacists.org/ar2018/complaints-and-investigations-statistics

[3] In February 2018, a Moncton pharmacist was fined and reprimanded by the New Brunswick College of Pharmacists for a dispensing error that led to the death of a patient in long-term care. Baclofen suspension, a muscle relaxant, was dispensed at five times the concentration on the label: https://www.cbc.ca/news/canada/new-brunswick/moncton-pharmacist-fined-1.4516216 ;
In October 2018, human error resulted in a three-year-old on Vancouver Island taking five times the amount of morphine he was prescribed, leading to an opioid overdose: https://www.cbc.ca/news/canada/british-columbia/shawnigan-lake-toddler-morphine-overdose-1.4862694

quality management program that includes a process for reporting, documenting and following up on known, alleged and suspected errors, incidents and discrepancies.

There appears to be a general lack of information with respect to medication errors and incidents being collected and shared throughout the province. Currently, there is no way to quantify the number and types of medication errors and incidents that are occurring within British Columbia pharmacies and there is no central database in which pharmacy staff can report medication errors and incidents. As a result, there is a missed opportunity for pharmacy professionals to learn from errors occurring in other pharmacies.

Updated Interjurisdictional Scan

Several provinces in Canada have also implemented, or are in the process of implementing, new quality management requirements that include mandatory error reporting to an independent third party.

An updated interjurisdictional scan is summarized below. More detailed information regarding the specific quality management requirements in various provinces is outlined in Appendix 2.

Mandatory Medication Error Reporting to an Independent Third Party[4]								
AB	**MB**	**NB**	**NL**	**NS**	**ON**	**PE**	**QC**	**SK**
No	*Yes (ISMP-Pilot)*	*Yes (Not Specified)*	*No*	*Yes (ISMP)*	*Yes (Pharmapod)*	*No*	*No*	*Yes (ISMP)*

= Program in place or in progress towards full implementation
= Exploring options
= No immediate plans for exploration/implementation

Two provinces (Nova Scotia and Saskatchewan) have mandatory medication error reporting and three provinces (Manitoba, New Brunswick and Ontario) are in the process of fully implementing mandatory medication error reporting. Such reporting is a critical component of an overall standardized continuous quality improvement (CQI) program that generally involves:

- Medication safety self-assessment (MSSA) done at regular intervals by pharmacies, and monitoring the progress of the resulting enhancement plan.

[4] ISMP stands for Institute for Safe Medication Practices. More information can be found on the ISMP website: https://www.ismp.org/
More information about Pharmapod can be found on its website: https://www.pharmapodhq.com/

- Mandatory anonymous reporting of medication incident data (including near misses) to an independent third party organization with expertise in medication incident analyses and sharing learning from trends and patterns of such incidents, with an ultimate goal to feed into a national database.
- Emphasis of learning and accountability over blame and punishment, through a culture where individuals are comfortable bringing forward medication incidents without fear of punitive outcomes which leads to heightened awareness regarding potential errors.
- Incident reviews and regular CQI meetings with pharmacy staff to allow open discussion on incidents and root causes, followed by formal documentation of quality improvements made.
- Anonymized aggregate data reports and/or bulletins available to pharmacies and the pharmacy regulatory authority. This allows shared learning at the pharmacy level and gives the regulatory authority data to guide communications to registrants and the development of policies and legislation for the pharmacy profession.

Options

It is proposed that the Board determine whether the College should explore implementation of mandatory medication error reporting to an independent third party. In making this determination, there are several factors to consider, including the following:

- The alignment of a mandatory medication error reporting program with the College's mandate in serving and protecting the public.
- The adequacy of the College's current quality management program.
- The operational impact of new requirements on pharmacies' and pharmacy professionals' practices.
- The feasibility of a new quality management program from the College's operational perspective:
    - The College would need to devote resources into assessing, developing and implementing a new program.
    - If a mandatory error reporting system is implemented, the College may be subject to ongoing costs that must be budgeted for.
    - The College must determine how to enforce new requirements.

<u>Option 1</u>
Do not explore implementation of medication error reporting to an independent third party. Instead, the College will further develop the current requirements for quality management and propose adding additional policies to enable enhanced monitoring and enforcement by the College.

Advantages

- Minimal cost (resources) to the College for development, implementation and enforcement.

- Minimal cost (resources) to pharmacies for implementation and maintenance.

Disadvantages

- Potential decrease in public trust in pharmacy systems; appearance that patient safety and medication errors are not a priority.
- Not well-aligned with the trend occurring in other provincial regulatory bodies.
- No way to quantify the number and types of medication errors and incidents that are occurring within British Columbia.
- Does not allow for shared learning regarding the number and types of incidents provincially and nationally.

Option 2

Explore implementation of mandatory medication error reporting to **any** independent third party (not specified by the College).

Advantages

- Enhances accountability and increases communication and awareness to the public.
- Aligns well with other provincial regulatory bodies (New Brunswick).
- Enables sharing of lessons learned from participating pharmacies (if/where data is available to the College or shared between pharmacies).
- Guides development of policies and legislation for the pharmacy profession (if/where data is available to the College).
- Minimal additional cost (resources) to the College for enforcement.

Disadvantages

- Absence of College coordination and involvement with a specific vendor could result in a lack of consistency and access to data. As such, there would be a continued lack of ability to quantify the number and types of medication errors and incidents that are occurring within British Columbia.
- Data and lessons learned may not be adequately captured or shared due to the lack of a uniform provincial platform/database.
- Additional cost to the College for development, implementation and enforcement (but less than Option 3 due to less/no direct involvement between the third party vendor(s) and the College).
- Potential negative stakeholder response due to additional costs and resources (third party vendor fees, staffing resources).
- Potential resistance from pharmacy staff due to fear of changes and increased work-load.

Option 3
Explore implementation of mandatory medication error reporting to a College-specified independent third party.

Advantages

- Enhances accountability and increases communication and awareness to the public.
- Aligns well with other provincial regulatory bodies (MB, NS, ON, SK).
- Potential coordination with the vendor may ensure a consistent approach and could provide the College with customized resources (education, newsletters, CQI tools etc.) and support (implementation, enforcement tools etc.).
- Enables sharing of lessons learned from all pharmacies which results in complete data.
- Ability to quantify the number and types of medication errors and incidents that are occurring within British Columbia pharmacies.
- Availability of data to guide development of policies and legislation for the pharmacy profession.

Disadvantages

- Most significant cost (more than Option 1 or 2) to the College for development, implementation and enforcement.
- Requires longer development and implementation time (more than Option 1 or 2) due to vendor selection and potential coordination.
- Potential negative stakeholder response due to required costs and resources (third party vendor fees and/or increase in College fees, staffing resources).
- Potential resistance from pharmacy staff due to fear of changes and increased work-load.

Recommendation

The College recommends that the Board choose Option 3, to explore implementation of mandatory medication error reporting to a College-specified independent third party, for the following reasons:

- Enhanced accountability and increased communication and awareness for the public.
- Alignment with other provincial regulatory bodies (MB, NS, ON, SK).
- Consistency of approach for all pharmacies and pharmacy professionals.
- Customized resources and support from the third party vendor.
- Sharing of lessons learned from all pharmacies, resulting in complete data.
- Ability to quantify the number and types of medication errors and incidents that are occurring within British Columbia pharmacies.
- Availability of data to guide development of policies and legislation for the pharmacy profession.

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

Next Steps

If the Board chooses Option 3, the following are the next steps to be taken by the College:

- Develop Request for Proposal (RFP) for third party vendors.
- Define program details:
    - Determine need for new bylaws and/or policies.
    - Determine need for, and process of oversight.
    - Determine internal resource needs, i.e. budget, IT implications, and training.
    - Determine external resource needs, i.e. budget, IT implications, and training.
    - Determine timeline.
    - Develop communication and engagement plans to support implementation.
- Develop a recommendation for a specific independent third party for decision by the Board at their September 2019 meeting.

Appendix	
1	November 2017 Briefing Note: Mandatory Medication Error Reporting
2	Interjurisdictional Scan – Medication Error Reporting (October 2018)

College of Pharmacists of British Columbia

BOARD MEETING
November 17, 2017

8. Legislation Review Committee
a) Mandatory Medication Error Reporting

DECISION REQUIRED

Recommended Board Motion:

Direct the Registrar to explore potential alternatives to the College's existing quality management requirements, including mandatory medication error reporting to an independent third party.

Purpose

To determine whether the College of Pharmacists of British Columbia (the "College") should explore alternatives to its existing quality management requirements, including a standardized quality management program that includes mandatory error reporting to an independent third party.

Background

The second most common complaint received at the College are ones made in relation to medication dispensing errors by pharmacists.[1] In addition, recent high profile cases of medication errors have prompted the College to examine its existing quality management requirements for registrants.[2] In August 2017, Registrar Bob Nakagawa met with Melissa Sheldrick, an advocate whose son passed away due to a prescription drug dispensing error in Ontario.

[1] College of Pharmacists of B.C. 2015/2016 Annual Report
http://annualreport.bcpharmacists.org/ar2016/wp-content/uploads/2015/05/CPBC_Annual-Report_2016_FINAL_secure.pdf

[2] In March 2016, 8-year old Andrew Sheldrick died after taking a toxic dose of Baclofen that had been dispensed in error by an independent compounding pharmacy in Mississauga, Ontario.
http://www.cbc.ca/news/canada/toronto/go-public-sleep-medication-accidentally-switched-1.3811972;
In October 2016, a pharmacy in Saskatoon provided a 4-year old boy with an antipsychotic drug (Risperidone) that was 10 times the correct dose. The overdose went unchecked and undetected for months with each refill.
http://www.cbc.ca/news/canada/saskatoon/4-year-old-acting-like-a-slobbering-drunk-after-pharmacy-dispenses-wrong-dose-of-antipsychotic-drug-1.3801461

Several provinces in Canada have implemented, or are in the process of implementing, new quality management requirements that include mandatory error reporting to an independent third party. The error reports are submitted anonymously and are analyzed for the purposes of shared learning rather than discipline. Through anonymous reporting, it is hoped that pharmacists will be able to analyze medication incidents and learn about the possible causes of the incidents.

Discussion

Current State

Sections 10 and 14(1) of the Bylaws made under the *Pharmacy Operations and Drug Scheduling Act* ("PODSA") requires pharmacy managers of community and hospital pharmacies to develop, document and implement an ongoing quality management program that includes, among other things, a process for reporting, documenting and following up on known, alleged and suspected errors, incidents and discrepancies. The specific requirements of the program are left to the discretion of the pharmacy manager. The program may or may not include requirements for mandatory reporting of medication incidents to a third party. The College does not assess the adequacy of the program.

The College has some oversight over quality management through its Practice Review Program, an in-person review of pharmacy professionals' practices and the pharmacies where they work. The Practice Review Program is comprised of two components: the Pharmacy Review and the Pharmacy Professionals Review. During a practice review, compliance officers adjudicate compliance with College Bylaws and Professional Practice Policies. Compliance Officers record and document areas of compliance and non-compliance while observing pharmacy professionals throughout the review process. For areas of non-compliance action-items are assigned, if necessary. All pharmacies and pharmacy professionals will be reviewed under Practice Review Program on a cyclical basis.[3]

Interjurisdictional Scan

Several provinces in Canada have implemented, or are in the process of implementing, new quality management requirements that include mandatory error reporting to an independent third party such as the Institute of Safe Mediation Practices Canada ("ISMP"), an independent national not-for-profit organization focused on the advancement of medication safety in healthcare settings. An interjurisdictional comparison of the quality management requirements across Canada is summarized in Appendix 1. In provinces that have adopted new quality management requirements, those requirements are generally more prescriptive than the College's current requirements.

[3] http://www.bcpharmacists.org/practice-review-program

Currently, Nova Scotia is the only province that requires error reporting to an independent third party, ISMP. Saskatchewan and Ontario are proposing to implement new quality management requirements that include mandatory error reporting to an independent third party in 2018. Manitoba began a pilot project with ISMP in September 2017. New Brunswick completed a pilot project with ISMP in 2016, but has not implemented a mandatory error reporting program with an independent third party.

In Saskatchewan, Nova Scotia and New Brunswick, provinces that have completed pilot projects with ISMP, the feedback on this program appears to have been very positive.[4]

Pilot Projects

Nova Scotia

The first pilot project, SafetyNET-Rx, began in Nova Scotia in 2008. The first phase of the pilot project involved 13 community pharmacies in Nova Scotia. At the beginning of the pilot project, pharmacy staff were invited as continuous quality improvement ("CQI") facilitators to attend a training session about quality management, quality related events ("QREs"), and the SafetyNET-Rx program. The SafetyNET-Rx program also included the following: a central anonymous reporting tool to an independent third party database as part of an integrative information system that was used to identify, report, analyze and learn from QREs; quarterly staff meetings to discuss and learn from reported QREs as well as suggest changes to prevent recurrence; and an annual self-assessment tool for evaluating performance on a continual basis, the Medication Safety Self-Assessment. The pilot project covered a 12-month intervention period that ended in June 2009.

Following the completion of the pilot project, SafetyNET-Rx was expanded to 68 community pharmacies across the province, and then further expanded to all community pharmacies. The current program is based on the program used in the pilot project, with some adjustments. The off-site training of CQI facilitators, the self-assessment tool, and the quarterly meetings remained key components of the CQI program, however, changes were made to enhance the online reporting tool and an iPad application was created for the provincial pharmacy inspectors.

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[4] SafetyNET-Rx: Insights and Lessons Learned From a Pilot Project
https://dalspace.library.dal.ca/bitstream/handle/10222/15805/Deal%2cHeidi%2cMAHSR%2cDec2012.pdf?sequence=1&isAllowed=y;
An Assessment of the COMPASS Quality Improvement Initiative: A Summary of Key Findings
https://scp.in1touch.org/uploaded/web/files/SCPP-COMPASS%20Report-2016-FINAL-%20PHARMV2.pdf;
The Business Case for A Standardized Continuous Quality Assurance Program in Saskatchewan Pharmacies – COMPASS by the Saskatchewan College of Pharmacy Professionals
http://saskpharm.ca/uploaded/web/site/COMPASS_Business_Case_20170206.pdf;
Multi-Incident Analysis on Incidents Involving Patients: Lessons Learned from Provincial Pilot Study
https://www.ismp-canada.org/download/PharmacyConnection/PC2016-LessonsLearnedProvincialPilotStudy.pdf

Saskatchewan

Saskatchewan has completed three phases of its pilot program, COMPASS, which began in 2013. Ten pharmacies participated in the first phase, 87 pharmacies participated in the second phase, and 119 pharmacies participated in the third phase. Program requirements included anonymous reporting of incidents (errors and near misses) to a central database (the Community Pharmacy Incident Reporting program developed by ISMP ("CPhIR")), and the biennial completion of a Medication Safety Self-Assessment. Other program requirements included discussing specific incidents and improvement strategies at continuous quality improvement meetings and designating at least one individual from pharmacy staff to be the quality improvement coordinator. Saskatchewan has proposed full implementation of a new quality management program based on COMPASS in 2018.

New Brunswick

A multi-incident analysis was performed on incidents reported from New Brunswick pharmacies to CPhIR from July 2015 to February 2016. Of the 223 pharmacies in New Brunswick, 82 were enrolled in a complimentary pilot project for the use of CPhIR. The objective of this multi-incident analysis was threefold; first, to understand how and why medication incidents occur; second, to identify the potential contributing factors of these incidents; and third, to provide recommendations to prevent future medication incidents. Based on the analysis, recommendations were developed to improve the medication workflow process, including inventory management, receiving/shelving, prescription order entry, dispensing, compliance packaging, and counselling/pick-up.

Service Providers

ISMP has developed the CPhIR Program to allow community pharmacies to document and analyze contributing factors that may lead to errors in the medication-use system.[5] CPhIR offers community pharmacies a systematic incident reporting tool, an analytical interface which allows users to compare their incident statistics with the national aggregate incident data, and a continuing professional development section dedicated to medication safety. A stated goal of the CPhIR Program is to analyze medication incident reports and develop recommendations for enhancing medication safety in all healthcare settings. Some B.C. pharmacies may already be voluntarily participating in this program.

Pharmapod is a company based in the U.K. and Ireland that provides software for tracking pharmacy medication incidents. Pharmapod states that its system enables pharmacists to systematically record medication-related incidents and risks in practice and carry out effective root-cause analysis. The system analyses the collated data and disseminates the learning back to the profession and to key stakeholders internationally, preventing recurrence of patient harm.

[5] www.cphir.ca

Both ISMP and Pharmapod have expressed interest in working with the College to run a pilot project in B.C.

Options

The Board should determine whether to explore alternatives to its existing quality management requirements. In making this determination, there are several factors to consider, including the following:

- The adequacy of the College's current quality management program.
- The effect of new requirements on pharmacies' and registrants' practices.
- The feasibility of a new quality management program from an operational perspective:
  - The College would need to devote resources into assessing, developing and implementing a new program.
  - If a mandatory error reporting system is implemented, the College may be subject to ongoing costs that must be budgeted for.
  - The College's compliance and investigations staff must determine how to enforce new requirements.

1. **Option 1**

   Do not explore alternatives to its existing quality management requirements at this time.

   <u>Advantages</u>

   - The College would not be required to devote additional resources to this issue, at this time.
   - Initial data from the Practice Review Program is being compiled and have indicated a positive impact on registrants' practice and compliance with College requirements. The College could focus on the development and further implementation of this program, as its key quality assurance program.

   <u>Disadvantages</u>

   - The College could appear to be unresponsive to emerging issues in patient safety.
   - The adequacy of quality management programs in the province may be limited and/or uneven.

2. **Option 2**

   Begin to explore alternatives to its existing quality management requirements.

   Advantages

   - The College will have an opportunity to assess its current requirements, and propose improvements, if necessary.
   - The College may have an opportunity to develop a program to reduce medication incidents and improve patient safety, consistent with its mandate.
   - The College would obtain a better understanding of the resources required for a new quality management program.
   - The College could also conduct engagement on the issue, to obtain a better understanding of stakeholder responses to such an initiative.

   Disadvantages

   - It is not a certainty that new quality management requirements would be an improvement over existing requirements.
   - There may be some negative response from stakeholders, as new quality management requirements might increase the workload for pharmacies and registrants.

Recommendation

The College recommends that the Board choose Option 2 for the following reasons:

- Due to the potentially serious consequences of medication errors, this topic warrants further consideration from College staff and the Board.
- The risk of taking this option is low, in that the College is not required to commit to any program that it explores. Conversely, the risk in not exploring this issue could be a lost opportunity to improve patient safety and respond to concerns from the public.

Appendix	
1	Interjurisdictional scan – Incident reporting

Appendix to Briefing Note – Mandatory Medication Error Reporting (November 17, 2017)

Interjurisdictional Scan – Incident Reporting

Jurisdiction	Provisions	Comments
British Columbia	**PODSA Bylaws** 10. 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**. 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.	No mandatory error reporting to third party.
Alberta	**Standards of Practice for Pharmacists and Pharmacy Technicians** https://pharmacists.ab.ca/sites/default/files/StandardsOfPractice.pdf	No mandatory error reporting to third party.

Jurisdiction	Provisions	Comments
	1.9 Each pharmacist and pharmacy technician must participate in the quality assurance processes required by the Standards for the Operation of Licensed Pharmacies or another workplace quality assurance program applicable to the pharmacists' or the pharmacy technicians' practice. 1.10 A pharmacist who provides patient care in an environment where a quality assurance program does not exist or does not meet the minimum standards established under the Standards for the Operation of Licensed Pharmacies must implement a program that meets or exceeds the requirements outlined in the Standards for the Operation of Licensed Pharmacies. **Standards for the Operation of Licensed Pharmacies** https://pharmacists.ab.ca/sites/default/files/StandardsPharmacies.pdf Standard 6 – Implement a quality assurance program 6.3 A licensee must ensure that a quality assurance process is implemented and maintained in a licensed pharmacy. The quality assurance process should: a) **provide for reporting, investigating, documenting and evaluating drug incidents that occur in the pharmacy**; b) include regular review and feedback mechanisms to prevent drug incidents; and c) include a process or procedure for responding to complaints or concerns. (See detailed requirements in Standard 6)	
Saskatchewan	**The Business Case for a standardized continuous quality assurance program in Saskatchewan pharmacies – COMPASS** (December 2016) https://scp.in1touch.org/uploaded/web/site/COMPASS_Business_Case_20170206.pdf Appendix A Proposed program requirements: 1) **Requires anonymous reporting of quality related events (QREs) to an independent, objective third party organization**: for population of a national aggregate database from which learnings arising from trends and patterns can be communicated across the profession. 2) Requires completion of a medication safety self-assessment biennially.	3-phase pilot project with ISMP completed in 2016. Full implementation of mandatory error reporting to third party in 2018.

Jurisdiction	Provisions	Comments
	3) Requires development and monitoring of the progress of an improvement plan at CQI meetings. 4) Requires CQI meetings to be held for the purpose of providing staff education, discussing of QRE's, completing of the MSSA, and developing and monitoring of the improvement plan. The number of CQI meetings held per year will be determined by the quality assurance coordinator and pharmacy manager in order to meet the above requirements. Recommended to meet no less than annually. 5) Requires documentation of quality improvements discussed at CQI meetings. Discussion and outcomes of the CQI meetings are to be documented using the quality improvement tool in CPhIR. 6) Requires each pharmacy to have designated at least one QI coordinator. Recommend to have two to be co-coordinators but will depend on the size of the safety workload within the pharmacy. Other components of the program: 7) Manages known, alleged and suspected medication errors that reach the patient consistent with the best practices for this activity. 8) Encourages open dialogue on QREs between pharmacy staff and management through review of the pharmacy's aggregate QRE data (e.g. total number of incidents, type of incidents, etc.). 9) Achieves the purposes of an effective CQI program through ongoing education of pharmacy staff on the current best practices in QRE management and adoption of these practices, with the goal of discouraging punitive identification or other approaches that is detrimental to reporting and learning. Service provider: ISMP Canada	
Manitoba	**Pilot Project: Safety Improvement in Quality (Safety IQ) (2017)** http://www.cphm.ca/uploaded/web/Newsletters/Spring%202017/College%20of%20Pharmacists%20of%20Manitoba%20Spring%20Newsletter%202017.pdf • Safety IQ is a standardized continuous quality improvement program that enables community pharmacies in Manitoba to **anonymously report medication errors and near misses, also known as quality related events (QREs) to ISMP Canada**.	One year pilot project with ISMP to begin in September 2017.

Jurisdiction	Provisions	Comments
	• 20 community pharmacies will be participating in pilot project beginning in September 2017.	
Ontario	**NAPRA Model Standards of Practice –** Adopted by Ontario (see provisions below under "NAPRA") **Proposed Continuous Quality Assurance Program** http://www.ocpinfo.com/library/consultations/download/Continuous_Quality_Assurance_Programs_in_Pharmacies.pdf http://www.ocpinfo.com/about/consultations/consultation/implementation-cqa/ • Enable and **require anonymous reporting of all medication incidents by pharmacy professionals to a specified independent, objective third-party organization** for population of an aggregate incident database to identify issues and trends to support patient safety improvement. • Require pharmacy professionals to document appropriate details of medication incidents and near misses in a timely manner to support the accurateness of information reported. • Document CQI plans and outcomes of staff communications and quality improvements implemented. • Necessitate that when a medication incident occurs pharmacy professionals analyze the error in a timely manner for causal factors and commit to taking appropriate steps to minimize the likelihood of recurrence of the incident. • Require completion of a medication safety self-assessment (MSSA) within the first year of implementation of the Standard, then at least every 2-3 years. The Designated Manager may determine an MSSA is required more frequently if a significant change occurs in the pharmacy. • Analyze individual and aggregate data to inform the development of quality improvement initiatives. • Require prompt communication of appropriate details of a medication incident to all pharmacy staff, including causal factors of the error and actions taken to reduce the likelihood of recurrence. • Ensure the scheduling of regular CQI communication with pharmacy staff to educate pharmacy team members on medication safety, encourage open dialogue on medication incidents, complete an MSSA, and develop and monitor quality improvement plans. • Support the development and monitoring of CQI plans, outcomes of CQI communications and quality improvements implemented. • To be implemented in 2 phases	Proposed standards for mandatory error reporting to third party posted for public comment. Propose full implementation by December 2018.

Jurisdiction	Provisions	Comments
	1st phase: • approximately six to eight months • would involve volunteer pharmacies that are representative of pharmacy practice across Ontario (e.g. independent, chain, rural, urban) and would provide an opportunity to assess the program requirements. 2nd phase: • expand by incorporating the changes and best practices identified by pharmacies in the first phase to improve successful incorporation into pharmacy workflow • full implementation in all pharmacies is expected by December 2018. **Feedback for Implementation of Continuous Quality Assurance for Medication Safety** http://www.ocpinfo.com/about/consultations/consultation/implementation-cqa/feedback/#read	
New Brunswick	**NAPRA Model Standards of Practice –** Adopted by New Brunswick (see provisions below under "NAPRA") **Regulations of the New Brunswick College of Pharmacists** https://nbcp.in1touch.org/document/1733/2015%2007%2023%20REGS%20bilingual.pdf 14.2 On or before December 31, 2015, the manager must implement a documented, ongoing quality management program that includes, but is not limited to, monitoring staff performance, equipment, facilities, and adherence to Standards of Practice, including the following: (a) **a process for documenting and reporting known, alleged and suspected medication errors, discrepancies, near misse**s and the steps taken to resolve the problem; (b) provisions to protect the confidentiality of information relating to clients. **Results of Pilot Study with ISMP Canada (2016)** https://nbcp.in1touch.org/document/1733/2015%2007%2023%20REGS%20bilingual.pdf	Pilot study with ISMP Canada completed in 2016. No mandatory error reporting to a third party.
Newfoundland and Labrador	**Standards of Pharmacy Practice – Standards for Hospital Pharmacies** http://www.nlpb.ca/media/SOPP-Hospital_Pharmacy-June2007.pdf 5.8.1 The pharmacy department shall participate in a medication incident and medication discrepancy reporting program.	No mandatory error reporting to third party.

Jurisdiction	Provisions	Comments
	5.8.2 **There shall be written policies and procedures to report, document, analyze and follow-up medication incidents and medication discrepancies**. 5.8.3 A written report shall be prepared for the designated hospital committee(s) describing medication incidents and medication discrepancies occurring in prescribing, dispensing or administration of a medication. **NAPRA Model Standards of Practice –** Adopted by N.L. (see provisions below under "NAPRA")	
Nova Scotia	**Pharmacy Practice Regulations made under Section 80 of the *Pharmacy Act*** https://novascotia.ca/just/regulations/regs/pharmprc.htm 22 (1) Every pharmacy manager shall establish and maintain a continuous, documented quality assurance program according to the standards of practice that monitors staff performance; adequacy of staff levels; equipment and facilities; and adherence to standards of practice. (2) The quality assurance program shall include a process for documenting, reporting and analyzing known, suspected, intercepted and corrected medication errors and discrepancies, and the steps taken to resolve the problems and prevent their recurrence. (3) The quality assurance program must demonstrate how the analysis of known, suspected, intercepted and corrected medication errors and discrepancies and regular pharmacy self-assessment has been acted upon to improve the quality of patient care. (4) The quality assurance program shall include provisions to protect the confidentiality of information relating to specific patients. **Standards of Practice: Continuous Quality Assurance Programs in Community Pharmacies** http://www.nspharmacists.ca/wp-content/uploads/2017/04/StandardsOfPractice_ContinuousQualityAssurance_Jan2010.pdf A CQI process that fulfills a pharmacy's legislated requirements as set out in the Practice Regulations achieves the following: 1) Monitors staff performance, equipment, facilities and adherence to standards of practice.	Currently, the only province with mandatory error reporting to third party.

Jurisdiction	Provisions	Comments
	2) Manages known, alleged and suspected medication errors that reach the patient consistent with the best practices for this activity undertaken by others in the profession, including: i. Taking appropriate and necessary action to optimize patient care, including prompt consultation with the patient's other health care provider(s) for determination of appropriate action to minimize negative impact on the patient. ii. Ensuring the management of error process is appropriately communicated to the patient. iii. Ensuring the management of error minimizes undue stress and frustration for the patient. iv. Ensuring the management of error should include an apology (as enabled by the Apology Act) in which the pharmacist acknowledges the negative impact to the patient, and commits to taking the steps appropriate to minimize the likelihood of recurrence of the incident. v. Promptly analyzing the error for causal factors. vi. Communicating to the patient the causal factors of the error when appropriate, and actions taken to reduce the likelihood of recurrence. vii. Documenting the details of the known, alleged or suspected error or discrepancy promptly and thoroughly, including statements from all pharmacy staff involved and the steps taken to resolve the problem. viii. Communicating to all pharmacy staff the appropriate details of the error, including the causal factors of the error and actions taken to reduce the likelihood of recurrence. 3) Enables and requires **anonymous reporting of quality related events (QREs) to an independent, objective third party organization** for population of a national aggregate database from which learnings arising from trends and patterns can be communicated across the profession. (NOTE: QREs include errors that reach the patient as well as those that are intercepted prior to dispensing. The extent to which intercepted errors are reported will be a professional judgment decision of the pharmacy manager in consideration of the nature of the intercepted error, its implication for patient safety and the extent to which it is recurring). 4) Encourages open dialogue on QREs between pharmacy staff and management through quarterly review of the pharmacy's aggregate QRE data (e.g. total number of incidents, type of incidents, etc.).	

Jurisdiction	Provisions	Comments
	5) Documents quality improvements made as a result of the quarterly CQI meetings of staff. 6) Requires completion of a medication safety self-assessment annually, and monitoring the progress of the resulting enhancement plan at quarterly CQI meetings. 7) Includes provisions to protect the confidentiality of information relating to specific patients. 8) Achieves the purposes of an effective CQI program as described at the beginning of this document through ongoing education of pharmacy staff on the current best practices in QRE management and adoption of these practices, with the goal of discouraging punitive identification or other approaches that are detrimental to reporting and learning. Service Provider: ISMP	
Prince Edward Island	**NAPRA Model Standards of Practice –** Adopted by P.E.I. (see provisions below under "NAPRA")	No mandatory reporting to third party.
NAPRA	**NAPRA Model Standards of Practice** http://napra.ca/Content_Files/Files/Model_Standards_of_Prac_for_Cdn_Pharm_March09_Final_b.pdf Part 3 Pharmacists regardless of the role they are fulfilling: 10. manage errors, incidents and unsafe practices (2.6) 11. promptly disclose alleged or actual errors, incidents and unsafe practices to those affected and in accordance with legal and professional requirements (2.6) 12. **record and report alleged and actual errors, incidents and unsafe practices in accordance with legal and professional requirements** (2.6) 13. adhere to applicable laws, regulations and policies applicable to pharmacy practice (3.1) Pharmacists, when providing patient care: 14. **report the occurrence of adverse events and close-calls** (2.6) (Close calls are defined by the Canadian Patient Safety Institute as events with the potential for harm that did not result in harm due to timely intervention or good fortune.) Pharmacists, when managing a pharmacy:	Standards require error reporting, but do not require error reporting to third party.

Jurisdiction	Provisions	Comments
	15. review errors and incidents to determine patterns and causal factors that contribute to patient risk (2.6) 16. develop and implement policies and procedures that minimize errors, incidents and unsafe practices, including supporting staff in their obligation to report adverse events and close-calls (2.6)	

Interjurisdictional Scan – Medication Error Reporting (October 2018)

Province	Provisions	Mandatory Medication Error Reporting	Costs
British Columbia	**PODSA Bylaws** 24 (1) A community pharmacy's manager must develop, document and implement an ongoing quality management program that: (c) includes a process for reporting, documenting and following up on known, alleged and suspected errors, incidents and discrepancies. 29 (1) A hospital pharmacy's manager must develop, document and implement an ongoing quality management program that (c) includes a process for reporting, documenting and following up on known, alleged and suspected errors, incidents and discrepancies	**No**	N/A
Alberta	**Standards of Practice for Pharmacists and Pharmacy Technicians** https://abpharmacy.ca/sites/default/files/StandardsOfPractice_May2014_v2.pdf 1.9 Each pharmacist and pharmacy technician must participate in the quality assurance processes required by the Standards for the Operation of Licensed Pharmacies or another workplace quality assurance program applicable to the pharmacists' or the pharmacy technicians' practice. 1.10 A pharmacist who provides patient care in an environment where a quality assurance program does not exist or does not meet the minimum standards established under the Standards for the Operation of Licensed Pharmacies must implement a program that	**No** Drug incidents are required to be documented on a Drug Incident Report Form (https://abpharmacy.ca/sites/default/files/DrugIncidentReport.pdf) and retained for 10 years from discovery date Drug Incident reports must be reviewed quarterly to evaluate success of changes implemented. This is done on a Drug Incident Quarterly Review Report (https://abpharmacy.ca/sites/default/files/DrugIncidentQuarterlyReview.pdf) and retained for 10 years From June 2018 Council Meeting Minutes:	N/A

	meets or exceeds the requirements outlined in the Standards for the Operation of Licensed Pharmacies. **Standards for the Operation of Licensed Pharmacies** https://abpharmacy.ca/sites/default/files/Standards Pharmacies_May2014.pdf Standard 6: A licensee must implement a quality assurance program to monitor and improve processes to minimize risk. 6.3 A licensee must ensure that a quality assurance process is implemented and maintained in a licensed pharmacy. The quality assurance process should: a) provide for reporting, investigating, documenting and evaluating drug incidents that occur in the pharmacy; b) include regular review and feedback mechanisms to prevent drug incidents; and c) include a process or procedure for responding to complaints or concerns.	Regarding mandatory error reporting: "Direction was provided by Council to further explore solutions that support these critical success factors and to develop a plan for implementation in the future."	
Manitoba	**Standards of Practice #9: Medication Incidents and Discrepancies or Near-Miss Events** https://www.cphm.ca/uploaded/web/Legislation/Incidents%20and%20Discrepancies%20Practice%20Direction%20-%20FINAL.pdf 3.1.1 The pharmacy has written policies and procedures for addressing, reporting, investigating, documenting, disclosing and learning from medication incidents. In the case of a pharmacy owned by a Regional Health Authority, the manager/director of the pharmacy will collaborate with the regional health authority to ensure that there are written policies and procedures for	**Yes** (Pilot from September 2017-18, Council will decide next steps in Fall 2018) **Safety IQ** https://www.cphm.ca/site/safetyiq/q&a The College of Pharmacists of Manitoba (College) partnered with the Institute for Safe Medication Practices Canada (ISMP Canada) to develop Safety Improvement in Quality (Safety IQ). Safety IQ is a standardized continuous quality improvement (CQI) pilot that enables community pharmacies in Manitoba to improve patient	N/A

	addressing, reporting, investigating, documenting, disclosing and learning from medication incidents. *(Specific requirements are outlined in the document above, and also within the general Standards of Practice)*	safety and ensure better patient health outcomes, while addressing the specific needs and workflow of community pharmacies. Participants in Safety IQ anonymously report medication incidents and near misses to ISMP Canada for analysis. ISMP Canada then shares learnings with pharmacies and makes suggestions for pharmacy practice improvements.	
New Brunswick	**Regulations of the New Brunswick College of Pharmacists** https://nbcp.in1touch.org/document/1733/2015%2007%2023%20REGS%20bilingual.pdf 14.2 The manager must ensure and document ongoing quality management including, but not limited to; evaluating staff performance, equipment and facilities and adherence to Standards of Practice including the following: (a) anonymous medication error reporting to an external Canadian database for errors that reach patients (NB: As of a date fixed by Council) (b) response to individual errors and trends (c) maintenance of a culture of safety within the practice (d) provisions to protect the confidentiality of information relating to clients. (2018)	**Yes** Mandatory Medication Incident Reporting Practice Directive pending, expected to be implemented early 2019	N/A
Newfoundland and Labrador	**Standards of Pharmacy Operation – Hospital Pharmacy** http://www.nlpb.ca/media/Standards-Pharmacy-Operation-Hospital-May2017-In-Force-Jan2018.pdf 1.1 (e) Continuous Quality Improvement. The pharmacist-in-charge must participate in the development, documentation and implementation of an ongoing quality management program that:	**No**	N/A

	(iii) includes a process for reporting, documenting and following up on known, alleged and suspected errors, incidents and discrepancies **NAPRA Model Standards of Practice –** Adopted by N.L. (see provisions below under "NAPRA")		
Nova Scotia	**Pharmacy Practice Regulations made under Section 80 of the Pharmacy Act** https://novascotia.ca/just/regulations/regs/pharmprc.htm 22 (1) Every pharmacy manager shall establish and maintain a continuous, documented quality assurance program according to the standards of practice that monitors staff performance; adequacy of staff levels; equipment and facilities; and adherence to standards of practice. (2) The quality assurance program shall include a process for documenting, reporting and analyzing known, suspected, intercepted and corrected medication errors and discrepancies, and the steps taken to resolve the problems and prevent their recurrence. (3) The quality assurance program must demonstrate how the analysis of known, suspected, intercepted and corrected medication errors and discrepancies and regular pharmacy self-assessment has been acted upon to improve the quality of patient care. (4) The quality assurance program shall include provisions to protect the confidentiality of information relating to specific patients.	**Yes** **Standards of Practice: Continuous Quality Assurance Programs in Community Pharmacies** https://www.nspharmacists.ca/wp-content/uploads/2018/01/SOP_ContinuousQualityAssuranceProgramsInCommunityPharmacies.pdf 3. Enables and requires anonymous reporting of quality related events (QREs)[1] to an independent, objective third party organization for population of a national aggregate database from which learnings arising from trends and patterns can be communicated across the profession *Community Pharmacy Incident Reporting Program (CPhIR) website by ISMP: https://secure.ismp-canada.org/CPHIR/Reporting/login.php* 6. Requires completion of a medication safety self assessment annually, and monitoring the progress of the resulting enhancement plan at quarterly CQI meetings. *Medication Safety Self Assessment for Community/Ambulatory Pharmacy (MSSA-CAP) by ISMP: https://www.ismp-canada.org/products/*	Pharmacies subscribe directly to ISMP: $340 annually for CPhIR and $340 annually for MSSA program (~$680 total per year)

Ontario	**NAPRA Model Standards of Practice –** Adopted by Ontario (see provisions below under "NAPRA") **Supplemental Standard of Practice: Mandatory Standardized Medication Safety Program in Ontario Pharmacies** *(Approved by Council Sept 2018)* http://www.ocpinfo.com/library/consultations/download/Supplemental%20Standard%20of%20Practice.pdf Anonymous recording of all medication incidents and near misses by pharmacy professionals to a specified independent, objective third-party organization to support quality improvement within the pharmacy, and for population of an aggregate incident database to facilitate anonymous reporting that will identify issues and incident trends to support shared learnings. *(Other requirements are outlined in the document above)*	**Yes** **Medication Safety Program** http://www.ocpinfo.com/about/key-initiatives/cqa/ The program began implementation in late fall 2017 with approximately 100 pharmacies, with the goal of having the program commence full implementation among all community pharmacies in Ontario by the end of 2018. Pharmapod is the third party selected by the College following a formal request for proposals process, to create and manage the program reporting system. Their platform will be used by pharmacies to enter medication incident data. Pharmapod will also be providing training, resources and data analysis for pharmacies and the College	Paid for by the College As per September 2018 Council Briefing Note: "Roll-out of the Medication Incident Reporting system will take place in 2019 at a cost of $1.85 million" *(As per 2017 Annual Report, Ontario has 4327 accredited community pharmacies)*
Prince Edward Island	**NAPRA Model Standards of Practice –** Adopted by P.E.I. (see provisions below under "NAPRA")	**No**	N/A
Quebec	*(English content not available)*	**No**	N/A
Saskatchewan	**Regulatory Bylaws** https://scp.in1touch.org/document/3584/Bylaws_Regulatory_20170825.pdf 12 (2) Every pharmacy must have a Continuous Quality Improvement program that meets the following requirements:	**Yes** **COMPASS** https://scp.in1touch.org/site/compass/compass?nav=sidebar	$500 permit fee per pharmacy annually https://scp.in1touch.org/site/co

	(a) anonymous reporting of Quality Related Events to an independent, objective third party organization for the population of a national aggregate database, in which learnings can be communicated across the profession; (b) completion of a Medication Safety Self-Assessment every two years by all pharmacy staff; (c) development and monitoring of a Continuous Quality Improvement plan; (d) documentation of all Continuous Quality Improvements; and (e) participation in Continuous Quality Improvement meetings as follows: (i) the number of Continuous Quality Improvement meetings held per year will be determined by the Quality Improvement Coordinator and pharmacy manager in order to meet the requirements of clauses 12(2)(a), (b), (c), and (d) of Part I; and (ii) there shall be no less than one Continuous Quality Improvement meeting held annually. (*Other requirements contained in Regulatory Bylaws above)*	Requires anonymous reporting of medication incidents to an independent, objective third party organization for population of a national aggregate database from which learnings arising from trends and patterns can be communicated across the profession (CPhIR) Requires completion of a medication safety self-assessment biennially (every two years) Requires development and monitoring of the progress of an improvement plan at CQI meetings. Requires CQI meetings to be held for the purpose of providing staff education, discussing of medication incidents that have reached the patient regardless of harm, discussing near misses that had they not been caught could have caused patient harm, other near misses, completing of the MSSA, and developing and monitoring of the improvement plan. The number of CQI meetings held per year will be determined by the quality improvement coordinator and pharmacy manager in order to meet the above requirements. Recommended to meet no less than annually. Requires documentation of quality improvements discussed at CQI meetings. Discussion and outcomes of the CQI meetings are to be documented using the quality improvement tool in CPhIR	mpass/fees?nav=sidebar ($340 for CPhIR/MSSA subscription, $160 for ongoing administrative fees)

		Requires each pharmacy to have designated at least one Quality Improvement (QI) Coordinator. The number of QI coordinators will depend upon the safety workload of the pharmacy	
NAPRA	**Model Standards of Practice for Canadian Pharmacists** https://napra.ca/sites/default/files/2017-09/Model_Standards_of_Prac_for_Cdn_Pharm_March09_layout2017_Final.pdf Part 3 Pharmacists regardless of the role they are fulfilling: 10. manage errors, incidents and unsafe practices (2.6) 11. promptly disclose alleged or actual errors, incidents and unsafe practices to those affected and in accordance with legal and professional requirements (2.6) 12. record and report alleged and actual errors, incidents and unsafe practices in accordance with legal and professional requirements (2.6) 13. adhere to applicable laws, regulations and policies applicable to pharmacy practice (3.1) Pharmacists, when providing patient care: 14. report the occurrence of adverse events and close-calls (2.6) (Close calls are defined by the Canadian Patient Safety Institute as events with the potential for harm that did not result in harm due to timely intervention or good fortune.) Pharmacists, when managing a pharmacy: 15. review errors and incidents to determine patterns and causal factors that contribute to patient risk (2.6) 16. develop and implement policies and procedures that minimize errors, incidents and unsafe practices, including supporting staff in their obligation to report adverse events and close-calls (2.6)		

College of Pharmacists of British Columbia

8. Potential Alternatives to the College's Existing Quality Management Program

Ashifa Keshavji

Director of Practice Reviews and Quality Assurance

College of Pharmacists of British Columbia

Overview

- Background
- Current State
- Environmental Scan
- Factors to Consider
- Options
- Next Steps
- Decision

College of Pharmacists of British Columbia

Background

July 2017

Melissa Sheldrick requested that the College consider implementation of mandatory medication error reporting

November 2017 –Board Motion

Direct the Registrar to explore potential alternatives to the College's existing quality management requirements, including mandatory medication error reporting to an independent third party.

College of Pharmacists of British Columbia

Public Safety

- Most common complaints received at the College are related to medication dispensing errors
- High profile cases of medication errors across Canada have gained notoriety and further highlight the relationship between medication error reporting systems and public safety
- Mandatory medication error reporting allows access to data to:
  - Help identify trends in errors that are occurring
  - Provide opportunities to learn from mistakes, improve practice and better protect the public.

College of Pharmacists of British Columbia

Current State

- PODSA Bylaws require community and hospital pharmacy managers to *"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"*
- The program and processes are left to the discretion of the pharmacy manager
- The College does not assess the adequacy of a pharmacy's quality management program

College of Pharmacists of British Columbia

Current State

- The College has some oversight over quality management through the Practice Review Program

- Of the pharmacies reviewed in the 2017-18 fiscal year, approximately 10% of pharmacies **did not** develop, document or 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"

College of Pharmacists of British Columbia

Current State – Challenges

- Lack of information with respect to medication errors and incidents being collected and shared throughout the province
- No way to quantify the number and types of medication errors and incidents that are occurring within British Columbia pharmacies
- No central database in which pharmacy staff can report medication errors and incidents
- Missed opportunity for pharmacy professionals to learn from errors occurring in other pharmacies
- Not aligned with other provincial pharmacy regulatory authorities

College of Pharmacists of British Columbia

Updated Interjurisdictional Scan

Mandatory Medication Error Reporting to an Independent Third Party									
BC	**AB**	**SK**	**MB**	**ON**	**QC**	**NB**	**NS**	**NL**	**PEI**
?	*No*	*Yes (ISMP)*	*Yes (ISMP – Pilot)*	*Yes (Pharmapod)*	*No*	*Yes (Not Specified)*	*Yes (ISMP)*	*No*	*No*

Program in place or in progress towards full implementation

Exploring options

No immediate plans for exploration/implementation

College of Pharmacists of British Columbia

Mandatory Medication Error Reporting -Benefits

- Anonymized aggregate data reports for pharmacies and the pharmacy regulatory authority
  - Shared learning at the pharmacy level
  - Gives the regulatory authority data to guide
    - Communications to registrants and
    - Development of programs, policies and legislation for the pharmacy profession

College of Pharmacists of British Columbia

Factors to Consider:

- Adequacy of the College's current quality management program
- Operational impact of new requirements on pharmacies' and pharmacy professionals' practices
- Feasibility of a new quality management program from the College's operational perspective

College of Pharmacists of British Columbia

Option 1

Do not explore implementation of medication error reporting to an independent third party.

The College could further develop the current requirements for quality management to add additional policies that can enable enhanced monitoring and enforcement by the College.

College of Pharmacists of British Columbia

Option 2

Explore implementation of mandatory medication error reporting to an independent third party (not specified by the College).

Option 3

Explore implementation of mandatory medication error reporting to a College-specified independent third party.

College of Pharmacists of British Columbia

Recommendation

Option 2 and 3, to explore implementation of mandatory medication error reporting to an independent third party, for the following reasons:

- Enhanced accountability and increased communication and awareness for the public
- Alignment with other provincial regulatory bodies (MB, NS, ON, SK, NB)
- Consistency of approach between all pharmacies and pharmacy professionals

College of Pharmacists of British Columbia

Recommendation

- Customized resources and support from the third party vendor
- Sharing of lessons learned from all pharmacies, resulting in complete data
- Ability to quantify the number and types of medication errors and incidents that are occurring within British Columbia pharmacies
- Availability of data to guide development of policies and legislation for the pharmacy profession

College of Pharmacists of British Columbia

Next Steps

- Develop Request for Proposal (RFP) for third party vendors
- Define program details:
  - Determine need for new bylaws and/or policies
  - Determine need for, and process of oversight
  - Determine internal and external resource needs
  - Determine timeline
  - Develop communication and engagement plans to support implementation
- Develop a recommendation for decision by the Board at their September 2019 meeting

College of Pharmacists of British Columbia

8. Potential Alternatives to the College's Existing Quality Management Program

MOTION:

Direct the Registrar to explore implementation of mandatory medication error reporting to an independent third party.

College of Pharmacists of British Columbia

Questions

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

9. Update: ActionADE Software and Research Program

INFORMATION ONLY

Presenter's Biography

Katherin Badke

Katherin Badke is a Clinical Pharmacy Specialist, who works in the Emergency Department at Vancouver General Hospital. She has worked with Dr. Corinne Hohl and Dr. Ellen Balka as research pharmacist during both the design and implementation phases of ActionADE

Ellen Balka

Ellen Balka is a professor in Simon Fraser University's School of Communication, where the focus of her research has been on health informatics and involving end users in the design of health information technology. She began working with Dr. Corinne Hohl on the adverse drug event program in 2012-2013.

Presentation Synopsis

Each year, 276,000 patients present to BC emergency departments with an adverse drug event (ADE). 102,000 of those visits result in hospital admissions, which last an average of 6 days. Approximately 4,514 deaths occur annually in BC due to adverse drug events. 30% of ADEs are repeat events due to unintentional re-exposures to medications that previously caused harm. 80% of repeat events can be prevented by enabling clinicians to communicate ADEs to other care providers and health sectors, including community pharmacies.

With financial support from several research funders, Dr. Corinne Hohl and Ellen Balka Ph.D. have led a research program aimed at reducing the number of preventable ADEs in BC by designing a reporting system to bridge informational continuity of care gaps related to ADEs. A key component of the team's work has focused on end user involvement in the design of the ADE reporting system, called ActionADE. With funding from the BC College of Pharmacists and other research funders, ActionADE was built and is currently implemented at Vancouver General Hospital.

This presentation will provide an overview of the project, include a demonstration of the software, and an overview of plans to scale the implementation of ActionADE provincially.

ActionADE Software and Research Program

November 23, 2018

B.C. College of Pharmacists

Ellen Balka, Ph.D.
Corinne Hohl, FRCPC, CCFP, MHSc, MDCM, B.S.
Katherin Badke, B.Sc. (Pharm), ACPR, PharmD

MICHAEL SMITH FOUNDATION FOR HEALTH RESEARCH
Discover. Connect. Engage.
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CIHR IRSC
Canadian Institutes of Health Research | Instituts de recherche en santé du Canada

College of Pharmacists of British Columbia

CENTRE for Clinical Epidemiology and Evaluation

SFU SIMON FRASER UNIVERSITY
THINKING OF THE WORLD

Vancouver CoastalHealth Research Institute
Healthier lives through discovery

UBC

Overview

- Background
  - The problem
  - What is ActionADE?
- ActionADE Software
  - Project overview
  - Project history
  - Demo
  - Where we are now and where we are going

Adverse Drug Events:

- 276,000 patients present to a BC emergency departments with an adverse drug event/yr
- 100,000 admissions/yr lasting an average of 6 days
- 4,514 deaths occur/yr

[1]Zed PJ, Abu-Laban RB, Balen RM, et al. Incidence, severity and preventability of medication-related visits to the emergency department: a prospective study. *Canadian Medical Association Journal* 2008; 178: 1563-1569.

[2]Hohl CM, Brubacher J, Hunte G, et al. Clinical Decision Rules to Improve the Detection of Adverse Drug Events in Emergency Department Patients. *Academic Emergency Medicine* 2012; 19: 640-649.

[3]Canadian Institute for Health Information. Emergency Department Visits in 2014–2015, https://secure.cihi.ca/free_products/NACRS_ED_QuickStats_Infosheet_2014-15_ENweb.pdf (2016, accessed December 30 2016).

[4]Hohl CM, Dankoff J, Colacone A, et al. Polypharmacy, adverse drug-related events, and potential adverse drug interactions in elderly patients presenting to an emergency department. *Ann Emerg Med* 2001; 38: 666-671.

Adverse Drug Events

32.5% of these events are **repeat** events

3 of 4 are **preventable**

[1]Hohl CM, Woo SA, Cragg A, et al. Repeat adverse drug events to outpatient medications. 2018 (submitted)

The Problem:

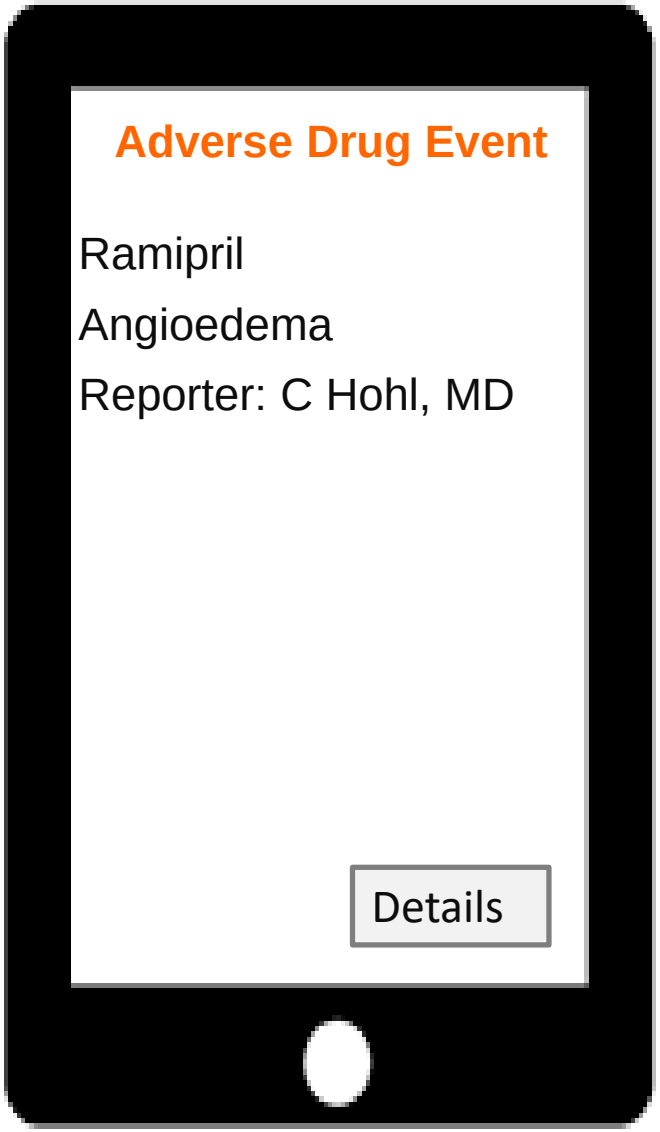
Informational Discontinuity

Existing Documentation Systems

- Focus on allergy documentation
  - Structure often inappropriate for adverse drug events
- Not enough structure
  - Free text format
    - Unable to categorize by drug
    - Nonstandard abbreviations

[1]van der Linden CM, Jansen PA, Grouls RJ, et al. Systems that prevent unwanted represcription of drugs withdrawn because of adverse drug events: a systematic review. Ther Adv Drug Saf 2013;4:73-90.
[2]Bailey C, Peddie D, Wickham ME, et al. Adverse drug event reporting systems: a systematic review. Br J Clin Pharmacol 2016;82:17-29.

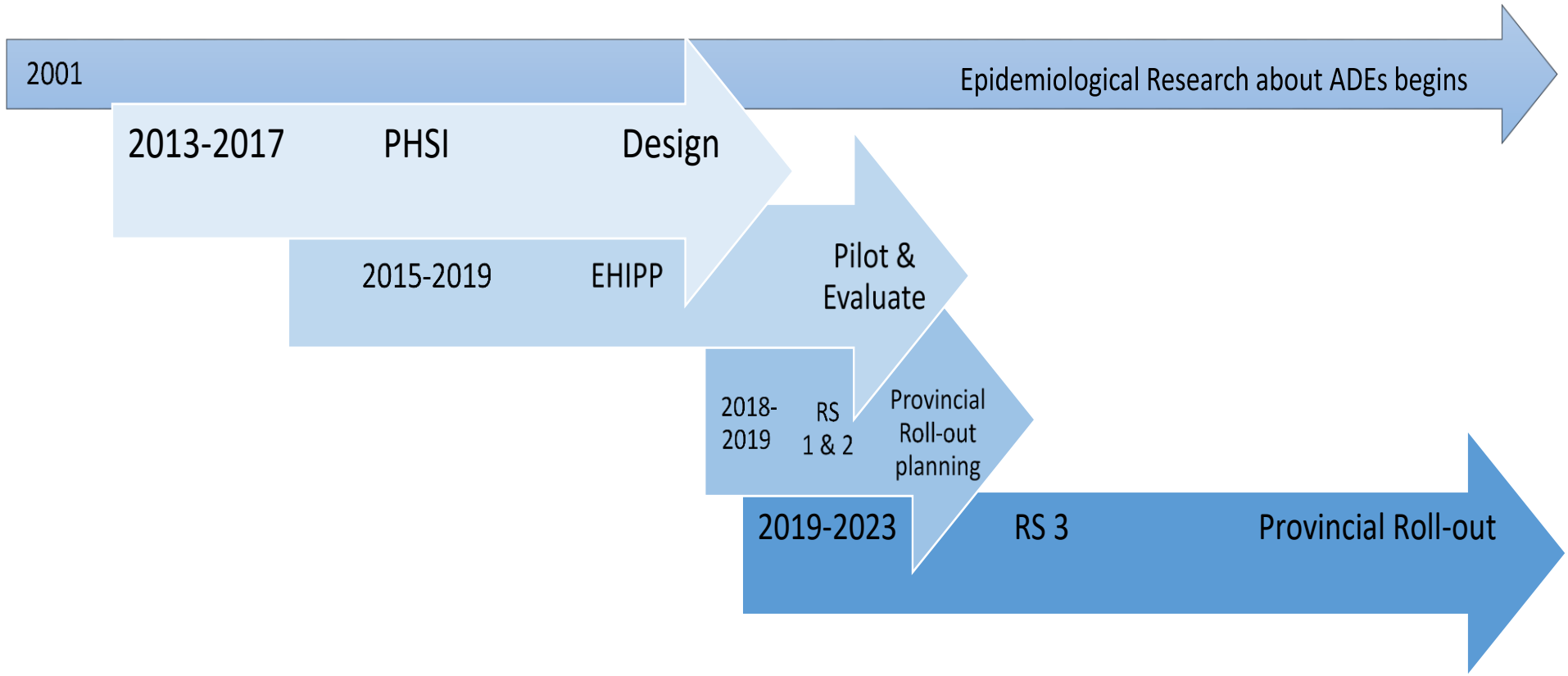
What is *ActionADE*?



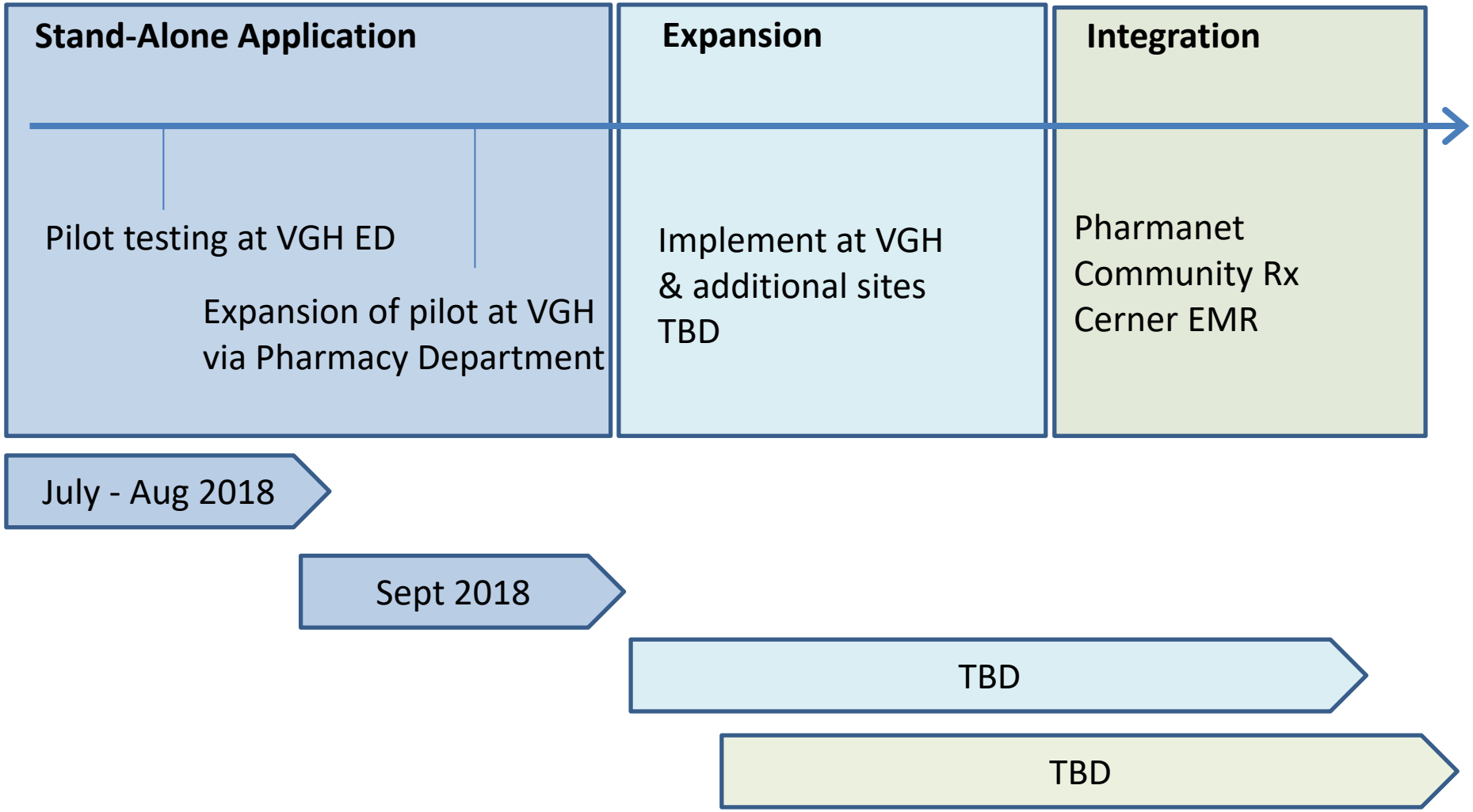
Software application

- Standardizes ADE documentation & creates brief unambiguous reports
- Can be integrated with electronic medical records & PharmaNet
- Generates patient-specific, medication-level alerts to warn providers before re-prescribing/dispensing culprit medications

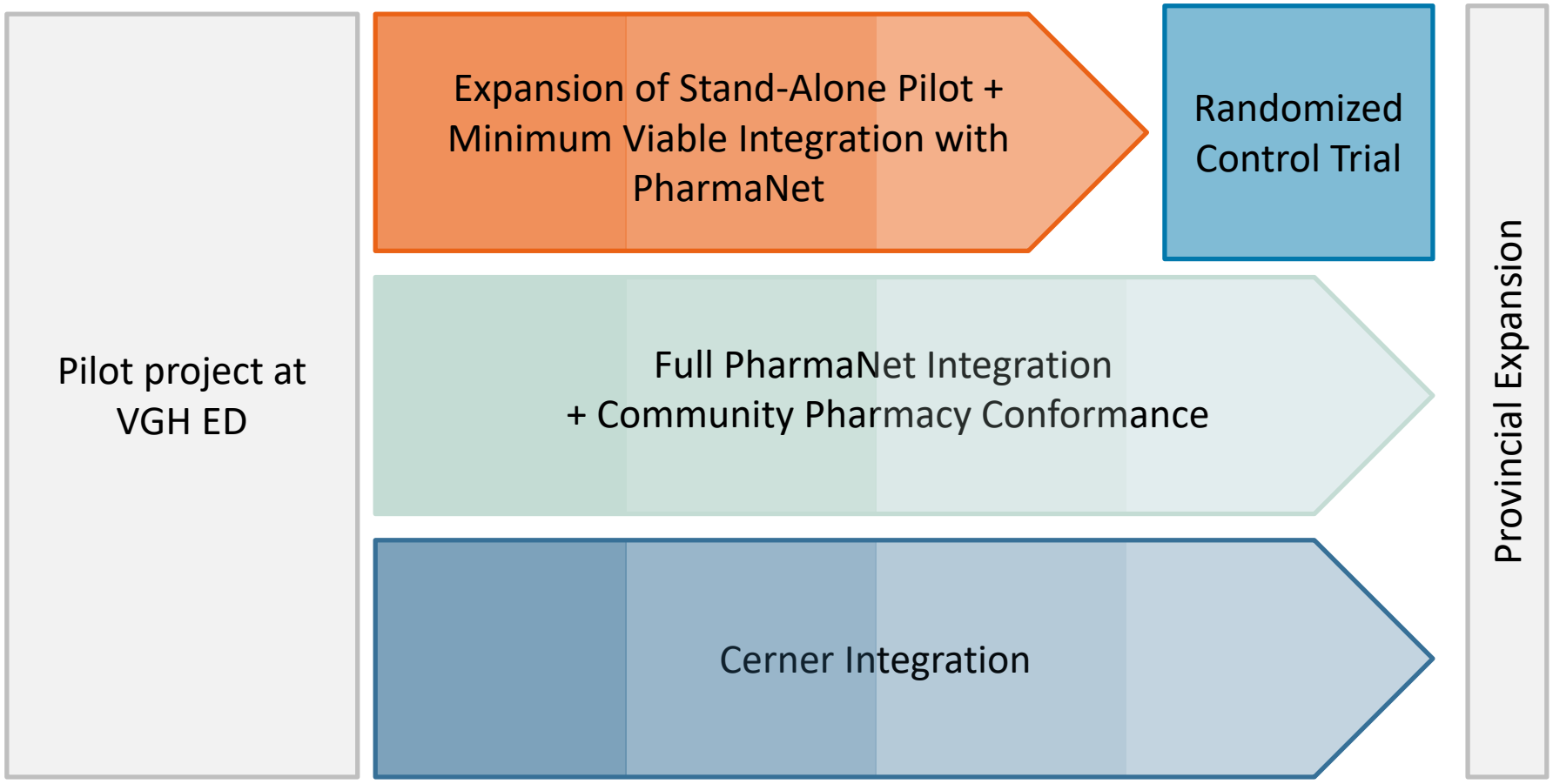
Project History



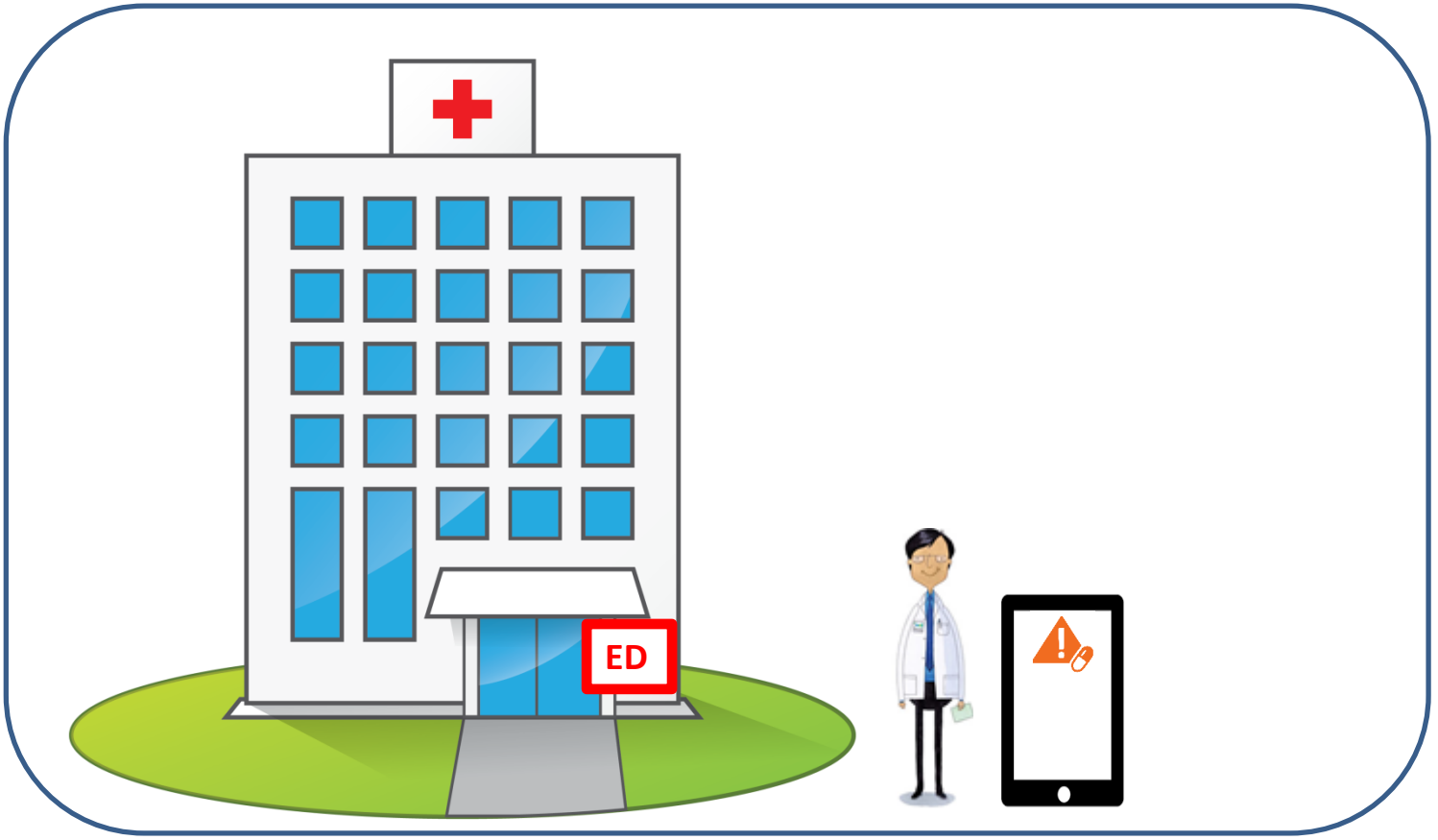
Big Picture


Stand-Alone Application
Expansion
Integration
Pilot testing at VGH ED
Expansion of pilot at VGH via Pharmacy Department
Implement at VGH & additional sites TBD
Pharmanet
Community Rx
Cerner EMR
July - Aug 2018
Sept 2018
TBD
TBD

Big Picture

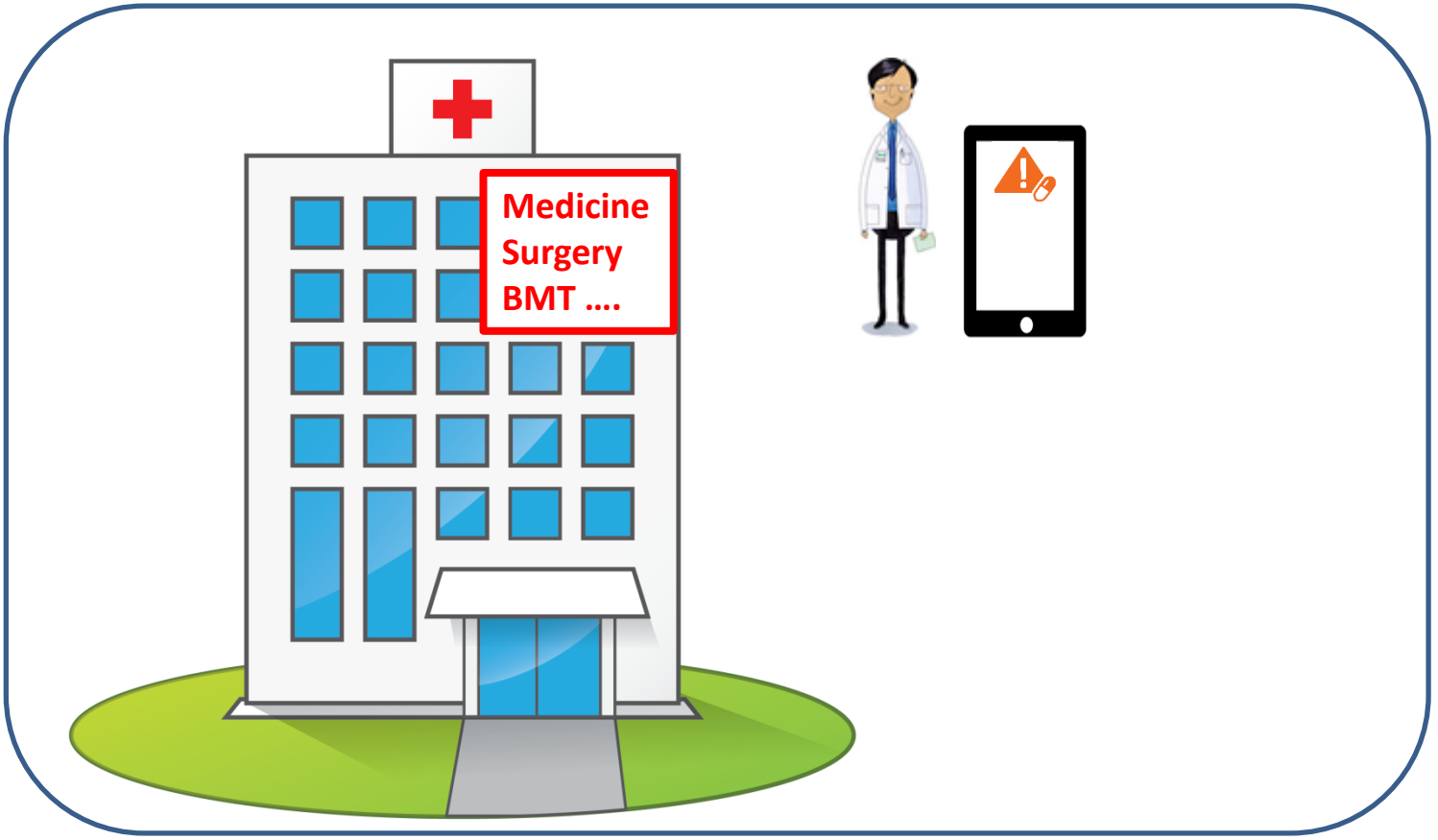

Pilot project at VGH ED
Expansion of Stand-Alone Pilot + Minimum Viable Integration with PharmaNet
Randomized Control Trial
Full PharmaNet Integration + Community Pharmacy Conformance
Cerner Integration
Provincial Expansion
Summer 2018
Fall 2018
2019
2020
2021

Pilot Phase



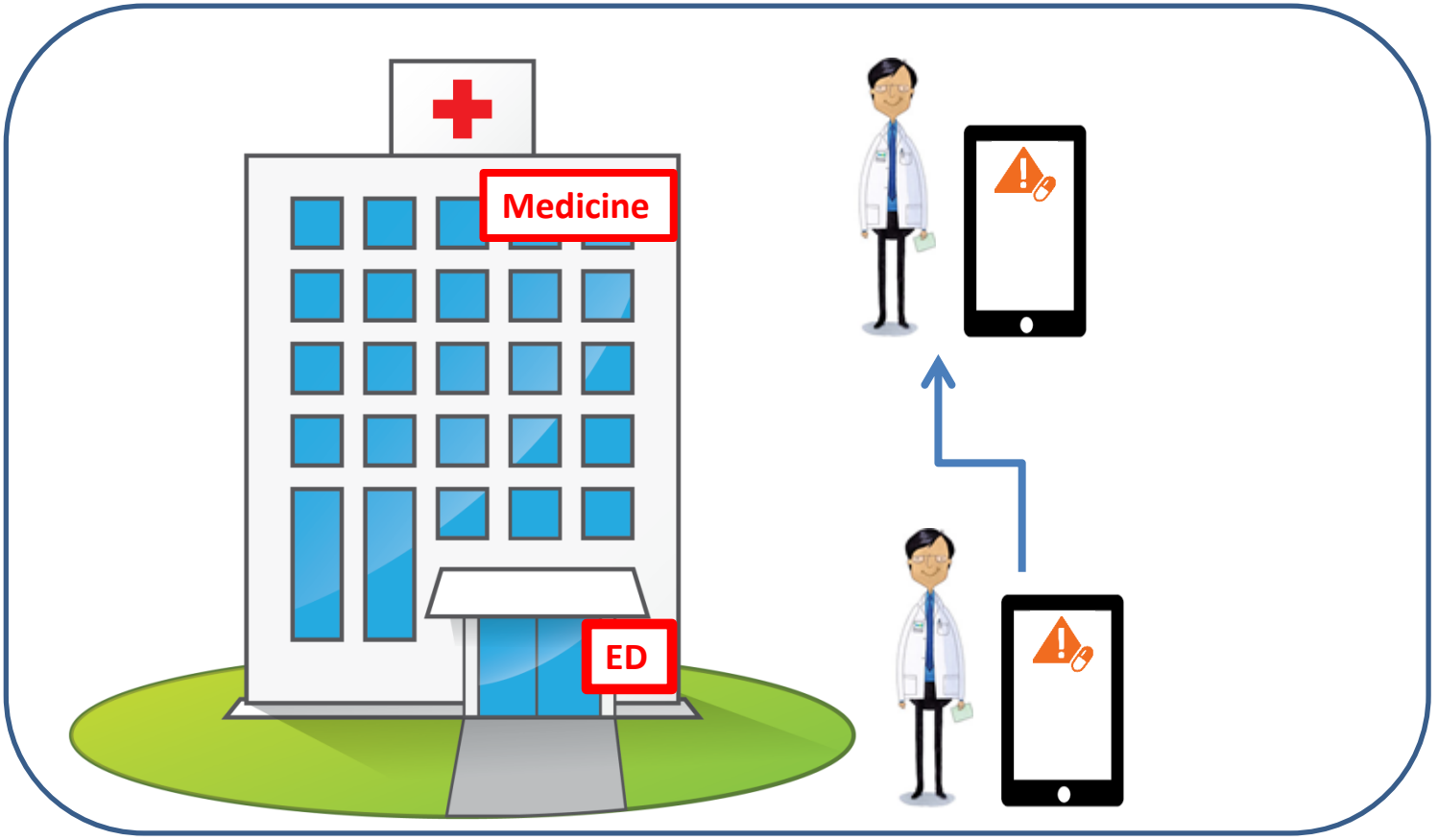
http://images.clipartpanda.com/hospital-clipart-hospital4.png
http://wellcareers.co.uk/wp-content/uploads/2015/04/Relief-manager.jpg

Pilot Phase



http://images.clipartpanda.com/hospital-clipart-hospital4.png
http://wellcareers.co.uk/wp-content/uploads/2015/04/Relief-manager.jpg

Pilot Phase

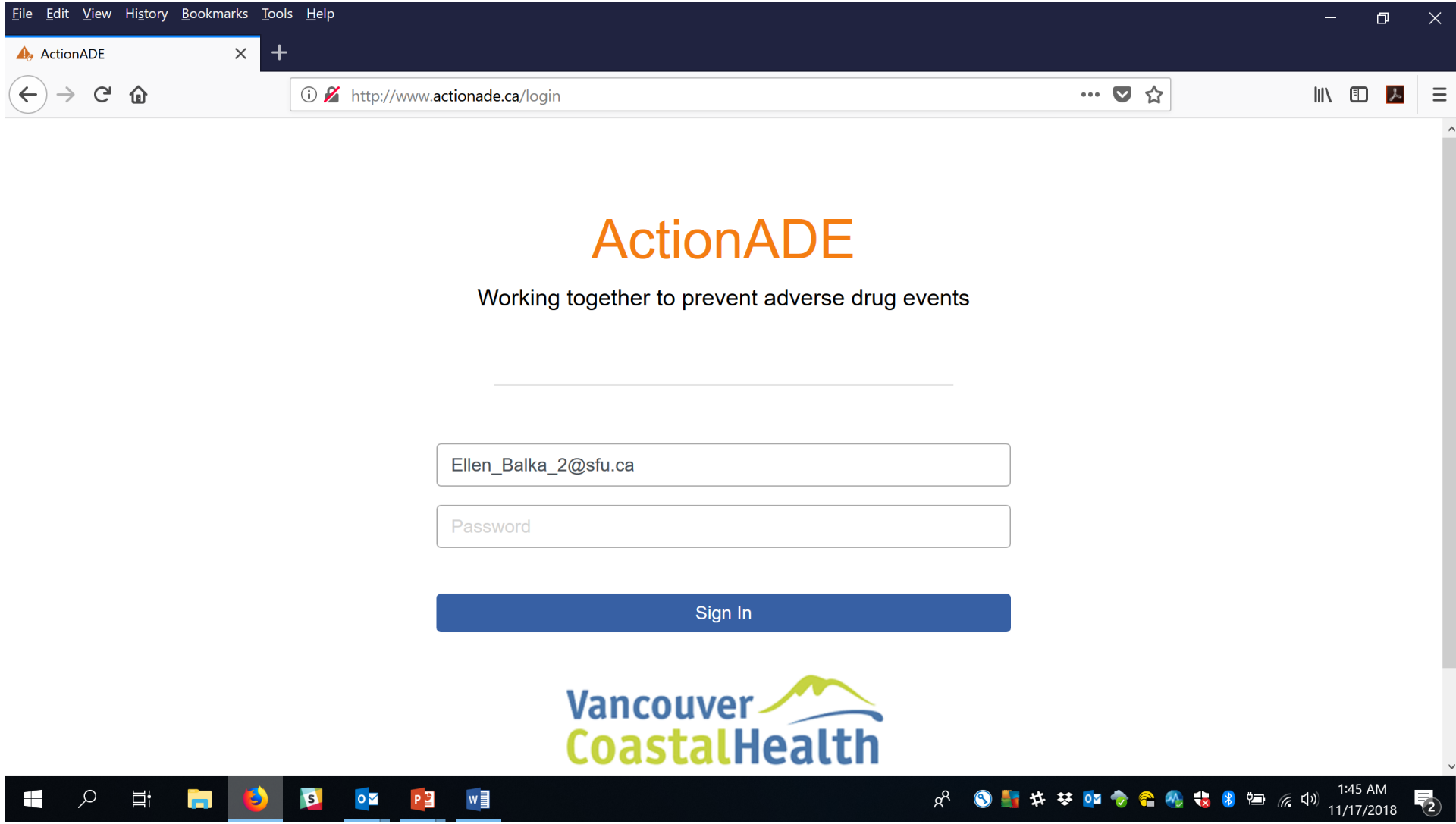


http://images.clipartpanda.com/hospital-clipart-hospital4.png
http://wellcareers.co.uk/wp-content/uploads/2015/04/Relief-manager.jpg

Pilot Phase

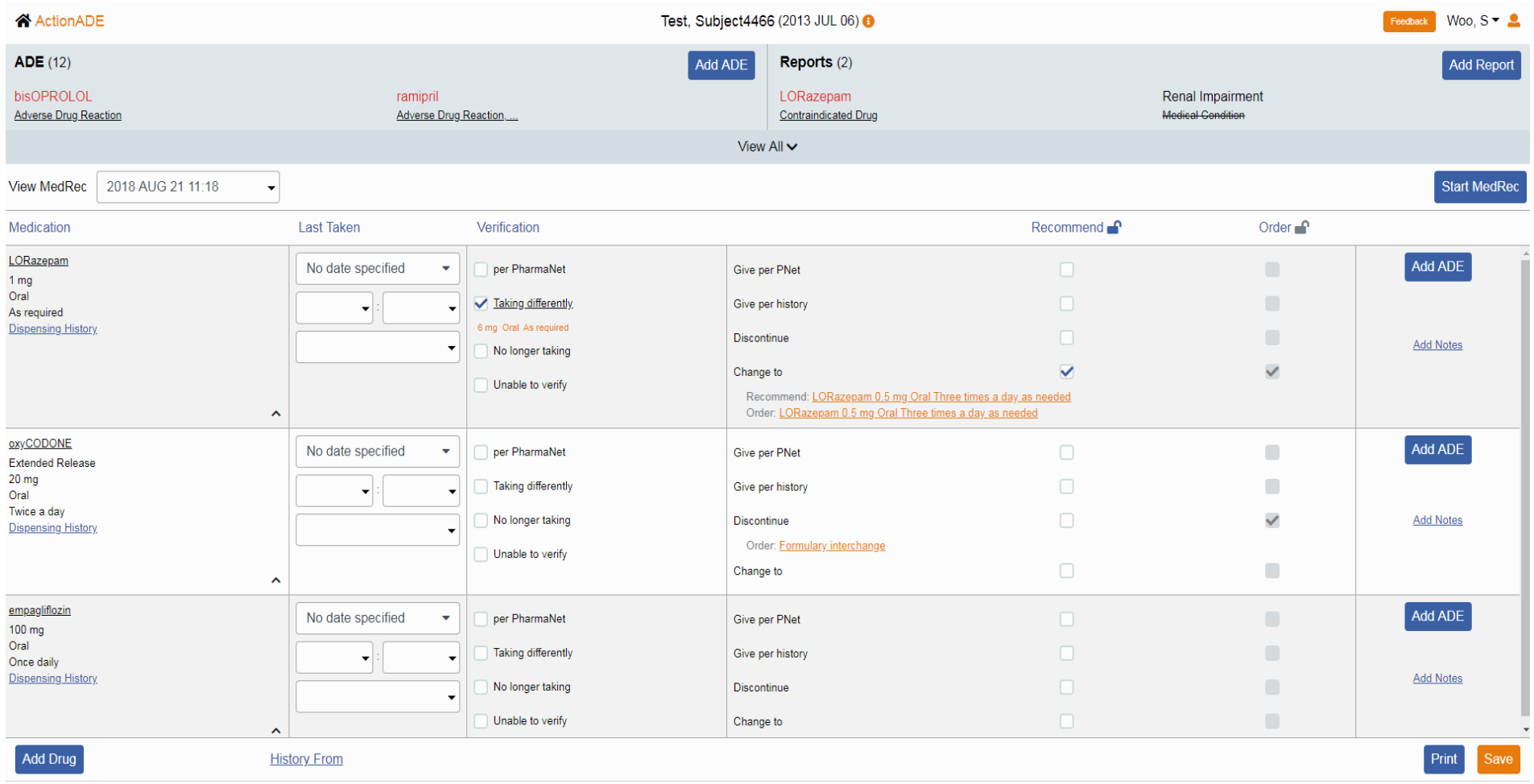
- Observations
  - Usability
  - User experience
  - Uptake
  - Functionality
- Feedback on output
  - Desktop/iPad display
  - Paper printouts to mark up

Demo environment

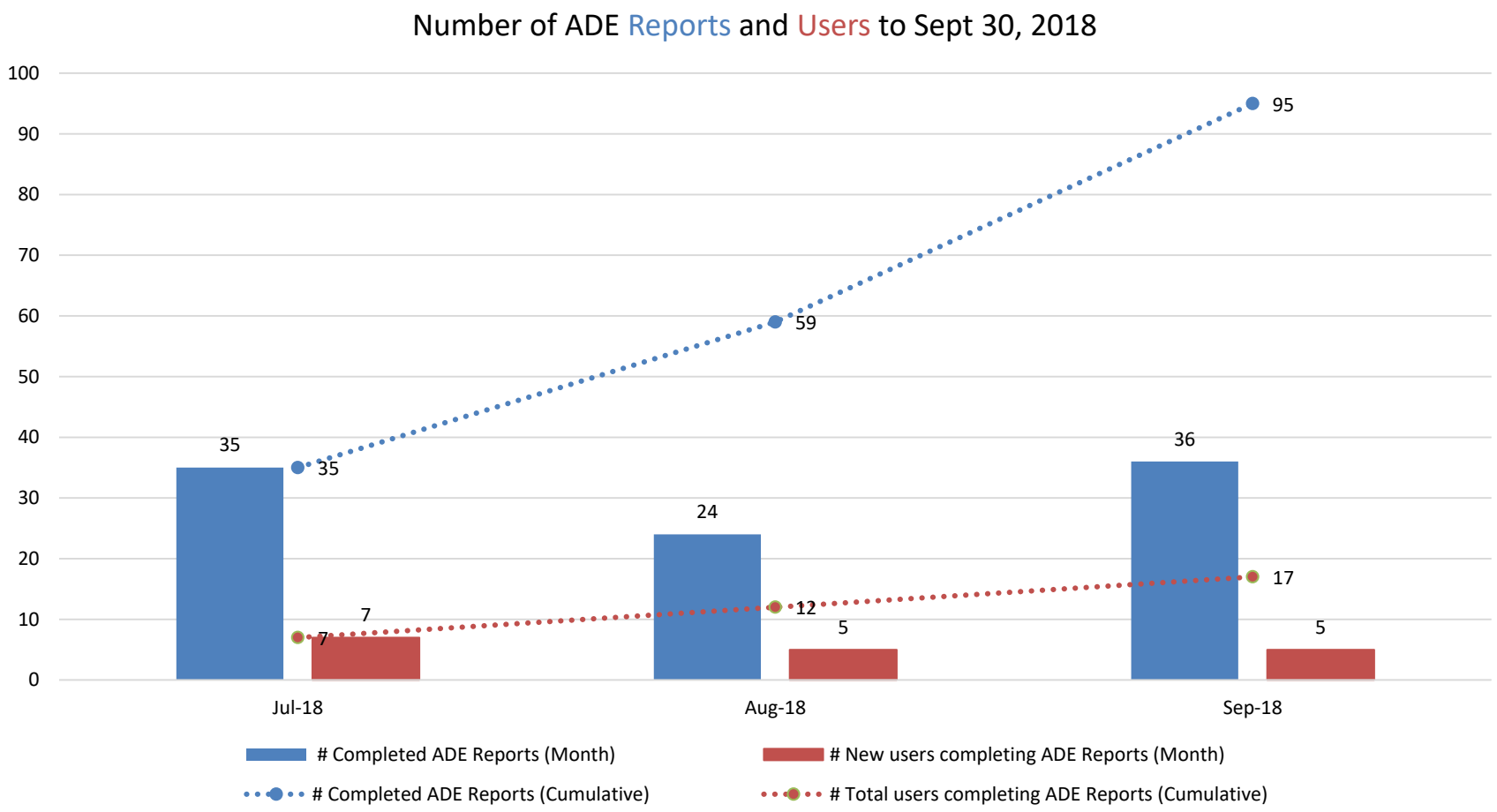


ActionADE

https://actionade.vch.ca

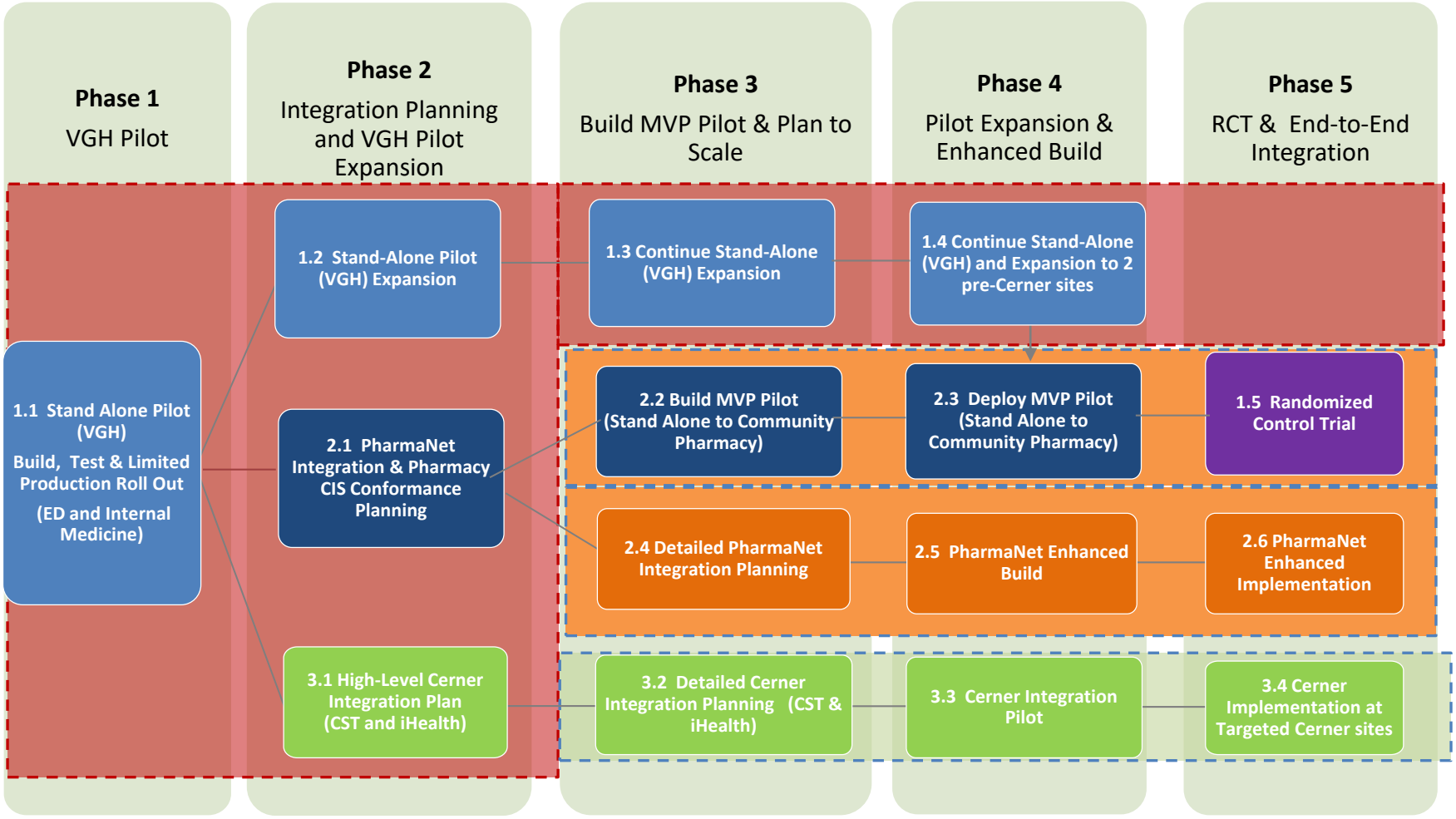


Preliminary Results



July – September 2018

Where we are now and where we are going?



ActionADE Overview – Funding Approach

Rewarding Success Grant Structure

Research Grant (Matched Funding)

$4.8 M

FOR RESEARCH

$2.4 M

Cash from CIHR

+

$2.4 M

Matching funds from partner organizations

+

Outcomes-Based Contract

$ TBD

WE DECIDE

Budget, % Contingent, Desired Outcomes

$ TBD

% Not Contingent

SUGGEST:

For Software Build and Change Management

+

$ TBD

% Contingent

SUGGEST:

For Reinvestment of averted costs

Next Steps

1. VCH ActionADE Pilot

- Assess impact to broaden scope of deployment to all pharmacists (Done)
- Gather approval to onboard pharmacists across VGH (Done)
- Broaden deployment (Jan to Mar 31, 2019)

2. PharmaNet Integration Planning

Complete:

- MVP change management plan (Nov 30, 2019)
- Conceptual Solution Architecture for Future State (Done)
- Order of magnitude (OOM) estimates for MVP and Future State (Nov 30, 2018)

3. Cerner Integration Planning

Complete:

- Conceptual Solution Architecture for Future State (Nov 21, 2018)
- OOM estimates for High Level Solution Architecture (Nov 30, 2018)

4. Complete Rewarding Success Grant Requirements

Complete by Dec 15 2018:

- Solution Architecture & Timelines
- Outcomes-Based Contract
- Letters of Support confirming Matched Funding
- OOM estimates for PharmaNet and Cerner implementation
- Rewarding Success Grant Submission

Committees & Ongoing Tasks

Provincial Steering Committee

Sub-Committees

Outcomes Based Contract Cttee

- Pre-workshop orientation meetings (Oct.2&3)
  - Introduced ActionADE and Objectives
- Kick off Workshop completed October 4, 2018
  - Clarified grant + OBC structure
- Weekly meetings planned Oct & Nov
  - Build OBC structure and gain partner support

Solution Architecture Committee

- CST Cerner first meeting - October 17, 2018 (Amr Kabesh)
- iHealth Cerner first meeting – October 17, 2018 (MaryLyn Fife)
- Committee participants to be confirmed

Metrics Committee

Clinical Workflow Committee

Ongoing

Regular Meetings with Ministry of Health / PharmaNet

Continuous Evaluation for Improvement

Change Management and Communication Planning

How can we help one another?

- We will need Community Pharmacies, particularly those using Kroll, Shopper's HealthWatch and Applied Robotics Inc. (ARI) WinRx software to allow us to observe;

- What kinds of communication would the College find useful from us?

Thanks!

https://imgflip.com/memetemplate/38390688/corgi-hacker

Adverse Drug Events:

- Adverse Drug Events (ADE): harm caused by a drug or the inappropriate use of a drug, consistent with its effective definition in clinical practice

[1]Nebeker JR, Barach P, Samore MH. Clarifying adverse drug events: a clinician's guide to terminology, documentation, and reporting. Ann Intern Med 2004;140:795-801.

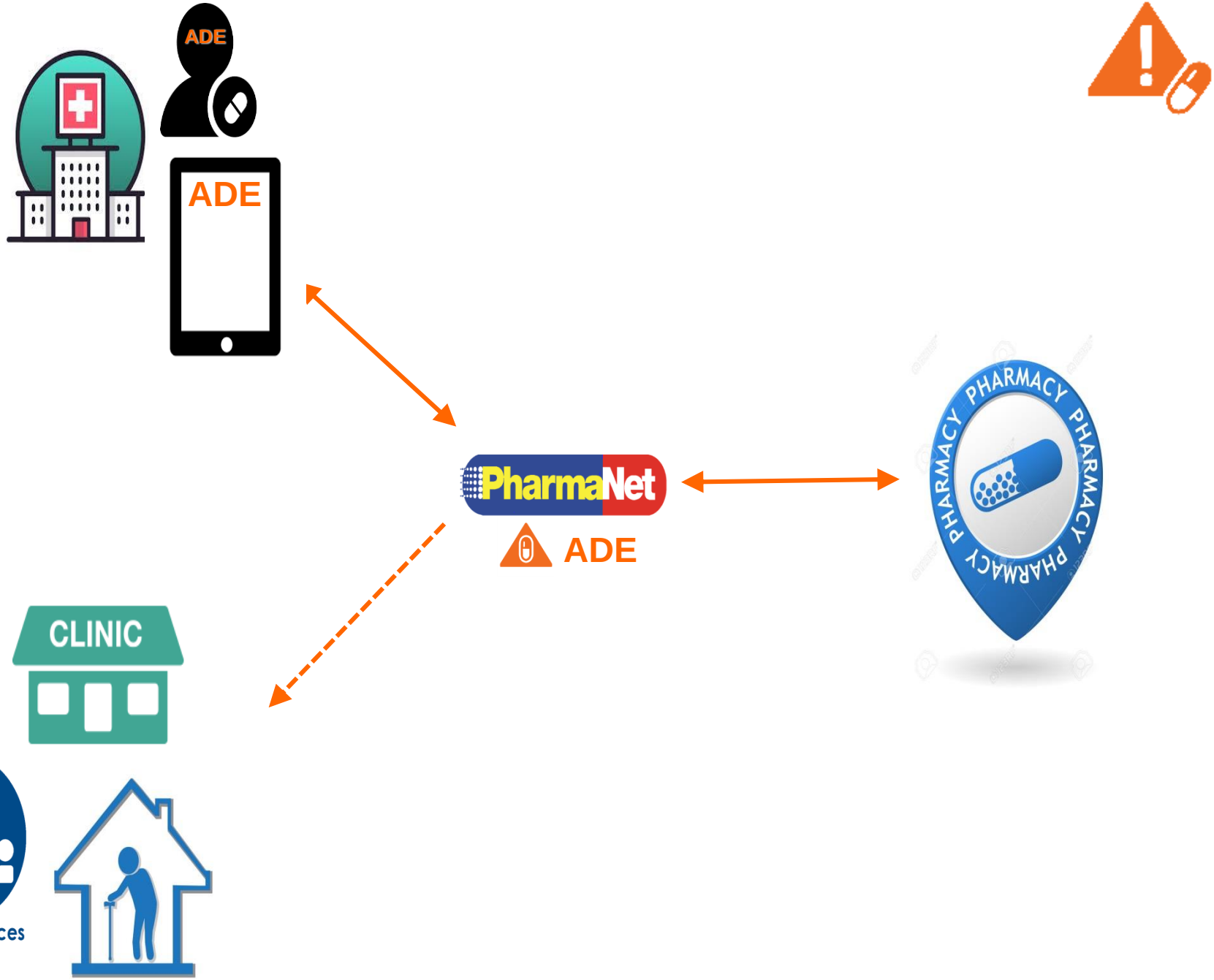

ADE


PharmaNet


PHARMACY
PHARMACY
PHARMACY


CLINIC


Rehab Services


ADE
ADE
PharmaNet
ADE
PHARMACY
CLINIC
Rehab Services

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

10. BCPhA Opioid Agonist Treatment Compliance and Management Program for Pharmacy (OAT-CAMPP)

INFORMATION ONLY

Purpose

To provide an overview on the development of the BC Pharmacy Association's (BCPhA) OAT-CAMPP training program.

Background

In 2017, in consultation with the Ministry of Health (MOH), the BC Centre for Substance Use (BCCSU), the BCPhA and other stakeholders, the CPBC updated Professional Practice Policy-66 "Opioid Agonist Treatment" (PPP-66) to include the addition of buprenorphine/naloxone and slow release oral morphine maintenance treatments as new opioid agonist treatment (OAT) options. These options augment the College's existing methadone maintenance treatment (MMT) requirements.

One of the College's existing requirements regarding MMT is the completion of a CPBC MMT training program. When amending PPP-66, College staff recognized that the current MMT training program would no longer be current and would require revisions. Specifically, a significant gap of the College's MMT training program is that it does not address the two new options, buprenorphine/naloxone and slow release oral morphine maintenance treatments.

In conjunction with the Ministry of Health (MOH), the BCPhA developed an OAT training program for pharmacists called OAT-CAMPP. This program aims to be a tool for registrants to help address the current opioid crisis in the province. It aligns with the College's PPP-66 and provides training on recommendations from the BCCSU, including buprenorphine/naloxone, methadone and slow release oral morphine maintenance treatments, and on opioid use disorder itself.

The OAT-CAMMP training program, which consists of both online and in-person components will fully commence in January 2019. The CPBC intends to use this program to replace the current required MMT training program to better equip registrants with the tools needed to best care for patients with opioid use disorder.

MOH and the BCPhA propose that within six months of the launch date, all community pharmacies that deliver OAT will have one pharmacist on staff complete the training program. And, within two and a half years all pharmacists who dispense OAT in their practice will have completed the OAT-CAMPP course. Pharmacy technicians will only need to complete the online component of the training, as the in-person training is clinically-focused. Over the two and half year transition period, the College will accept the CPBC MMT training program or the OAT-CAMPP course as a requirement to dispense OAT. The MMT training program will sunset at the end of this transition period and will be replaced with the OAT-CAMPP[1].

Presenter's Biography

Bryce Wong, Director, Special Projects for the BC Pharmacy Association

As the Director of Special Projects for the BC Pharmacy Association Bryce is responsible for leading initiatives including the development of the OAT-CaMPP and operation of RxOme Pharmacogenomics Canada. Previously, Bryce was the Senior Manager of Pharmacy Practice Support at the Association and advocated for the role of pharmacists as immunizers, in addition to educating and supporting members on issues such as PharmaCare and third party compliance and expanded pharmacy services. Prior to joining the Association, Bryce held positions as a staff pharmacist and pharmacy manager. He received his Bachelor of Science degree in Pharmacy from the University of British Columbia in 2006.

Presentation Synopsis

This presentation will provide an overview on the purpose, background, learning objectives and implementation plan for the OAT-CaMPP.

[1] Please also see the materials regarding item 11(c) on the Board meeting agenda for related information on the College's OAT training program requirements.

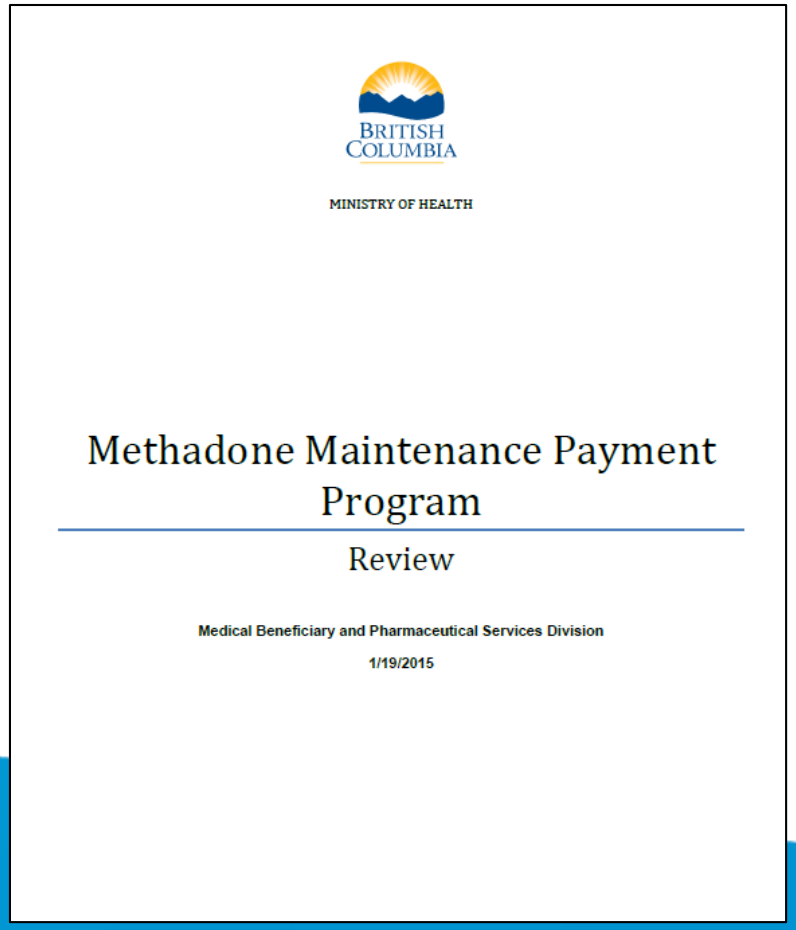
Opioid Agonist Treatment Compliance and Management Program for Pharmacy (OAT-CAMPP)

College of Pharmacists of BC

Nov 23 2018

British Columbia
Pharmacy Association

Background


BRITISH COLUMBIA

MINISTRY OF HEALTH

Methadone Maintenance Payment Program

Review

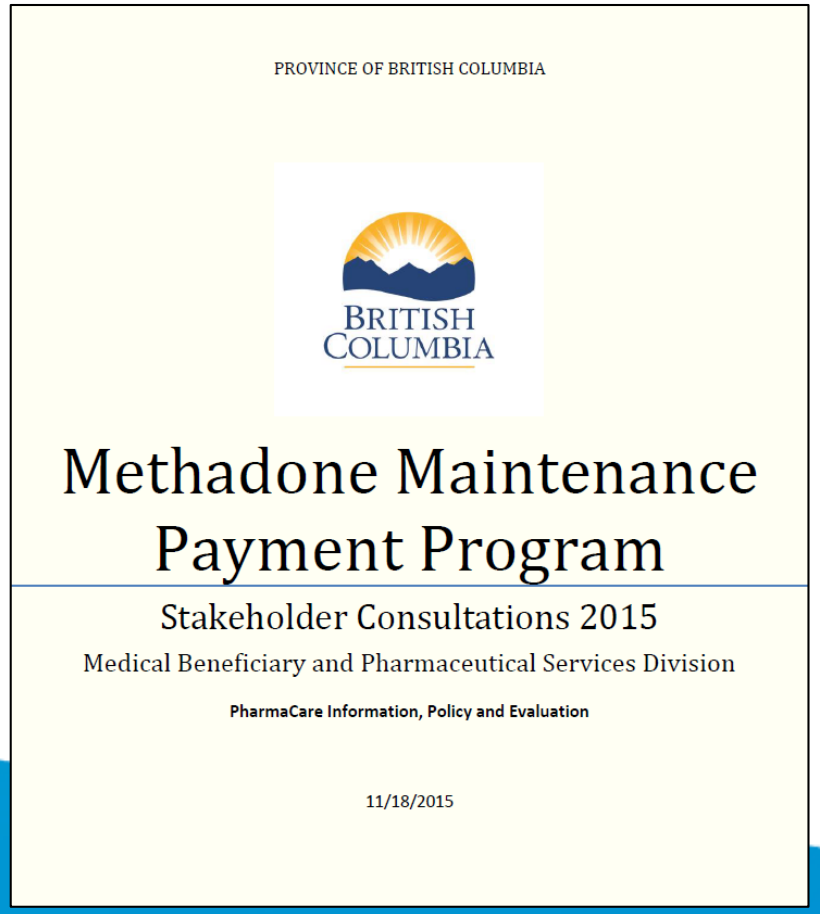
Medical Beneficiary and Pharmaceutical Services Division

1/19/2015

Major concerns raised by MoH

- Questions about level of reimbursement and distortion to the delivery of MMT services
- Growth of spending on the program
- Value of the service fees
- Problematic practices identified in audits
- Patients feeling stigmatized/discriminated against in pharmacies
- Concentrations of pharmacies aggressively competing for clients
- Lack of communication between pharmacists, patients, prescribers and circle of care

Background


PROVINCE OF BRITISH COLUMBIA

BRITISH COLUMBIA

Methadone Maintenance Payment Program

Stakeholder Consultations 2015

Medical Beneficiary and Pharmaceutical Services Division

PharmaCare Information, Policy and Evaluation

11/18/2015

Nineteen recommendations were generated out of the consultation:

Improve pharmacist training in treating patients with opioid use disorder.

Review the payment model for pharmacists treating patients on opioid agonist treatment medications.

Opioid Overdose Crisis

Provincial health officer declares public health emergency

Share

News Release

Victoria
Thursday, April 14, 2016 11:00 AM

Media Contacts

Kristy Anderson
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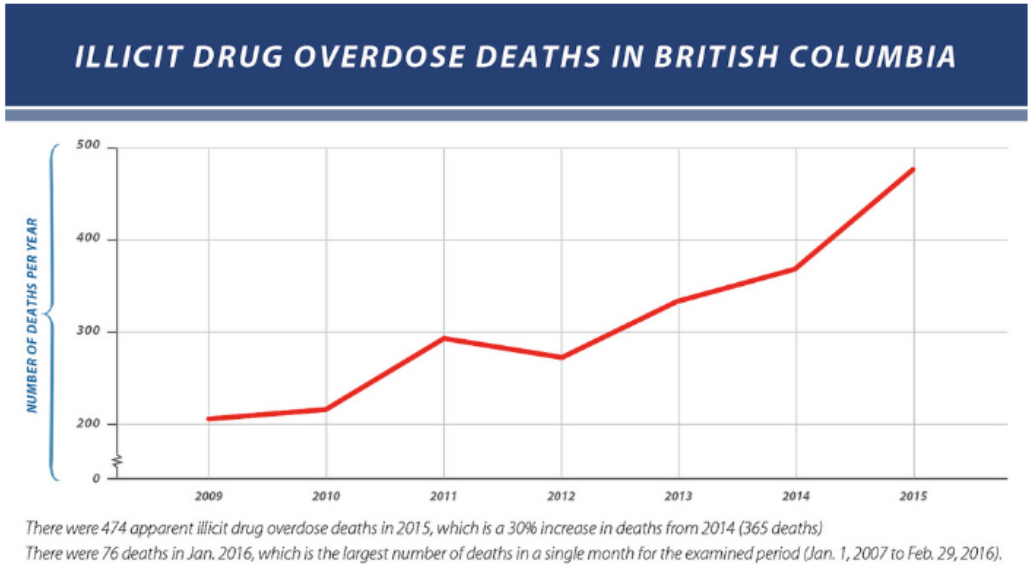
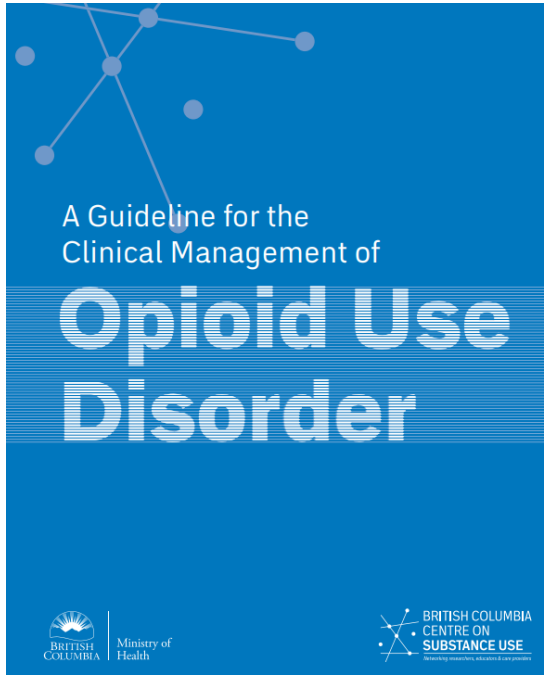


There were 474 apparent illicit drug overdose deaths in 2015, which is a 30% increase in deaths from 2014 (365 deaths)
There were 76 deaths in Jan. 2016, which is the largest number of deaths in a single month for the examined period (Jan. 1, 2007 to Feb. 29, 2016).



Increased Access to Treatment

B.C data	As of Jun 1, 2017 (TOTAL)	As of Mar 31, 2018 (TOTAL)	% change
OAT prescribers	853	1,602	88%
Patients on OAT	22,743	29,667	30%
New patients on OAT	2,472	7,029	185%
Pharmacies dispensing OAT medications	1,032	1,131	10%

Image Source: Progress Update: Responding to B.C's Illegal Drug Overdose Epidemic Feb/Mar 2018. BC Ministry of Mental Health and Addictions

Mental Health and Addictions

Reducing stigma, improving patient treatment focus of new pharmacists' training

Share

News Release

Victoria
Thursday, November 1, 2018 1:00 PM

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Program Objectives

- **Effectively manage changes in practice** – Support community pharmacists by providing them with the updated education/ knowledge and clinical skills required to effectively manage the pharmacy care of patients receiving opioid agonist treatment.
- **Enhance communication** – Promote a patient-centered approach and encourage effective communication between community pharmacists, patients and patients' circle of care, with the aim to reduce stigma as well as recognize the importance in cultural safety and humility practices with First Nation clients, in the goal to maximizing overall patient care and engagement.
- **Reinforcing regulatory compliance** – Support community pharmacists in meeting OAT-related regulatory and professional practice requirements as well as emphasizing the importance in OAT-related PharmaCare compliance.
- **Improve program consistency** – Encourage consistent delivery of OAT services in community pharmacies by having up-to-date streamlined information that is readily available and accessible to all community pharmacists across the province.

Advisory Committee

BRITISH COLUMBIA Ministry of Health

BC Centre for Disease Control

Health Canada

First Nations Health Authority
Health through wellness

BRITISH COLUMBIA CENTRE ON SUBSTANCE USE
Networking researchers, educators & care providers

College of Pharmacists of British Columbia

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Patient Voices

Topics Covered

- Current events
- Overview of Opioid Use Disorder
- Psychosocial Interventions and Support
- Clinical Management of Opioid Use Disorder
- Buprenorphine/naloxone Maintenance Treatment
- Methadone Maintenance Treatment
- Buprenorphine/naloxone vs Methadone
- Slow Release Oral Morphine
- Trauma, Stigma and Cultural Safety
- General OAT Regulatory Compliance
- Prescription Regulations
- Dispensing OAT medications
- PharmaCare Compliance
- Communication
- Health Promotion & Harm Reduction

Teaching Methods

OAT CAMPP Implementation

- Registrations will open December 2018
- In-person workshops will begin 3rd week of January
- MoH Training Requirement
  - One trained pharmacist per pharmacy by summer 2019
  - All pharmacists trained by spring 2021
- CPBC Training Requirement
  - All pharmacists & technicians trained by spring 2021 and going forward

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

11. Legislation Review Committee
a) Committee Updates

INFORMATION ONLY

Purpose

For the Committee Chair to provide updates on the Discipline, Registration and Legislation Review Committee.

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

11. Legislation Review Committee
b) Drug Schedules Regulation – Scheduling By Reference

DECISION REQUIRED

Recommended Board Motion:

Direct the Registrar to pursue drug scheduling by reference to federal legislation and the National Drug Schedules established by the National Association of Pharmacy Regulatory Authorities (NAPRA), with respect to the Drug Schedules Regulation.

Purpose

To provide information pertinent to considering drug scheduling by reference.

Background

Health Canada determines whether a drug must be sold by prescription only. Provincial regulatory authorities can further restrict the conditions of sale of non-prescription products, however they cannot be less stringent than the federal requirements. For example, a product that has not been designated federally as a prescription product, could be assigned prescription status by a province or territory. However, a product that is regulated under the *Food and Drug Act* with a prescription-only status cannot be given non-prescription status by a province or territory. Prescription drugs are classified as Schedule 1 on the *Drug Schedules Regulation* (DSR).

Typically, for those drugs determined by Health Canada to be non-prescription, most provincial regulatory authorities schedule by reference to recommendations made by National Association of Pharmacy Regulatory Authorities (NAPRA) in the National Drug Schedules.

- In 1995, NAPRA's members, comprised of representatives from each provincial pharmacy regulator, endorsed a proposal for a national drug scheduling model, to align the provincial drug schedules so that the conditions for the sale of drugs would be consistent across Canada.

- This harmonized national model is administered by NAPRA and is called the National Drug Schedules program. The program consists of three schedules or four categories of

drugs, consistent scheduling factors, a standard process, and a National Drug Scheduling Advisory Committee (NDSAC) which makes scheduling recommendations to NAPRA.[1]

- NDSAC members are chosen for their knowledge and expertise in such areas as pharmacotherapy, drug utilization, drug interactions and toxicology, pharmacy practice, academic research, the drug industry and pharmaceutical regulatory affairs at federal and provincial levels.[2] Their recommendations include an examination of the scientific evidence to support their rationale, along with allowing for public input through a public posting period.

B.C. is one of the few provinces in Canada that maintains its own list of scheduled drugs in the DSR[3], which results in a longer process for amendments to be brought into force. Nevertheless, most amendments to B.C.'s DSR are based on recommendations from NAPRA.

Other Provinces

All other provinces, except Quebec and Newfoundland and Labrador, adopt drug scheduling by reference to NAPRA and federal legislation. Please refer to Appendix 1 for a jurisdictional scan of drug scheduling legislation across Canada. Some provinces, such as Ontario, adopt entirely by reference to the federal legislation for prescription drugs, and by reference to NAPRA for non-prescription drugs, without exceptions. Other provinces, such as Alberta, also adopt by reference to those sources, but set out exceptions in which certain drugs are scheduled differently than in the adopted schedule. The Alberta model allows that province to benefit from the efficiencies of adopting by reference, while maintaining its authority to make its own drug scheduling decisions, which might differ from NAPRA's recommendations, or be more restrictive than the federal requirements.

Current Status

College's Legislative Authority

The legislative authority for the Board to amend the DSR is outlined in section 22 of PODSA, which states:

> *22 (1) Subject to the Food and Drugs Act (Canada), the board, by regulation, may make drug schedules specifying the terms and conditions of sale for drugs and devices.*
>
> *(2) A regulation under subsection (1) must be filed with the minister.*

[1] https://napra.ca/drug-scheduling-canada

[2] http://napra.ca/committee-membership

[3] In B.C., drugs are scheduled in the DSR as Schedule I, IA, II, III, and IV. The schedules are differentiated as follows:

- Schedule I (Prescription)
- Schedule IA (Prescription - Triplicate/Duplicate Prescription Program)
- Schedule II (Non-Prescription – Retained within the Professional Service Area)
- Schedule III (Non-Prescription – Available for self-selection in the Professional Products Area)
- Schedule IV (Prescription by Pharmacist)

The College's process for making drug scheduling amendments involves a review of federal requirements or NAPRA's recommendations, as applicable, in order to assess their appropriateness for B.C.'s population. Next, the College submits the proposed amendments to the Ministry of Health, Professional Regulation Branch. The Ministry completes their review and if satisfied, forwards the request to Legislative Counsel for a legal review. The full extent of the review is not known, however, College staff understand that the Ministry compares the proposed DSR amendments against federal legislation and NAPRA's recommendations, as applicable, to confirm consistency. If no issues are identified, Legislative Counsel provides the College with a tagged schedule of amendments. The tagged scheduled of amendments is presented to the College's Board for approval. The amendments are then filed with the Minister of Health for a 60 day period after which they will come into force.

Section 22(3) of PODSA authorizes the Board to create regulations that adopt by reference schedules created by any body approved by the Board:

> *22 (3) A regulation under this section may adopt by reference, in whole or in part and with any changes the board considers necessary, any code, schedule, specification, standard, rule or similar record issued or approved by the government of Canada, by the government of a province or by a body approved by the board for the purpose of this section.*

While there is no dispute that the Board has the statutory authority to adopt drug scheduling by reference, the Ministry has, in the past, indicated its preference for the College to continue to maintain its own list of scheduled drugs. However, more recent discussions with the Ministry indicate that it might now be more receptive to scheduling by reference.

College's Current Approach to DSR Amendments

Schedule I: Schedule I drugs are updated only if specifically requested by another health regulatory college, drug manufacturer, or other member of the public. Prescription drug status is determined by the federal government, and prescription drug lists are part of federal legislation that is publicly accessible.

Schedule IA: Schedule IA drugs are reviewed periodically by the Controlled Prescription Program Advisory Committee, and updated as required. The Committee is comprised of representatives from the College, the College of Physicians and Surgeons of B.C., the B.C. College of Nursing Professionals, the College of Dental Surgeons of B.C., and other regulatory colleges whose registrants prescribe Schedule IA drugs.

Schedule II and III: Schedule II and III drugs are periodically updated with reference to NAPRA's recommendations.

Schedule IV: Changes to drugs listed in Schedule IV would require concurrent changes to the *Pharmacists Regulation* made under the *Health Professions Act* and the *Pharmacy Operations General Regulation* made under PODSA, which are not within the College's jurisdiction.

In the past, the DSR has been updated sporadically, whenever there is a need or whenever resources are available. However, the College is creating processes whereby Schedule II and III drugs on the DSR would be updated at more regular intervals.

Discussion

The College's current approach of maintaining its own list of drugs under the DSR is problematic for several reasons. First, the DSR is presented as a complete list of scheduled drugs, which it is not. This is confusing for most readers, who may not be aware of the College's approach to updating the DSR (as described above).

Second, the federal government and NAPRA are continually updating their drug schedules. As a result of the lag time inherent to the process for DSR updates, there will always be inconsistencies between the DSR and the drug schedules established by the federal government and NAPRA. Most of the inconsistencies are unintentional and some of them remain for years. For example, in 2006, NAPRA scheduled "pseudoephedrine and its salts and preparations in single entity products" as Schedule II and "pseudoephedrine and its salts and preparations in combination products" as Schedule III. However, those drugs remained unscheduled in B.C. until the recent DSR update in June 2018.

Third, the regulations of several regulated health professions refer to the DSR. If the DSR is not up to date, it can unintentionally limit the scope of practice of those professions. Below are examples of this situation:

- Nurse practitioners are permitted by their regulations to prescribe only those drugs that are listed on the DSR .[4] This means that they are technically prohibited from prescribing drugs not listed on the DSR even if those drugs are prescription drugs on the Prescription Drug List or other federal legislation.

- Other regulated health professions, including dentists, midwives, naturopathic physicians, optometrists, and podiatrists face the same issue.[5]

- Medical practitioners are only permitted to sell drugs that are listed on the DSR.[6]

- Audiologists are only permitted to administer topically drugs that are listed on the DSR.[7]

---

[4] *Nurses (Registered) and Nurse Practitioners Regulation*, ss. 6(1)(k), 6(1)(l), 8(1)(a.1), and 9(1)(g).
Nurses (Licensed Practical) Regulation, ss. 6(1)(m), 6(1) (n), and 7(1)(h).
Nurses (Registered Psychiatric) Regulation, ss. 6(n), 6(o), and 7(1)(f).
[5] *Dentists Regulation*, s. 4(1)(l).
Midwives Regulation, s. 5(1)(k), (l), and (m).
Naturopathic Physicians Regulation, s. 5(1)(i).
Optometrists Regulation, s. 5(1)(d).
Podiatrists Regulation, s. 5(1)(i).
[6] *Medical Practitioners Regulation*, s. 5(1).
[7] *Speech and Hearing Health Professionals Regulation*, s. 5(3)(g).

From time to time, the College receives requests from other regulated health professionals (primarily with respect to nurse practitioners) to update the DSR so that they are able to prescribe prescription drugs that have not yet been added to the DSR. While the College responds to these requests in a timely manner, this reactive approach is not ideal. Recently, the College has been receiving more frequent requests from nurse practitioners to update the DSR. The College anticipates that the frequency of requests will continue to grow due to the Ministry's strategic focus on team-based primary care, which relies on health professionals practicing to the full extent of their scope.[8]

Fourth, under the *Pharmacists Regulation*, registrants may only compound and dispense a drug specified in the DSR.[9] Therefore, pharmacists who compound and dispense drugs that are not listed on the DSR are technically in violation of that Regulation.

Fifth, conducting a meaningful independent review of each drug scheduling decision is costly and time-consuming for the College. NDSAC is comprised of a team of experts who have been tasked with reviewing drug scheduling. While there is a significant level of clinical expertise among College staff, the College is not set up to conduct the same level of review. Furthermore, in conducting its own reviews, the College would be duplicating NDSAC's work, which has already been endorsed by most other provinces.

Options

1. Continue with the current approach of maintaining a list of scheduled drugs in the DSR.

   Advantages:
   - All drug scheduling decisions are reviewed by the College, which prevents the inadvertent adoption of a decision that the College does not agree with.
   - College staff are familiar with the current process.

   Disadvantages:
   - The process for drug scheduling is lengthy and resource intensive.
   - A meaningful review of drug scheduling amendments requires reliance on experts (internal or external), who may not be readily available.
   - The College is duplicating the work of NDSAC, which is comprised of experts.
   - The DSR is not a complete list of scheduled drugs, since Schedule I drugs are only added upon request and there is a "lag time" to add Schedule II and III drugs.

[8] https://news.gov.bc.ca/releases/2018PREM0034-001010
[9] *Pharmacists Regulation*, s. 4(1)(b) and (c).

2. Pursue drug scheduling by reference.

   Advantages:
   - The DSR will be a complete list of scheduled drugs.
   - Federal prescription drug amendments will be automatically incorporated, creating significant efficiencies.
   - NAPRA's recommendations for Schedule II and III drugs will be automatically incorporated, creating significant efficiencies.
   - If desired, the College can retain its authority to create exceptions to NAPRA's recommendations.
   - The DSR will be up to date and consistent with federal drug scheduling and NAPRA's recommendations, subject to exceptions created by the College.
   - The DSR will no longer be a barrier to prescribing by other regulated health professionals.
   - The College will no longer be required to duplicate NDSAC's work by conducting a fulsome independent review.

   Disadvantages:
   - Drug scheduling decisions would be adopted automatically, unless the College actively decides to carve out an exception. As a result, the College might inadvertently adopt decisions that it does not agree with. To help mitigate this concern, the governance structure for drug scheduling within the College would need to be assessed.
   - The College might be seen to be abdicating its authority to determine drug scheduling for B.C. However, similar to Alberta's approach, it is possible to develop regulation amendments that clearly retains the College's authority.

Recommendation

College staff recommend that the College pursue drug scheduling by reference (Option #2).

Next Steps

If the Board decides direct the Registrar to pursue drug scheduling by reference, the College would engage with the Ministry to discuss this approach. College staff would begin the process of updating the DSR to incorporate drug scheduling by reference, including research, identifying potential exceptions to the National Drug Schedules, consultation with legal counsel, and drafting.

Appendix	
1	Jurisdictional scan – Drug scheduling in Canada

Last updated: September 21, 2018

Drug Scheduling – Jurisdictional Scan

Jurisdiction	Drug Scheduling Provisions	Notes
British Columbia	**Pharmacy Operations and Drug Scheduling Act** 22 (1) Subject to the *Food and Drugs Act* (Canada), the board, by regulation, may make drug schedules specifying the terms and conditions of sale for drugs and devices. (3) A regulation under this section may adopt by reference, in whole or in part and with any changes the board considers necessary, any code, schedule, specification, standard, rule or similar record issued or approved by the government of Canada, by the government of a province or by a body approved by the board for the purpose of this section. (4) A code, schedule, specification, standard, rule or similar record adopted under subsection (3) may be adopted as amended from time to time. **Drug Schedules Regulation** [Note: Contains list of scheduled drugs.]	Drug scheduling decisions must be approved by the College. Recommendations in NAPRA's National Drug Schedules (NDS) are generally adopted, but not automatically.
Alberta	**Pharmacy and Drug Act** 1(1)(w.1) "Prescription Drug List" means the list established under section 29.1 of the Food and Drugs Act (Canada); 31(1) Schedule 1 drugs are (a) the drugs set out in a Schedule to the Controlled Drugs and Substances Act (Canada), (b) the drugs set out in the Prescription Drug List, and (c) the drugs designated as Schedule 1 drugs pursuant to section 34. 32(1) Schedule 2 drugs are (a) the drugs designated as Schedule 2 drugs pursuant to section 34, and (b) unless provided otherwise by regulation under section 34, the drugs removed from the Prescription Drug List and approved for non-prescription sale in Canada. 33(1) Subject to the regulations under section 34, Schedule 3 drugs are the drugs designated as Schedule 3 drugs pursuant to section 34.	Adopts by reference to NDS, Prescription Drug List (PDL) made under the Food and Drugs Act (FDA) and Controlled Drugs and Substances Act (CDSA), subject to exceptions identified in Regulations. Complicated drafting – may not be easy for registrants to determine which drugs are Schedule 1, 2, and 3. s. 32(1)(b) of Pharmacy and Drug Act – By default, drugs approved for non-prescription sale are Schedule II. s. 1(1)(b) of Scheduled Drugs Regulation – On NDS, vaccines that are part of a routine immunization program are Schedule II, so it appears that Alberta

Jurisdiction	Drug Scheduling Provisions	Notes
	34(1) The Minister may, after consulting with the council, make regulations respecting the designation of drugs, other than drugs described in section 31(1)(a) or (b), as Schedule 1, 2 or 3 drugs. (2) In addition to or instead of making a regulation under subsection (1), the Minister may, after consulting with the council, declare the whole or a part of (a) a list in an enactment of Alberta or of another jurisdiction, or (b) a code, standard or list published by an organization, that designates drugs and copies of which are available, to be in force with any variations that the Minister specifies and either as that list in the enactment or that code, standard or list, or the part of it, exists on a specified day or as amended from time to time. http://www.qp.alberta.ca/documents/Acts/P13.pdf **Scheduled Drugs Regulation** 1(1) Subject to subsection (2)[Note: repealed], the following drugs are designated as Schedule 1 drugs for the purposes of section 31(1)(c) of the Pharmacy and Drug Act: (a) drugs set out in Schedule I of the National Association of Pharmacy Regulatory Authorities Drug Schedules (as amended or replaced from time to time) published by the National Association of Pharmacy Regulatory Authorities, other than drugs described in section 31(1)(a) or (b) of the Act; (b) vaccines for diphtheria, tetanus, pertussis, polio, haemophilus B, measles, meningitis, mumps, rubella and pediatric hepatitis B. 2(1) Subject to subsection (2), the following drugs are designated as Schedule 2 drugs for the purposes of section 32(1)(a) of the Pharmacy and Drug Act: (a) the drugs set out in Schedule II of the National Association of Pharmacy Regulatory Authorities Drug Schedules (as amended or replaced from time to time) published by the National Association of Pharmacy Regulatory Authorities; (b) iodinated casein; (2) The following drugs are excluded from the designation under subsection (1)(a): (a) vaccines for diphtheria, tetanus, pertussis, polio, haemophilus B, measles, meningitis, mumps, rubella and pediatric hepatitis B; (b) diphenhydramine and its salts for topical use; (c) charcoal (activated) for use in poisoning treatment; (d) hydroquinone (topical preparations in concentrations of less than 2%); (e) naloxone and its salts, when indicated for emergency use for opioid overdose outside hospital settings.	has deviated from this and placed them in Schedule 1.

Last updated: September 21, 2018

Jurisdiction	Drug Scheduling Provisions	Notes
	3(1) Subject to subsection (2), the following drugs are designated as Schedule 3 drugs for the purposes of section 33(1) of the Pharmacy and Drug Act: (a) the drugs set out in Schedule III of the National Association of Pharmacy Regulatory Authorities Drug Schedules (as amended or replaced from time to time) published by the National Association of Pharmacy Regulatory Authorities; (b) drugs for veterinary use that are to be administered by injection. (2) The following drugs are excluded from the designation under subsection (1): [Note: List of drugs omitted] http://www.qp.alberta.ca/documents/Regs/2007_066.pdf	
Saskatchewan	**Pharmacy and Pharmacy Disciplines Act** 52(1) The Lieutenant Governor in Council may, after consulting with the council, make regulations: (a) establishing drug schedules; (b) prescribing any conditions and restrictions that apply to the drug schedules; (c) authorizing the council to make administrative or regulatory bylaws adding specific drugs to or deleting specific drugs from the drug schedules established pursuant to clause (a); http://www.qp.gov.sk.ca/documents/English/Statutes/Statutes/P9-1.pdf **The Drug Schedules Regulations, 1997** 2(1) Three drug schedules are established as set forth in this section. (2) Schedule I, entitled “Prescription Drugs”, consists of the following: (a) the drugs listed in the schedules to the Narcotic Control Regulations (Canada) other than a drug mentioned in section 36 of those regulations; (b) the drugs listed in Schedule F of the Food and Drug Regulations (Canada) other than a drug listed in Part II of that Schedule: (i) that is not in a form suitable for use by a human; or (ii) for which the main product panel of both the inner label and the outer label clearly indicates that the drug is for veterinary use only; (c) the drugs listed in the schedule to Part G of the Food and Drug Regulations (Canada); (d) those drugs determined by the council pursuant to section 3. (3) Schedule II, entitled “Non-Prescription Restricted Access Drugs”, consists of the following:	Adopts by reference to NDS, Narcotic Controlled Regulations, Food and Drug Regulations and PDL, subject to exceptions identified in Regulations/Bylaws. Complicated drafting, involving Act, Regulations and 2 sets of Bylaws. s. 2(2)(b) refers to Schedule F of the Food and Drug Regulations, which has been repealed. No other province refers specifically to Part G of the Food and Drug Regulations, which lists some controlled drugs.

Jurisdiction	Drug Scheduling Provisions	Notes
	(a) pseudoephedrine, pseudoephedrine hydrochloride or pseudoephedrine sulphate, but only with respect to products in which pseudoephedrine, pseudoephedrine hydrochloride or pseudoephedrine sulphate is the single active ingredient; (b) those drugs determined by the council pursuant to section 3. (4) Schedule III, entitled "Pharmacy Only Non-Prescription Drugs", consists of those drugs determined by the council pursuant to section 3. 3(1) Council shall determine the additional drugs to be listed in Schedule I by way of administrative bylaw. (2) Council may delete a drug listed in Schedule I that appears in any of the schedules mentioned in clauses 2(2)(a) to (c) by way of administrative bylaw. (3) Council may determine the additional drugs to be listed in Schedule II by way of administrative bylaw. (4) Council shall determine the drugs to be listed in Schedule III by way of regulatory bylaw. http://www.qp.gov.sk.ca/documents/English/Regulations/Regulations/P9-1R2.pdf **The Administrative Bylaws** **DRUG SCHEDULE I – PRESCRIPTION DRUGS** Drug Schedule I includes those drugs listed in the National Drug Schedule I maintained by the National Association of Pharmacy Regulatory Authorities and accessible at http://napra.ca/pages/Schedules/Search.aspx except those drugs as follows and as may be added or amended by Council from time to time. Drugs in Schedule I may only be sold by a licensed pharmacist or licensed pharmacy technician to the public for human or animal use pursuant to a prescription unless specified otherwise for animal use in the Prescription Drug List of the Food and Drug Regulations (Canada). Drugs INCLUDED in SCPP Schedule I: [Note: None listed] Drugs EXCLUDED from SCPP Schedule I: [Note: None listed]	

Jurisdiction	Drug Scheduling Provisions	Notes
	DRUG SCHEDULE II – PHARMACY ONLY RESTRICTED ACCESS NON-PRESCRIPTION DRUGS Drug Schedule II includes those drugs listed in the National Drug Schedule II maintained by the National Association of Pharmacy Regulatory Authorities and accessible at http://napra.ca/pages/Schedules/Search.aspx except those drugs as follows and as may be added or amended by Council from time to time. Schedule II drugs may be sold by a licensed pharmacist or licensed pharmacy technician to the public without a prescription. These drugs must, at all times, be kept or stored in a secure location in the pharmacy, such as the dispensary, that is not accessible to the public. The licensed pharmacist must be involved in the sale of these drugs, which includes arriving at the decision to sell the drug: Drugs INCLUDED in SCPP Schedule II: [Note: List of drugs excluded] Drugs EXCLUDED from SCPP Schedule II: [Note: None listed] **Regulatory Bylaws** DRUG SCHEDULE III – APRIL 1, 2015 SCPP SCHEDULE III – PHARMACY ONLY NON-PRESCRIPTION DRUGS SCPP Schedule III includes those drugs listed in the National Drug Schedule III maintained by the National Association of Pharmacy Regulatory Authorities and accessible at http://napra.ca/pages/Schedules/Search.aspx except those drugs as follows and as may be added or amended by Council from time to time. Drugs in SCPP Schedule III can only be sold from a pharmacy. They may be sold by a licensed pharmacist or a licensed pharmacy technician to the public without a prescription. These drugs may be located in the area of the pharmacy that is accessible to the public and which provides an opportunity for self-selection of the drug by the public. The pharmacist must be available, accessible and approachable to assist the public with selecting the drug. In accordance with their respective scopes of practice the licensed pharmacist or licensed pharmacy technician must be available, accessible and approachable to assist the public with selecting the drug. Drugs INCLUDED in SCPP Schedule III: [Note: List of drugs excluded] Drugs EXCLUDED from SCPP Schedule III: [Note: List of drugs excluded] https://scp.in1touch.org/document/3529/Bylaws_Administrative_20160226.pdf	

Last updated: September 21, 2018

Jurisdiction	Drug Scheduling Provisions	Notes
Manitoba	**Pharmaceutical Act** 73(3) A regulation may incorporate by reference, in whole or in part, any code, standard or drug schedule, and it may incorporate it as amended from time to time, and subject to any changes that the maker of the regulation considers necessary. https://web2.gov.mb.ca/laws/statutes/ccsm/p060e.php **Pharmaceutical Regulation** 1 "Manual" means the Manual for Canada's National Drug Scheduling System published by the National Association of Pharmacy Regulatory Authorities, as amended from time to time. https://mpha.in1touch.org/uploaded/web/Legislation/Manitoba%20Pharmaceutical%20Regulations%20current%20as%20of%202015.02.24.pdf	Adopts by reference to NDS. No exceptions to NDS have been identified. Regulation does not explicitly adopt National Drug Scheduling System, rather, it references the "Manual" and sets out requirements for each Schedule of drugs referenced in the Manual. Refer to references to Manual in the Pharmaceutical Regulation.
Ontario	**Drug and Pharmacies Regulation Act** 1(1) "Council" means the Council of the College; 161 (1) Subject to the approval of the Lieutenant Governor in Council, the Council may make regulations, (a) establishing Schedules I, II, III and U for the purposes of this Act, and prescribing the substances that are to be included in those Schedules; https://www.ontario.ca/laws/statute/90h04/v3 **O. Reg. 264/16: GENERAL** 1.(1) "National Drug Schedules" means the National Drug Schedules that are part of the National Drug Scheduling System published by the National Association of Pharmacy Regulatory Authorities, as those Schedules are amended from time to time; 3. (1) Schedules I, II, III and U are established for the purposes of the Act. (2) The following substances are prescribed as being included in Schedule I for the purposes of the Act: 1. The substances listed in Schedule I of the National Drug Schedules. 2. The substances listed in the Prescription Drug List established under section 29.1 of the *Food and Drugs Act* (Canada). 3. The substances listed in the Schedules to the *Controlled Drugs and Substances Act* (Canada).	Adopts by reference to NDS, PDL, and CDSA. There is no authority to make exceptions. Act permits Council to make regulations establishing drug schedules but does not explicitly allow council to adopt by reference.

Last updated: September 21, 2018

Jurisdiction	Drug Scheduling Provisions	Notes
	(3) The substances listed in Schedule II of the National Drug Schedules are prescribed as being included in Schedule II for the purposes of the Act. (4) The substances listed in Schedule III of the National Drug Schedules are prescribed as being included in Schedule III for the purposes of the Act. (5) The substances listed in the Unscheduled Category of the National Drug Schedules are prescribed as being included in Schedule U for the purposes of the Act. https://www.ontario.ca/laws/regulation/160264	
Quebec	https://napra.ca/implementation-national-drug-schedules	According to NAPRA's website, Quebec has not adopted NDS.
New Brunswick	**An Act Respecting the New Brunswick College of Pharmacists** 27(1) Council shall establish Drug Schedules, and: (a) shall establish in each schedule the conditions under which any drug or substance named in the schedule may be sold or dispensed; (b) shall establish the percentage of any substance to be contained in any preparation named in the schedule; (c) shall establish the manner in which prescriptions shall be dispensed in respect of any drug named in the schedule, and the conditions under which the prescriptions may be delivered; and (d) in any schedule, may adopt by reference, in whole or in part, any schedule or formulary recognized by Council, and, subject to paragraph 22(2)(d), may also provide that it is adopted as amended from time to time, except such amendments as are expressly disallowed by Council. 27(2) Where a Drug Schedule provides that a drug or substance may be sold or dispensed only in a pharmacy, no other person shall sell, dispense or deliver the drug or substance. 27(3) Council may amend the Drug Schedules, from time to time, subject to paragraph 22(2)(d). https://nbcp.in1touch.org/document/1734/2014%20Pharmacy%20Act.pdf **Regulations of the New Brunswick College of Pharmacists** 27.1 The following Drug Schedules are established: SCHEDULE I 1. All drugs and medicines listed in Schedule I of the Manual For Canada's National Drug Scheduling System published by the National Association of Pharmacy Regulatory Authorities, as amended from time to time (the "Manual").	Adopts by reference to NDS, FDA, and CDSA. There is no authority to make exceptions. Schedule 2 in the Regulations is missing #3. Probably a typo.

Jurisdiction	Drug Scheduling Provisions	Notes
	2. These products require a prescription for sale and are provided to the public by the pharmacist following the diagnosis and professional intervention of a prescriber. 3. The drugs and medicines in this Schedule shall be subject to the selling and dispensing conditions prescribed under the Manual, as amended from time to time. 4. No pharmacist, and no member under the supervision of a pharmacist, shall sell a Schedule I drug except pursuant to a prescription. 5. The Standards of Practice respecting dispensing of prescription drugs apply to dispensing of drugs and medicines in this Schedule. SCHEDULE II 1. All drugs and medicines listed in Schedule II of the Manual shall be subject to the selling and dispensing conditions prescribed under the Manual, as amended from time to time. 2. These products require professional intervention from the pharmacist at the point of sale and possibly referral to a prescriber. While a prescription is not required, the drugs are available only from the pharmacist and must be retained within an area of the pharmacy where there is no public access and no opportunity for client self-selection. 4. No pharmacist, and no member, or person, under the supervision of a pharmacist, shall sell a Schedule II drug except from the dispensary of a pharmacy. 5. The Standards of Practice respecting dispensing of non-prescription drugs apply to dispensing of drugs and medicines in this Schedule. SCHEDULE III 1. All drugs and medicines listed in Schedule III of the Manual shall be subject to the selling and dispensing conditions prescribed under the Manual, as amended from time to time. 2. These products may be sold from the self selection area of a pharmacy which is operated under the direct supervision of a pharmacist. Such an area should be accessible to the client and clearly defined as the "professional services area" of the pharmacy. The pharmacist should be available, accessible and approachable to	

Jurisdiction	Drug Scheduling Provisions	Notes
	assist the client in making an appropriate self-medication selection. 3. No pharmacist, and no member under the supervision of a pharmacist, shall sell a Schedule III drug except in the area immediately adjacent to the dispensary. 4. The Standards of Practice respecting dispensing of non-prescription drugs apply to dispensing of drugs and medicines in this Schedule. SCHEDULE U 1. All drugs and medicines listed in Schedule U of the Manual shall be subject to the selling and dispensing conditions prescribed under the Manual, as amended from time to time. 2. Adequate information is available for the client to make a safe and effective choice and labeling is deemed sufficient to ensure the appropriate use of the drug. These drugs are not included in Schedules I, II or III and may be sold from any retail outlet. FOOD AND DRUGS ACT (CANADA) 1. All schedules to the Food and Drugs Act (Canada) are adopted by reference. CONTROLLED DRUGS AND SUBSTANCES ACT (CANADA) (CDSA) 1. All schedules to the Controlled Drugs and Substances Act (Canada) are adopted by reference. https://nbcp.in1touch.org/document/1733/2015%2007%2023%20REGS%20bilingual.pdf	
Nova Scotia	**Pharmacy Act** 81 (1) The Council may, by regulation, prescribe the schedules required by this Act. (2) The Council may prescribe in the schedules (a) the conditions under which any drug or substance named in the schedule may be sold or dispensed; and (b) the manner in which prescriptions must be given in respect of any drug named in the schedule and the conditions under which the prescriptions may be given. (3) The Council may in any schedule adopt by reference, in whole or in part, any schedule, code, specification, standard or formulary recognized by the Council, and may also provide that it is adopted as amended from time to time, except such amendments as are expressly disallowed by the Council.	Adopts by reference to NDS. There is no authority to make exceptions.

Jurisdiction	Drug Scheduling Provisions	Notes
	Drug Schedules Regulations made under Section 81 of the Pharmacy Act Schedule I 1 The drugs and medicines in this Schedule are the drugs listed from time to time in Schedule I of the National Drug Schedules, which are part of Canada's National Drug Scheduling System published by the National Association of Pharmacy Regulatory Authorities, as that Schedule is from time to time amended. 2 The drugs and medicines in this Schedule require a prescription as a condition of sale. 3 The drugs and medicines in this Schedule, which are listed in the Controlled Drugs and Substances Act (Canada) and its regulations, must be sold in accordance with the Controlled Drugs and Substances Act (Canada) and its regulations, and the standards of practice from time to time approved by the Council. 4 The drugs and medicines in this Schedule, which are not listed in the Controlled Drugs and Substances Act (Canada) and its regulations, must be sold in accordance with the Food and Drugs Act (Canada) and its regulations, and the standards of practice from time to time approved by the Council. Schedule II 1 The drugs and medicines in this Schedule are the drugs listed from time to time in Schedule II of the National Drug Schedules, which are part of Canada's National Drug Scheduling System published by the National Association of Pharmacy Regulatory Authorities, as that Schedule is from time to time amended. 2 (1) The drugs and medicines listed in this Schedule do not require a prescription as a condition of sale, but are only available from a pharmacist or a certified dispenser and must be kept within an area of the pharmacy to which there is no public access and no opportunity for self-selection. (2) The direct involvement and professional intervention from a pharmacist or certified dispenser is required prior to the release of the drug to the patient or the patient's agent. 3 The drugs and medicines in this Schedule must be sold in accordance with the standards of practice from time to time approved by the Council.	

Last updated: September 21, 2018

Jurisdiction	Drug Scheduling Provisions	Notes
	Schedule III 1 The drugs and medicines in this Schedule are the drugs listed from time to time in Schedule III of the National Drug Schedules, which are part of Canada's National Drug Scheduling System published by the National Association of Pharmacy Regulatory Authorities, as that Schedule is from time to time amended. 2 (1) The drugs and medicines listed in this Schedule do not require a prescription as a condition of sale, but are sold from the self-selection area of the pharmacy maintained under the personal supervision of a pharmacist or certified dispenser. (2) A pharmacist or certified dispenser must be available to assist the patient in making an appropriate self-medication selection. 3 The drugs and medicines in this Schedule must be sold in accordance with the standards of practice from time to time approved by the Council. https://www.novascotia.ca/just/regulations/regs/pharmdrg.htm	
Newfoundland and Labrador	**Pharmacy Regulations, 2014 under the Pharmacy Act, 2012** Drug schedules 13. (1) The board may adopt the drug schedules established under the National Association of Pharmacy Regulatory Authorities National Drug Schedules System. (2) Notwithstanding subsection (1), a pharmacist in charge may, where he or she considers it necessary, exercise a higher degree of control over a particular drug than what is contemplated in the schedules. https://www.assembly.nl.ca/Legislation/sr/regulations/rc140094.htm#13_ **A Guide to Understanding the Provincial Drug Schedules** (Includes list of scheduled drugs) http://www.nlpb.ca/media/Drug-Schedules-August2017.pdf	NL has adopted the National Drug Scheduling System. However, scheduling decisions must first be approved by the Newfoundland and Labrador Pharmacy Board.

Last updated: September 21, 2018

Jurisdiction	Drug Scheduling Provisions	Notes
P.E.I.	**Pharmacy Act** 1. Interpretation In this Act (l) “National Drug Schedules” means the National Drug Schedules established and maintained by the National Association of Pharmacy Regulatory Authorities; (z) “Schedule I drug” means (i) a drug listed in Schedule I of the National Drug Schedules, and (ii) a drug designated in the regulations as a Schedule I drug; (aa) “Schedule II drug” means (i) subject to the regulations, a drug listed in Schedule II of the National Drug Schedules, and (ii) a drug designated in the regulations as a Schedule II drug; (bb) “Schedule III drug” means (i) subject to the regulations, a drug listed in Schedule III of the National Drug Schedules, and (ii) a drug designated in the regulations as a Schedule III drug; 22. Drug schedules The Council may, for the purposes of this Act, by regulation, (a) designate a drug that is not listed in Schedule I, II or III of the National Drug Schedules as a Schedule III drug, a Schedule II drug or a Schedule I drug; (b) designate a drug listed in Schedule III of the National Drug Schedules as a Schedule II drug or a Schedule I drug; (c) designate a drug listed in Schedule II of the National Drug Schedules as a Schedule I drug; or (d) revoke a designation made pursuant to clause (a), (b) or (c). 51. Regulations (1) The Council, subject to the approval of the Lieutenant Governor in Council, may make regulations (h) designating a drug that is not listed in Schedule I, II or III of the National Drug Schedules as a Schedule III drug, a Schedule II drug or a Schedule I drug; (i) designating a drug listed in Schedule III of the National Drug Schedules as a Schedule II drug or a Schedule I drug; (j) designating a drug listed in Schedule II of the National Drug Schedules as a Schedule I drug;	Adopts by reference to NDS, subject to exceptions identified in the Regulations.

Last updated: September 21, 2018

Jurisdiction	Drug Scheduling Provisions	Notes
	https://www.princeedwardisland.ca/sites/default/files/legislation/P-06-1-Pharmacy%20Act.pdf **Pharmacy Act General Regulations** 7. Designated Schedule II drug Dimenhydrinate and its salts are designated as a Schedule II drug. https://www.princeedwardisland.ca/sites/default/files/legislation/P%2606-1g-Pharmacy%20Act%20General%20Regulations.pdf	

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

11. Legislation Review Committee
c) Professional Practice Policy-66: Amendment to Training Requirements

DECISION REQUIRED

Recommended Board Motions:

1) Approve amendments to *Professional Practice Policy 66 Opioid Agonist Treatment* (PPP-66) to align with a new opioid agonist treatment training program for pharmacy, as circulated, effective on January 1, 2019.

2) Amend the following policy guides to incorporate consequential and housekeeping amendments, as circulated, effective on January 1, 2019:

- *PPP-66 Policy Guide – Methadone Maintenance Treatment (2013)*
- *PPP-66 Policy Guide – Buprenorphine/Naloxone Maintenance Treatment (2018)*,
- *PPP-66 Policy Guide – Slow Release Oral Morphine Maintenance Treatment (2018)*

Purpose

To seek Board approval to amend *PPP-66* to align with a new opioid agonist treatment (OAT) training program for pharmacy, and consequential and housekeeping amendments for the corresponding policy guides.

Background

PPP-66 requires pharmacists and technicians to complete the CPBC Methadone Maintenance Treatment (MMT) training program prior to dispensing methadone; in addition, the pharmacy manager must educate non-pharmacist staff of their relevant roles. However, neither PPP-66 nor the CPBC have specific training program requirements related to the other OAT drugs (i.e., buprenorphine/naloxone and slow release oral morphine). To date, there has been no identified fulsome OAT training program specifically tailored to pharmacies.

In conjunction with the Ministry of Health ("Ministry"), the British Columbia Pharmacy Association (BCPhA) has developed an OAT training program for pharmacy that covers all three OAT medications outlined in PPP-66 (i.e., buprenorphine/naloxone, methadone and slow release oral morphine). The resulting *Opioid Agonist Treatment Compliance and Management Program for Pharmacy* (OAT-CAMPP) training program is comprised of a four-hour online component and a one-day in-person workshop. OAT-CAMPP officially launches in January 2019.

Discussion

It is proposed that PPP-66 be amended to align with the new BCPhA training program, as it is pharmacy-specific and more fulsome than the current CPBC MMT training program. This will better equip registrants with the tools needed to provide the best care for patients with opioid use disorder.

The Ministry and the BCPhA propose that within six months of the January 2019 launch date, all community pharmacies that deliver OAT will have one pharmacist on staff complete the training program. And, within about two and a half years (i.e., by March 31, 2021) all community pharmacists who dispense OAT in their practice will have completed the OAT-CAMPP course.

Pharmacy Technician Training Requirement
The proposed amendment to PPP-66 with respect to the training requirement for pharmacy technicians, only requires the online component of OAT-CAMPP. The content of the in-person workshop focuses primarily on clinical cases that are not as relevant for pharmacy technicians.

Transition Period
Over the January 1, 2019 to March 31, 2021 transition period, PPP-66 will require either the CPBC MMT training program or the OAT-CAMPP course as a requirement to dispense OAT. The MMT training program will sunset at the end of this transition period (i.e., March 2021), and will be replaced with only the OAT-CAMPP[1].

It is important to note that currently, pharmacists and pharmacy technicians who dispense buprenorphine/naloxone and slow release oral morphine are not required to take the CPBC MMT training program. However, given that patients taking MMT may eventually be prescribed other OAT drugs, it is seen a good practice for registrants dispensing any OAT drug to take either the College's MMT training program or OAT-CAMPP.

Consequential and House-keeping Amendments
The above-noted proposed changes to PPP-66 require limited consequential amendments to the MMT policy guide. In addition, College staff are proposing minor house-keeping amendments to the PPP-66 and the corresponding policy guides (e.g., style consistency, formatting, and abbreviation).

[1] Please also see the materials regarding item 10 on the Board meeting agenda for related information on the BCPhA OAT-CAMPP training program.

Next Steps

If approved by the Board, the above-noted amendments would take effect on January 1, 2019. Key next steps would include:

- Communicate the amendments to the policy documents to the public and registrants; and
- Update the College website with revised policy documents.

Recommendation

The Legislation Review Committee recommends that the Board approve the proposed amendments the *PPP 66 - Opioid Agonist Treatment* and its three corresponding policy guides (i.e., *PPP 66-Policy Guide – Methadone Maintenance Treatment (2013), PPP 66-Policy Guide – Buprenorphine/Naloxone Maintenance Treatment (2018)*, and *PPP 66-Policy Guide – Slow Release Oral Morphine Maintenance Treatment (2018)).*

Appendix	
1	Amendments to *PPP-66 Opioid Agonist Treatment* (track changes and clean copy)
2	Amendments to *PPP-66 Policy Guide – Methadone Maintenance Treatment (2013)* (track changes)
3	Amendments to *PPP-66 Policy Guide – Buprenorphine/Naloxone Maintenance Treatment (2018)* (track changes)
4	Amendments to *PPP-66 Policy Guide – Slow Release Oral Morphine Maintenance Treatment (2018)* (track changes)

This policy provides guidance to registrants employed in a community pharmacy that provides pharmacy services related to opioid agonist treatment.

POLICY STATEMENTS:

Effective January 1, 2019:

1. All pharmacy managers, staff pharmacists, and relief pharmacists employed in a community pharmacy that provides pharmacy services related to buprenorphine/naloxone maintenance treatment, methadone maintenance treatment or slow release oral morphine maintenance treatment must:
    a. successfully complete the College of Pharmacists of BC (CPBC) Methadone Maintenance Treatment (MMT) training program (2013), or
    b. successfully complete the British Columbia Pharmacy Association (BCPhA) *Opioid Agonist Treatment Compliance and Management Program for Pharmacy* (OAT-CAMPP) training program, and
    c. record self-declaration of training completion in eServices.
2. All pharmacy technicians employed in a community pharmacy that provides pharmacy services related to buprenorphine/naloxone maintenance treatment, methadone maintenance treatment or slow release oral morphine maintenance treatment must:
    a. successfully complete the CPBC MMT training program (2013), or
    b. successfully complete the online component of the BCPhA OAT-CAMPP training program, and
    c. record self-declaration of training completion in eServices.
3. Pharmacy managers must:
    a. educate all non-pharmacist staff regarding their role in the provision of community pharmacy services related to opioid agonist treatment, and
    b. document the completion of the education of individual non-pharmacist staff members on a form signed and dated by the pharmacy manager and the non-pharmacist staff member, and retain the completed forms in the pharmacy's files.

Effective March 31, 2021:

The CPBC MMT training program (2013) will not be available beyond March 31, 2021. Registrants will no longer be able to fulfill the College's training requirements by completing that program, and must complete any applicable component(s) of the BCPhA OAT-CAMPP by March 31, 2021. The above-noted Policy Statements 1a and 2a will be repealed and all other requirements will continue to be in effect.

During the period between January 1, 2019 and March 31, 2021, registrants employed in a community pharmacy that provides pharmacy services related to opioid agonist treatment are strongly encouraged to complete the OAT-CAMPP program as soon as practicable.

1. BUPRENORPHINE/NALOXONE POLICY STATEMENTS:

~~***Effective January 1, 2018:***~~

1. Buprenorphine/naloxone maintenance treatment must only be dispensed as an approved, commercially available formulation.
2. The ~~College of Pharmacists of British Columbia (~~CPBC~~)~~ *Buprenorphine/Naloxone Maintenance Treatment Policy Guide* (2018) is in force.
3. All pharmacy managers, staff pharmacists, relief pharmacists and pharmacy technicians employed in a community pharmacy that provides pharmacy services related to buprenorphine/naloxone maintenance treatment must:
    a) know and apply the principles and guidelines outlined in the CPBC *Buprenorphine/Naloxone Maintenance Treatment Policy Guide (2018)* and all subsequent revisions,
    b) be familiar with the information included in the most recent version of the British Columbia Centre on Substance Use (BCCSU*) A Guideline for the Clinical Management of Opioid Use Disorder*, and
    c) be familiar with the information included in the product monographs of approved, commercially available formulations.

2. METHADONE MAINTENANCE POLICY STATEMENTS:

1. Methadone maintenance treatment (MMT) must only be dispensed as the commercially available 10mg/ml methadone oral preparation.
2. The CPBC *Methadone Maintenance Treatment Policy Guide (2013)* is in force.
3. All pharmacy managers, staff pharmacists, relief pharmacists and pharmacy technicians employed in a community pharmacy that provides pharmacy services related to methadone maintenance treatment must:
    a) know and apply the principles and guidelines outlined in the CPBC *Methadone Maintenance Treatment Policy Guide (2013)* and all subsequent revisions,
    b) be familiar with the information included in the most recent version of the BCCSU *A Guideline for the Clinical Management of Opioid Use Disorder*, and
    c) be familiar with the information included in the commercially available 10mg/ml methadone oral preparation product monographs.~~, and~~
    ~~d) successfully complete the mandatory CPBC MMT training program (2013), record self-declaration of training completion in eServices prior to dispensing the 10mg/ml preparation.~~
4. ~~Upon completion of the mandatory CPBC MMT training program pharmacy managers must educate all non-pharmacist staff regarding their role in the provision of community pharmacy services related to methadone maintenance treatment. (Note: documentation forms that confirm the education of individual non-pharmacist staff members must be signed and dated by the community pharmacy manager and the non-pharmacist staff member and retained in the pharmacy files).~~

The Methadone Maintenance Policy Statements must be read in conjunction with *PPP-71 Delivery of Methadone Maintenance Treatment*.

Required References

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:

- CPBC *Methadone Maintenance Treatment Policy Guide (2013)* and subsequent revisions.
- The most recent version of the BCCSU *A Guideline for the Clinical Management of Opioid Use Disorder.*
- The most current version of the Centre for Addiction and Mental Health *Opioid Agonist Maintenance Treatment: A Pharmacist's Guide to Methadone and Buprenorphine for Opioid Use Disorders ~~(2015)~~*.
- Product monographs for the commercially available 10mg/ml methadone oral preparations.

3. SLOW RELEASE ORAL MORPHINE POLICY STATEMENTS:

~~***Effective January 1, 2018:***~~

1. Slow release oral morphine maintenance treatment must only be dispensed in approved, commercially available strengths and formulations.
2. The CPBC *Slow Release Oral Morphine Maintenance Treatment Policy Guide (2018)* is in force.
3. All pharmacy managers, staff pharmacists, relief pharmacists and pharmacy technicians employed in a community pharmacy that provides pharmacy services related to slow release oral morphine maintenance treatment must:
    a) know and apply the principles and guidelines outlined in the CPBC *Slow Release Oral Morphine Maintenance Treatment Policy Guide (2018)* and all subsequent revisions,
    b) be familiar with the information included in the most recent version of the BCCSU *A Guideline for the Clinical Management of Opioid Use Disorder*, and
    c) be familiar with the information included in the product monographs of approved, commercially available strengths and formulations.

This policy provides guidance to registrants employed in a community pharmacy that provides pharmacy services related to opioid agonist treatment.

POLICY STATEMENTS:

Effective January 1, 2019:

1. All pharmacy managers, staff pharmacists, and relief pharmacists employed in a community pharmacy that provides pharmacy services related to buprenorphine/naloxone maintenance treatment, methadone maintenance treatment or slow release oral morphine maintenance treatment must:
    a. successfully complete the College of Pharmacists of BC (CPBC) Methadone Maintenance Treatment (MMT) training program (2013), or
    b. successfully complete the British Columbia Pharmacy Association (BCPhA) *Opioid Agonist Treatment Compliance and Management Program for Pharmacy* (OAT-CAMPP) training program, and
    c. record self-declaration of training completion in eServices.
2. All pharmacy technicians employed in a community pharmacy that provides pharmacy services related to buprenorphine/naloxone maintenance treatment, methadone maintenance treatment or slow release oral morphine maintenance treatment must:
    a. successfully complete the CPBC MMT training program (2013), or
    b. successfully complete the online component of the BCPhA OAT-CAMPP training program, and
    c. record self-declaration of training completion in eServices.
3. Pharmacy managers must:
    a. educate all non-pharmacist staff regarding their role in the provision of community pharmacy services related to opioid agonist treatment, and
    b. document the completion of the education of individual non-pharmacist staff members on a form signed and dated by the pharmacy manager and the non-pharmacist staff member, and retain the completed forms in the pharmacy's files.

Effective March 31, 2021:

The CPBC MMT training program (2013) will not be available beyond March 31, 2021. Registrants will no longer be able to fulfill the College's training requirements by completing that program, and must complete any applicable component(s) of the BCPhA OAT-CAMPP by March 31, 2021. The above-noted Policy Statements 1a and 2a will be repealed and all other requirements will continue to be in effect.

During the period between January 1, 2019 and March 31, 2021, registrants employed in a community pharmacy that provides pharmacy services related to opioid agonist treatment are strongly encouraged to complete the OAT-CAMPP program as soon as practicable.

1. BUPRENORPHINE/NALOXONE POLICY STATEMENTS:

1. Buprenorphine/naloxone maintenance treatment must only be dispensed as an approved, commercially available formulation.
2. The CPBC *Buprenorphine/Naloxone Maintenance Treatment Policy Guide* (2018) is in force.
3. All pharmacy managers, staff pharmacists, relief pharmacists and pharmacy technicians employed in a community pharmacy that provides pharmacy services related to buprenorphine/naloxone maintenance treatment must:
    a) know and apply the principles and guidelines outlined in the CPBC *Buprenorphine/Naloxone Maintenance Treatment Policy Guide (2018)* and all subsequent revisions,
    b) be familiar with the information included in the most recent version of the British Columbia Centre on Substance Use (BCCSU*) A Guideline for the Clinical Management of Opioid Use Disorder*, and
    c) be familiar with the information included in the product monographs of approved, commercially available formulations.

2. METHADONE MAINTENANCE POLICY STATEMENTS:

1. Methadone maintenance treatment (MMT) must only be dispensed as the commercially available 10mg/ml methadone oral preparation.
2. The CPBC *Methadone Maintenance Treatment Policy Guide (2013)* is in force.
3. All pharmacy managers, staff pharmacists, relief pharmacists and pharmacy technicians employed in a community pharmacy that provides pharmacy services related to methadone maintenance treatment must:
    a) know and apply the principles and guidelines outlined in the CPBC *Methadone Maintenance Treatment Policy Guide (2013)* and all subsequent revisions,
    b) be familiar with the information included in the most recent version of the BCCSU *A Guideline for the Clinical Management of Opioid Use Disorder*, and
    c) be familiar with the information included in the commercially available 10mg/ml methadone oral preparation product monographs.

The Methadone Maintenance Policy Statements must be read in conjunction with *PPP-71 Delivery of Methadone Maintenance Treatment*.

Required References

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:

- CPBC *Methadone Maintenance Treatment Policy Guide (2013)* and subsequent revisions.
- The most recent version of the BCCSU *A Guideline for the Clinical Management of Opioid Use Disorder.*
- The most current version of the Centre for Addiction and Mental Health *Opioid Agonist Maintenance Treatment: A Pharmacist's Guide to Methadone and Buprenorphine for Opioid Use Disorders.*
- Product monographs for the commercially available 10mg/ml methadone oral preparations.

3. SLOW RELEASE ORAL MORPHINE POLICY STATEMENTS:

1. Slow release oral morphine maintenance treatment must only be dispensed in approved, commercially available strengths and formulations.
2. The CPBC *Slow Release Oral Morphine Maintenance Treatment Policy Guide (2018)* is in force.
3. All pharmacy managers, staff pharmacists, relief pharmacists and pharmacy technicians employed in a community pharmacy that provides pharmacy services related to slow release oral morphine maintenance treatment must:
    a) know and apply the principles and guidelines outlined in the CPBC *Slow Release Oral Morphine Maintenance Treatment Policy Guide (2018)* and all subsequent revisions,
    b) be familiar with the information included in the most recent version of the BCCSU *A Guideline for the Clinical Management of Opioid Use Disorder*, and
    c) be familiar with the information included in the product monographs of approved, commercially available strengths and formulations.

College of Pharmacists
of British Columbia

Professional Practice Policy #66

Policy Guide

Methadone Maintenance Treatment (2013)

Forward

Opioid dependence is a health concern with implications for the individual patient as well as the public. Methadone maintenance treatment is recognized internationally as among the most effective treatments for opioid ~~dependenc~~y use disorder (OUD). Addiction treatment experts recommend that methadone treatment for ~~opioid dependence~~ OUD be delivered with a maintenance-oriented, rather than abstinence-oriented, philosophy. This approach acknowledges ~~opioid dependence~~ OUD as a chronic disease.

Many studies, conducted over several decades in different countries, have clearly demonstrated that the effective delivery of methadone maintenance treatment reduces non-medical opioid use, other problematic substance use, criminal activity, mortality, injection-related risks and transmission of blood-borne disease. Additional positive results are improvement in physical and mental health, social functioning, quality of living and pregnancy outcomes.

Methadone, a long-acting, orally effective opioid, is used as a substitute for heroin or other narcotics when treating opioid dependence. Methadone eliminates withdrawal from and reduces cravings for, opioids. Methadone does not produce euphoria, and it blocks the euphoric effects of other opioids. When used in the treatment of opioid dependence, a single oral dose of methadone is effective for at least 24 hours. Eventual withdrawal from methadone is not necessarily the goal of the program, although some individuals may work with their physician and pharmacist to decrease their dose and eventually stop using methadone.

Methadone prescribing is controlled by both federal and provincial legislation, as well as administrative procedures and guidelines.

Registered pharmacists are permitted to purchase and dispense methadone without federal exemption. However, the College of Pharmacists of BC~~'s~~ (CPBC) *Professional Practice Policy (PPP-66) – Opioid Agonist Treatment* requires that the pharmacy manager and all staff pharmacists employed in a community pharmacy that provides services related to methadone maintenance treatment complete the CPBC~~'s~~ *Methadone Maintenance Treatment* (MMT) or the British Columbia Pharmacy Association's (BCPhA) *Opioid Agonist Treatment Compliance and Management Program for Pharmacy* (OAT-CAMPP) training program, and any subsequent updates. You must log into eServices to complete the "*Declaration of Completion and Understanding*" prior to providing methadone maintenance treatment services.

How to Use This Guide

Note:

This document is not intended to cover all possible practice scenarios.

This Policy Guide (the Guide) is a companion to *Professional Practice Policy (PPP-66) –Opioid Agonist Treatment* (Appendix 1) ~~and supports the 'live' and 'online' training~~. The intention of the *Guide* is to provide pharmacists with further detail and clarity (including practical examples) to assist in the implementation of the policy into practice to ensure consistency in the safe and effective delivery of methadone maintenance treatment services.

As always the expectation is that pharmacists will practice in compliance with their legislative requirements, including the principles outlined in this *Guide*. It is understood however that pharmacy practice is not always 'black and white' and when navigating the 'grey' pharmacists must use sound professional judgment, ensuring that their decisions are made in the best interest of the patient and with appropriate collaboration, notification and most importantly, documentation.

The *Guide* is to be read in conjunction with completion of the mandatory training session. Information regarding the mandatory sessions can be found on the CPBC website at **www.bcpharmacists.org.**

Declaration

After completing the mandatory ~~'live' or 'online'~~ training ~~session~~ program, and subsequently reading this *Guide*, pharmacists must log into eServices to complete the '*Declaration of Completion and Understanding*'.

Acknowledgement

The development of this *Guide* involved a collaborative and consultative process with input and feedback gathered from a volunteer group of dedicated community pharmacists currently engaged, in varying capacities, in the delivery of methadone maintenance treatment services.

The group was comprised of both frontline pharmacists and pharmacy managers and represented a cross-section of practice types (independent to large chain retailers) and practice settings including pharmacies located in Vancouver's Downtown Eastside whose primary focus is on the provision of methadone maintenance treatment.

Feedback was also solicited from other stakeholder groups including; the Ministry of Health Services, the College of Physicians and Surgeons of BC, the BCPhA ~~Pharmacy Association,~~ the City of Vancouver, patient advocacy groups Vancouver Area Network of Drug Users (VANDU), and the BC Association for People on Methadone (BCAPOM).

The College of Pharmacists of BC would like to sincerely thank each of these individuals and organizations for their invaluable feedback in the creation of this significant resource for pharmacists.

Feedback

Questions and comments about this *Guide* are welcome and can be sent to:

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200 – 1765 West 8th Avenue
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Methadone Maintenance Treatment Policy Guide

In accordance with *Professional Practice Policy (PPP-66) – Opioid Agonist Treatment* (Appendix 1), all pharmacy managers, staff pharmacists, relief pharmacists and pharmacy technicians employed in a community pharmacy that provides pharmacy services related to methadone maintenance treatment must know and apply the principles and guidelines outlined here in the ~~College of Pharmacists of BC's (~~CPBC~~)~~ *Methadone Maintenance Treatment Policy Guide* (2013) and all subsequent revisions. The responsibility of pharmacy technicians in the dispensing of MMT is consistent with their scope of practice outlined in the *Health Professions Act* (HPA) Bylaws Schedule F Part 1 section 4.

Administration

1.1 Pharmacy Operating Hours

Principle 1.1.1

Patients must attend the pharmacy unless exceptional circumstances are provided for under *Professional Practice Policy (PPP-71) – Delivery of Methadone Maintenance Treatment*. The pharmacy hours of service must be consistent with the supervised dosing requirements of your patient.

Guideline: When a pharmacy accepts a patient who requires daily witness ingestion (ie; 7 days per week) the pharmacy hours of service must accommodate this dosing requirement. A pharmacist does not have the independent authority to adapt a prescription for methadone maintenance treatment from 'daily witness' to a 'take-home' dose.

1.2 Privacy and Confidentiality – Premise

Principle 1.2.1

All pharmacies offering methadone maintenance treatment must be in compliance with all relevant legislation pertaining to the structure of the licensed premise with particular attention given to ensuring there is sufficient space to accommodate patients waiting for witnessed ingestion and/or take home methadone doses while simultaneously maintaining privacy for pharmacist-patient consultation.

Guideline: It may be appropriate to establish a staggered schedule for regular patients requiring witnessed ingestion to ensure that there is adequate space within the pharmacy to accommodate patients who are waiting and ensure privacy of pharmacist-patient consultation.

1.3 Security – Premise

Principle 1.3.1

All pharmacies offering methadone maintenance treatment must ensure that their pharmacy is in compliance with all relevant legislation pertaining to pharmacy security requirements including those outlined in *Professional Practice Policy (PPP-74) – Community Pharmacy Security.*

2.0

Receiving Methadone Prescriptions

2.1 Methadone Maintenance Controlled Prescription Forms – Overview

Principle 2.1.1

Methadone maintenance prescriptions can **only** be accepted when written using an original Methadone Maintenance Controlled Prescription form.

Guideline: When accepting a methadone maintenance prescription a pharmacist must ensure that the Methadone Maintenance Controlled Prescription form is completed by the prescriber as outlined in the *Methadone Maintenance Controlled Prescription Form Guidelines* (Appendix 3).

Principle 2.1.2

The pharmacist must ensure that the patient, as well as themselves, sign the form, in the space indicated on the bottom of the form.

Principle 2.1.3

Faxed Methadone Maintenance Controlled Prescription forms are not acceptable unless under extenuating circumstances where the prescriber has determined, following consultation with the pharmacist, that the urgency of the situation warrants it.

Note:

The Emergency Fax Controlled Prescription Program Form Documentation (Appendix 4) can be used for this purpose.

Guideline: In such cases the pharmacy, prior to dispensing the medication, must receive, in addition to a fax of the Methadone Maintenance Controlled Prescription form, written confirmation (fax acceptable) signed by the prescriber that briefly describes the emergency situation and guarantees the delivery of the original Methadone Maintenance Controlled Prescription form to the pharmacy the next business day or as soon as possible when the physician is not available.

The faxed Methadone Maintenance Controlled Prescription form and related documentation, as described in Appendix 4, must be attached to the original Methadone Maintenance Controlled Prescription form once received.

Principle 2.1.4

In an effort to maximize the effectiveness of the methadone maintenance treatment program, the pharmacist may find it beneficial to engage in a specific dialogue with the patient, either when they initiate treatment or at various times throughout treatment, that clearly outlines the expectations of both the patient and the pharmacist.

Guideline: The *Methadone Maintenance Treatment Expectation Form* (Appendix 5) can be used for this purpose.

Principle 2.1.5

In the rare circumstance (disruptive or threatening behavior or verbal or physical abuse) where a pharmacist finds that they must terminate the pharmacist-patient relationship, reasonable notice must be provided to the patient to ensure their continuity of care.

Guideline: It is important to remember that the decision to terminate a pharmacist-patient relationship is a serious one and must be made with due consideration and based on appropriate rationale. It is unethical for a pharmacist to terminate the pharmacist-patient relationship or refuse to treat a patient on morally irrelevant grounds. The pharmacist's decision should be documented and retained in the patient record.

2.2 Methadone Maintenance Controlled Prescription Forms – Alterations

Principle 2.2.1

Alterations to the Methadone Maintenance Controlled Prescription form are the exception to the rule and should not be normal practice as they increase the likelihood of errors and drug diversion and put the public at risk.

In the rare circumstance when an alteration is necessary to ensure the continuity of care pharmacists must always use due diligence to ensure authenticity and accuracy of the prescription.

Note:

The Pharmacist-Prescriber Communication Form (Appendix 6) can be used for this purpose.

Guideline:

Alterations completed at the prescriber's office:

Alterations are only permitted on the sections of the form that the prescriber completes provided that the prescriber has initialed the alteration.

Alterations are not permitted to the pre-printed sections of the form.

Alterations completed at the pharmacy:

Pharmacists do not have independent authority to make any alterations or changes to a Methadone Maintenance Controlled Prescription form. Any required or requested change(s) must be patient-specific and authorized by the patient's prescriber through direct consultation with the pharmacist. Any prescriber-authorized changes must be confirmed in writing, signed by the prescriber, received by the pharmacy (fax is acceptable) prior to dispensing the medication whenever possible and attached and filed with the original prescription.

2.3 Out-of-Province Prescriptions

Principle 2.3.1

Pharmacists are permitted to dispense methadone prescriptions from prescribers in provinces other than BC.

Note:

It's important to realize that not all provinces are required to use Controlled Prescription Program Forms.

Guideline: If there are any doubts regarding the authenticity of the out-of-province prescription, the pharmacist must contact the out-of-province prescriber to confirm the legitimacy of the prescription. When satisfied that the prescription is authentic, the pharmacist can dispense and process the prescription in the same manner as other prescriptions from out-of-province prescribers.

3.0

Processing (Dispensing) Methadone Prescriptions

3.1 Accepting a Prescription

Principle 3.1.1 Methadone for maintenance must be dispensed to patients in a concentration of 10 mg/ml.

Guideline: Only commercially available 10 mg/ml oral preparations are permitted for use.

Principle 3.1.2 Positive identification is required for all patients presenting a prescription for the first time, and reasonable steps to positively identify the patient must be taken prior to dispensing any subsequent prescriptions.

Guideline: The CPBC's *Professional Practice Policy (PPP-54) – Identifying Patients for PharmaNet Purposes* requires the pharmacist to view one piece of "primary identification" or two pieces of "secondary identification" as verification of a positive identification. If a patient cannot provide the required identification, the prescriber may be contacted to assist with verifying the patient's identity.

Principle 3.1.3 Pharmacists and pharmacy technicians must review the prescription to ensure that it is completed by the prescriber as outlined in the *Methadone Maintenance Controlled Prescription Form Guidelines* (Appendix 3) and that the directions for use appropriately meet the specific needs of the patient and can be accommodated by the pharmacy.

Guideline: Each prescription must be reviewed in detail in consultation with, and consideration given to the specific needs of, the patient. The following list is a sample only:

- Evaluate the end date of the prescription to ensure that the authorization for dispensing does not end on a weekend when the patient will not be able to see a physician for a new prescription.
- Review the prescription directions to determine the dosing schedule (daily witnessed ingestion, divided dose, take-home doses), including the specific days of the week for each witnessed dose or take-home doses, to confirm that the pharmacy operating hours match the dosing schedule.
- Confirm that stamped or preprinted sticker directions do not conflict with written directions.

Any ambiguous or conflicting information identified must be clarified with the prescriber. Should an alteration or change to the prescription be required, it must be done in compliance with the Principles and Guidelines outlined in section 2.2.

3.2 Assessment of a Prescription

Principle 3.2.1

Pharmacists and pharmacy technicians must correctly identify the product as prescribed for 'pain' or 'opioid use disorder' by using the appropriate Drug Identification Number (DIN) or Product Identification Number (PIN) to ensure patient safety and accurate PharmaNet patient records.

Principle 3.2.2

As with all medications a pharmacist **must** review each individual PharmaNet patient record, as stated in HPA Bylaws (Schedule F Part 1), and resolve any drug-related problems prior to dispensing any methadone prescription.

This step is particularly critical for methadone prescriptions as the automated drug usage evaluation (DUE) built into the PharmaNet system does not include methadone. Pharmacists providing methadone maintenance treatment must therefore ensure they maintain their knowledge with respect to potential drug interactions related to methadone. General information in this regard can be found in Appendix 7.

Guideline: A PharmaNet patient record review must be completed for all prescriptions, including those patients obtaining their prescription on a daily basis or those long-term patients whom the pharmacist may know well.

Principle 3.2.3

Mood altering drugs, including benzodiazepines and narcotics, are not generally prescribed to patients on the methadone maintenance program. Should a patient present a prescription for a mood altering drug or if the pharmacist discovers that a mood altering drug is also being prescribed to the patient in their review of the PharmaNet patient record, they must contact both the prescriber of methadone and, if different, the prescriber of the mood altering drug, prior to dispensing the medication. The purpose of the consultation is to ensure the prescriber(s) are aware that the patient is currently on the methadone maintenance program.

Guideline: The pharmacist should document the outcome of the consultation(s) with the prescriber(s) and attach it to the original prescription.

Principle 3.2.4

The 'sig field' on the prescription label must include the start and end dates of the original current prescription.

Principle 3.2.5

As required by HPA Bylaws Schedule F Part 1 the 'dispensing date' on the prescription label must accurately reflect the actual date dispensed on the PharmaNet system.

3.3 Preparing Methadone Prescriptions

Principle 3.3.1

Methadone doses must be accurately measured in a calibrated device that minimizes the error rate to no greater than 0.1 ml.

Guideline: 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.

Principle 3.3.2

Reconciliation procedures must be conducted in accordance with *Professional Practice Policy (PPP-65) – Narcotic Counts and Reconciliations*.

Guideline: As per *PPP-65,* the pharmacy manager must ensure that narcotic counts and reconciliations, which include methadone, are completed:

- At a minimum of every 3 months, and
- After a change of manager, and
- After a break-in or robbery.

Reconciliation means the quantity of methadone on hand must equal the quantity received minus the quantity dispensed over a specific period of time.

3.4 Loss or Theft and Disposal of Methadone

Principle 3.4.1

The Narcotic Control Regulations require that pharmacists report the loss or theft of controlled drugs and substances to the Office of Controlled Substances, Health Canada within 10 days of the discovery of the loss or theft.

In the event of a loss or theft the pharmacy should also notify the CPBC as soon as possible.

Guideline: The form for reporting loss or theft of narcotics can be found on the CPBC website **www.bcpharmcists.org** under *Resources.*

Principle 3.4.2

Methadone, like any other narcotic or controlled drug, can only be disposed of with authorization from Health Canada and after being rendered unusable.

Guideline: To receive authorization to dispose of methadone the pharmacist must submit a written *Authorization to Destroy for Expired Narcotic and Controlled Drugs* to the Office of Controlled Substances, Health Canada.

An acceptable method of rendering methadone unusable is to place the product in a leak-proof container or plastic bag and add kitty litter until the mixture is almost solid.

Once the required authorization is received from Health Canada the pharmacist must record the amount of product to be disposed of, having a second healthcare professional sign for the disposal, and place the now rendered unusable product in the pharmacy's medication return container.

3.5 Methadone in Tablet Form for Air Travel

Principle 3.5.1

Hand luggage restrictions governing the transportation of fluids in air travel may be problematic for patients and in certain circumstances may necessitate the prescription of methadone in tablet form. Only commercially available methadone in tablet form may be dispensed. Pharmacists need to be aware that the prescription of methadone in tablet form may result in increased risk for both patients and the public.

Note: dispensing of methadone powder by way of sachet, capsule, or other format is never acceptable due to the increased potential for diversion and misuse.

Guideline: Long-term methadone maintenance treatment clearly limits patients' ability to travel because of the need for regular follow-up as well as the restrictions associated with the dispensing of methadone. If patients receiving MMT wish to travel for a period of time that exceeds their regular carry period, the usual standard of care should not be compromised, particularly if the patient is not stable and still requires daily supervised ingestion.

Patients are significantly limited in their ability to transport methadone across international borders but it is possible to arrange for methadone dispensing in some jurisdictions. The CPSBC advises physicians to research each case to ensure decisions do not compromise patient safety. In some cases, patients may require documentation for the purpose of crossing international borders or to assist in accessing temporary care from a methadone program at their destination. The physician is responsible to provide the required travel documentation.

4.0

Releasing Methadone Prescriptions

4.1 Releasing a Prescription

Principle 4.1.1

A pharmacist must be present and witness the release of a methadone prescription to a patient. This function cannot be delegated to a pharmacy technician or any other pharmacy support staff.

Principle 4.1.2

Prior to releasing a methadone prescription the pharmacist must assess the competence of the patient (i.e. ensure that the patient is not currently intoxicated or otherwise mentally impaired) to ensure that it is safe to release the medication to them.

Guidelines: Pharmacists must assess patients for symptoms such as slurred speech, ataxia, drowsiness, alcohol smell or unusual behaviour. It is important for the pharmacist to be familiar with each patient's 'normal' behaviour in order to be able to detect significant deviations from normal.

If the pharmacist believes that it is not safe for the patient to receive their prescription they must consult with the prescriber and document the outcome of the dialogue and attach it to the original prescription.

Principle 4.1.3

Prior to releasing a methadone prescription the patient and pharmacist must acknowledge receipt by signing a patient/prescription-specific log (the sample *Methadone Part-Fill Accountability Log* (Appendix 9) can be used for this purpose).

Guidelines: Every part-fill dispensed must be accounted for. The pharmacist must be able to review every part-fill dispensed as a complete history on one document.

The pharmacist releasing and the patient receiving the part-fill of the prescription must sign for each witnessed ingestion dose and each take-home dose. **Neither the pharmacist nor the patient is permitted to pre-sign for future doses or backdate signing.**

The patient/prescription specific log (the sample *Methadone Part-Fill Accountability Log* (Appendix 9) can be used for this purpose) must be attached to the original Controlled Prescription Program form and once complete filed sequentially by the first prescription or transaction number assigned to the prescription.

Principle 4.1.4

As with all prescriptions, prior to releasing a methadone prescription, the pharmacist must counsel the patient on the risks (including common side effects) and benefits of taking their medication. As per HPA Bylaws Schedule F Part 1 section 12.

Guidelines: The most common adverse reactions with methadone include; sweating, constipation, sexual dysfunction, change in menstruation, drowsiness, sleep disturbances, muscle and bone aches, weight changes (usually gain), skin rash, gastrointestinal upset, headaches and edema. Patients will benefit from information about the non-drug approaches, nonprescription products and prescription items that can provide relief from these side effects.

Principle 4.1.5

With respect to witnessed ingestion doses, the pharmacist must directly observe the patient ingesting the medication and be assured that the entire dose has been swallowed.

Guidelines: Given the concentrated solution of 10mg/ml, it may be helpful to provide a glass of water to the patient to enable rinsing out of the dispensing container to ensure full dose administration.

Immediately following observing the patient's ingestion of the medication the pharmacist should engage the patient in a short conversation to ensure that the entire dose has been swallowed.

Principle 4.1.6

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.

Note:

The decision to authorize take-home doses can only be made by the prescriber. However, should a pharmacist believe that a patient is or is not ready to manage take-home doses they should discuss their recommendations or concerns with the prescriber.

Guidelines: Each dose must be dispensed in an individual, appropriately sized, child-resistant container.

Each container must be individually labeled.

If a pharmacist determines that due to a specific patient circumstance a non-child-resistant container will be used for take-home doses it must be documented on the patient record.

Patients should be reminded that methadone should be stored out of the reach of children, preferably in a locked cupboard or small lock box if stored in the refrigerator.

Principle 4.1.7

In extraordinary situations, when a patient cannot attend the pharmacy, the patient's representative may pick up and sign for their authorized take-home dose(s) if confirmed in writing by the prescriber.

Note:

Patient representative is defined in HPA Bylaws.

Guidelines: This authorization must be date specific, and the representative and circumstances must be clearly defined. The written and signed authorization from the prescriber (fax acceptable) must be attached to the original Methadone Maintenance Controlled Prescription form.

Principle 4.1.8

Delivery of methadone is **prohibited** under federal legislation except as provided for in extraordinary circumstances according to *Professional Practice Policy (PPP-71) – Delivery of Methadone Maintenance Treatment.*

Guidelines: The pharmacist must read and understand *Professional Practice Policy (PPP-71) – Delivery of Methadone Maintenance Treatment.*

Responding to Methadone Dosing Issues

5.1 Divided (Split) Doses

Principle 5.1.1 Only the prescriber, by stating this on the original Methadone Maintenance Controlled Prescription form, can authorize a divided (split) dose of a prescription. Unless otherwise specified by the prescriber, the first portion of the daily dose must be by witnessed ingestion.

Guideline: The decision to authorize a divided dose can only be made by the prescriber however, should a pharmacist believe that a patient would benefit from this they should discuss this option with the prescriber.

5.2 Missed Doses

Principle 5.2.1 Any methadone prescription that has been processed and prepared but is not consumed or picked up by the patient on the prescribed day is considered cancelled and must be reversed on PharmaNet before the end of the business day.

Guideline: It is imperative that the PharmaNet patient record reflects accurate and current information in terms of consumed and picked-up methadone doses as other healthcare practitioners rely on this information in making treatment decisions.

Principle 5.2.2 If a patient misses a dose, they cannot receive the missed dose at a later date.

Principle 5.2.3 The pharmacist must notify the prescriber of any missed doses (unless a specified number of missed doses has been indicated by the prescriber) before the next scheduled release of medication.

Guideline: The notification document must be retained and filed with the prescription consistent with filing retention requirements. The *Pharmacist-Prescriber Communication Form* (Appendix 6) can be used for this purpose.

5.3 Partial Consumption of Doses

Principle 5.3.1 If a patient refuses to consume their full dose, the pharmacist must not insist that they ingest the total amount. The unconsumed portion however cannot be given as a take-home dose.

Guideline: The patient's partial consumption of a dose and their reason(s) for it must be documented and reported to the prescriber. *The Pharmacist-Prescriber Communication Form* (Appendix 6) can be used for this purpose.

All patient documentation including the *Methadone Part-Fill Accountability Log* (Appendix 9) and PharmaNet record must accurately reflect the actual dose consumed by the patient.

5.4 Vomited Doses

Principle 5.4.1

If a patient reports that they vomited their dose, a replacement dose cannot be provided without authorization from the patient's prescriber.

Guideline: The pharmacist must contact the prescriber and provide them with information about the incident (time the dose was taken, time of vomiting, and other relevant points). Should the prescriber authorize a replacement dose, it must be confirmed in writing, signed by the prescriber, received by the pharmacy (fax is acceptable) prior to dispensing the medication and attached and filed with the original prescription.

5.5 Lost or Stolen Doses

Principle 5.5.1

If a patient reports that their take-home dose(s) have been lost, stolen or misplaced, a replacement dose(s) cannot be provided without authorization from the patient's prescriber.

Guideline: The pharmacist must contact the prescriber and discuss the situation with them. Should the prescriber determine that the situation warrants it they may authorize the acceptance of a new Methadone Maintenance Controlled Prescription form by fax (refer to Principle 2.1.3) or the prescriber may advise the pharmacy that they must wait until the patient presents a new original Methadone Maintenance Controlled Prescription form.

5.6 Tapering

Principle 5.6.1

If a patient has decided to initiate a self-tapering regimen by decreasing their daily dose consumption, the pharmacist must record the dose consumed on the patient/prescription specific log (refer to Principle 4.1.3), record the actual dose consumed on the patient's PharmaNet record and notify the prescriber.

Guideline: The *Pharmacist-Prescriber Communication form* (Appendix 6) can be used for the purpose of notifying the prescriber.

5.7 Emergency Dosing

Principle 5.7.1

Emergency dosing is not recommended. If however a pharmacist feels in their professional judgement that an emergency dose is required to ensure continuity of patient treatment the pharmacist may provide an emergency dose. The pharmacist must counsel the patient to obtain a new prescription as soon as possible. This practice is the exception to the rule and not the normal practice, refer to *Professional Practice Policy (PPP-31) – Emergency Prescription Refills*.

Guideline: Pharmacists need to document, as per *PPP-31*, the attempt to reach the prescriber with information about the situation. The prolonged half-life of methadone ensures that a patient maintains a single dose for at least 36 hours. Although the patient may feel uncomfortable an emergency dose may not be necessary. Emergency doses may hinder treatment success and health outcomes. It is a patient's responsibility to make sure they have a valid prescription.

6.0

Continuity of Care

6.1 Transfer of Pharmacy

Principle 6.1.1 When a patient chooses to move from one pharmacy to another to receive their methadone prescription it is the responsibility of the new pharmacy to contact the previous pharmacy and prescriber (if applicable) to discuss the exact transfer date and any other pertinent concerns. The previous pharmacy must cooperate fully with the request from the new pharmacy.

Guideline: Communication between the previous and new pharmacy is critical to ensure the patient's continuity of care and to avoid duplicate or missed methadone doses. A review of the patient's PharmaNet patient record can be of assistance in determining the previous pharmacy and prescriber.

6.2 Hospitalization or Incarceration

Principle 6.2.1 When a patient is discharged or released to the community from a hospital or correctional facility it is the responsibility of the community pharmacist receiving the patient to verify the date and amount of the last dose administered.

Guideline: Effective communication sharing among those who provide the patient's methadone maintenance treatment (hospital or correctional facility and pharmacy) is essential to ensure the patient's continuity of care and to avoid duplicate or missed methadone doses.

6.3 Compounding in Exceptional Circumstances

Principle 6.3.1 The only situation that would constitute consideration of exceptional circumstances is when a commercially available 10 mg/ml oral preparation is not available.

Principle 6.3.2 Methadone for maintenance must be at the strength of 10 mg/ml to ensure minimization of errors.

Principle 6.3.3 A compounding log must be established to record when methadone solutions are prepared, how much was prepared, and who prepared the product. The *Compounding Log* (Appendix 8) can be used for this purpose.

Guideline: The compounding log must incorporate the following elements:

- Preparation date,
- Methadone powder and/or liquid concentrate manufacturer's lot number and expiry date,
- Methadone powder and/or liquid concentrate quantity used and quantity prepared,
- Batch number and use-by date assigned by the pharmacy,
- Preparer's and pharmacist's identification.

A separate compounding log must be maintained for each strength of stock solution.

Principle 6.3.4

All concentrated solution containers must be clearly labeled with the drug name, strength, use-by date and appropriate warning labels.

Guideline: If different concentrations are prepared for pain management, they must be easily identifiable with clear labeling. A best practice would be to use different styles of storage container for each concentration or use food grade dyes to differentiate between the different concentrations prepared.

In order to help ensure liquid methadone preparations remain stable for up to 30 days from the date of pharmacy dispensing and to minimize the growth of bacteria, mold and fungus the *American Association for the Treatment of Opioid Dependence (2004)* recommends that pharmacists should:

- Use distilled water for the dilution of methadone products,
- Use new, clean, light-resistant containers for dispensing,
- Refrigerate take-home containers as soon as possible and keep refrigerated until used.

Principle 6.3.5

Methadone for maintenance solutions must be made with full-strength Tang™ or similar full-strength beverage crystals with daily doses (witnessed ingestion or take-home). Plain water is never an acceptable vehicle for dispensing to patients in the methadone maintenance treatment program.

Guideline: The beverage crystals are full-strength when made according to the manufacturer's directions found on the product's packaging.

Dispensing as a standard volume (e.g. all doses dispensed as a volume of 100 mL) is not acceptable.

References

Centre for Addiction and Mental Health. Methadone Maintenance: A Pharmacist's Guide to Treatment (2000)

Centre for Addiction and Mental Health. Methadone Maintenance Treatment: A Community Planning Guide (2009)

Centre for Addiction and Mental Health. Methadone Maintenance Treatment: Recommendations for Enhancing Pharmacy Services (2009)

Centre for Addictions Research of BC (CARBC): Methadone Maintenance Treatment in British Columbia, 1996 – 2008 Analysis and Recommendations (May 2010 Report)

Health Canada. Best Practices: Methadone Maintenance Treatment (2002)

Health Canada. Literature Review: Methadone Maintenance Treatment (2002)

Health Canada. Methadone Maintenance Treatment (2002)

Health Canada. The Use of Opioids in the Management of Opioid Dependence (1992)

British Columbia Centre on Substance Use. A Guideline for the Clinical Management of Opioid Use Disorder

Recommendations for the Use of Methadone for Pain. College of Physicians and Surgeons of BC (2010)

Stockley's Drug Interactions. Pharmaceutical Press (2010)

This Appendix will be updated to align with the amended PPP-66

CPBC Professional Practice Policy 66 – Opioid Agonist Treatment

1. BUPRENORPHINE/NALOXONE POLICY STATEMENTS:

Effective January 1, 2018:

1. Buprenorphine/naloxone maintenance treatment must only be dispensed as an approved, commercially available formulation.
2. The College of Pharmacists of British Columbia (CPBC) *Buprenorphine/Naloxone Maintenance Treatment Policy Guide (2018)* is in force.
3. All pharmacy managers, staff pharmacists, relief pharmacists and pharmacy technicians employed in a community pharmacy that provide pharmacy services related to buprenorphine/naloxone maintenance treatment must:
    a) know and apply the principles and guidelines outlined in the CPBC *Buprenorphine/Naloxone Maintenance Treatment Policy Guide (2018)* and all subsequent revisions,
    b) be familiar with the information included in the most recent version of the British Columbia Centre on Substance Use (BCCSU) *A Guideline for the Clinical Management of Opioid Use Disorder*, and
    c) be familiar with the information included in the product monographs of approved, commercially available formulations.

2. METHADONE POLICY STATEMENT:

1. Methadone maintenance treatment (MMT) must only be dispensed as the commercially available 10mg/ml methadone oral preparation.
2. The CPBC *Methadone Maintenance Treatment Policy Guide (2013)* is in force.
3. All pharmacy managers, staff pharmacists, relief pharmacists and pharmacy technicians employed in a community pharmacy that provide pharmacy services related to methadone maintenance treatment must:
    a) know and apply the principles and guidelines outlined in the CPBC *Methadone Maintenance Treatment Policy Guide (2013)* and all subsequent revisions,
    b) be familiar with the information included in the most recent version of the BCCSU *A Guideline for the Clinical Management of Opioid Use Disorder*,
    c) be familiar with the information included in the commercially available 10mg/ml methadone oral preparation product monographs
    d) successfully complete the mandatory CPBC MMT training program (2013), record self-declaration of training completion in eServices prior to dispensing the 10mg/ml preparation.

4. Upon completion of the mandatory CPBC MMT training program pharmacy managers must educate all non-pharmacist staff regarding their role in the provision of community pharmacy services related to methadone maintenance treatment. (Note: documentation forms that confirm the education of individual non-pharmacist staff members must be signed and dated by the community pharmacy manager and the non-pharmacist staff member and retained in the pharmacy files).

The Methadone Maintenance Policy Statements must be read in conjunction with PPP-71 Delivery of Methadone Maintenance Treatment.

Required References

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:

- CPBC Methadone Maintenance Treatment Policy Guide (2013) and subsequent revisions
- The most recent version of the BCCSU's "*A Guideline for the Clinical Management of Opioid Use Disorder*"
- Most current edition of Methadone Maintenance: A Pharmacist's Guide to Treatment, Centre for Addiction and Mental Health
- Product monographs for the commercially available 10mg/ml methadone oral preparations

3. SLOW RELEASE ORAL MORPHINE POLICY STATEMENTS:

Effective January 1, 2018:

1. Slow release oral morphine maintenance treatment must only be dispensed in approved, commercially available strengths.
2. The College of Pharmacists of British Columbia (CPBC) *Slow Release Oral Morphine Maintenance Treatment Policy Guide (2018)* is in force.
3. All pharmacy managers, staff pharmacists, relief pharmacists and pharmacy technicians employed in a community pharmacy that provide pharmacy services related to slow release oral morphine maintenance treatment must:
    a) know and apply the principles and guidelines outlined in the CPBC *Slow Release Oral Morphine Maintenance Treatment Policy Guide (2018)* and all subsequent revisions,
    b) be familiar with the information included in the most recent version of the British Columbia Centre on Substance Use (BCCSU) *A Guideline for the Clinical Management of Opioid Use Disorder*,
    c) be familiar with the information included in the product monographs of approved, commercially available strengths.

CPBC Professional Practice Policy 71 – Delivery of Methadone Maintenance Treatment

Policy Statement

Under extraordinary circumstances, if the patient has severe restrictions in mobility and if the prescribing physician has provided written authorization on the prescription by signing the declaration, pharmacists may provide home delivery of Methadone Maintenance Treatment (MMT). This practice is the exception to the rule and not normal practice.

Neither the pharmacy manager nor the staff pharmacist may authorize the provision of home delivery for MMT in the absence of the prescriber's authorization on the prescription.

Delivery Standards:

1. **Prescribing Physician Authorization of Home Delivery**

   a. Should the prescribing physician determine that, due to the patient's immobility, delivery is required; the physician may authorize delivery by signing the declaration on the MMT CPP form.

      i. If the pharmacist or pharmacy technician has concerns regarding the authenticity of the prescriber's signature they must contact the prescriber for verification.

      ii. Physicians will not authorize delivery unless patient safety is assured and severe restrictions in mobility have been identified.

      iii. Distance between patient home and pharmacy does not qualify as a severe restriction in mobility.

2. **Home Delivery Schedule and Location**

   If delivery is authorized as noted in section 1 above, the pharmacist must be present to do the delivery and meet the following requirements:

   a. The pharmacist must determine whether home delivery is feasible within the services and resources the pharmacy provides. If the pharmacy does not provide delivery service – it may be appropriate to refer the patient to a pharmacy that can provide the delivery.

   b. If the pharmacy is able to provide home delivery the pharmacist must work with the patient to make appropriate arrangements for delivery. Arrangements must include:

      i. Address for delivery - MMT may only be delivered to a patient's home with a valid street address; delivery to a public location is not permitted.

      ii. Time for delivery

iii. Procedure if patient not available at address to receive methadone delivery including communication of appropriate alternate arrangements for the patient to obtain their prescription.

Note: it is not acceptable for the pharmacist to deliver the methadone to an alternate person or location or to leave the methadone unattended.

3. **Secure Transportation and Storage**

   a. The dispensing pharmacist is responsible for securely transporting and appropriately storing methadone.

   b. Methadone must be transported directly from the dispensing pharmacy to the patient's home address; methadone may not be stored outside of the pharmacy under any circumstances.

4. **Release of Methadone for Maintenance**

   The pharmacist must be present to:

   a. Confirm the identity of the patient.

   b. Assess the competence of the patient.

   c. Witness the release and ingestion of methadone to the patient, this responsibility cannot be delegated to a pharmacy technician or any other pharmacy support staff.

   d. Provide appropriate patient counseling.

   e. If carries are provided, the pharmacist must always witness first dose of the take-home prescription; all subsequent doses must be dispensed in child-resistant containers with explicit warning label(s).

5. **Documentation**

   The pharmacist must:

   a. At the time of release of a methadone prescription the patient and pharmacist must acknowledge receipt by signing a patient/prescription-specific part-fill accountability log. Neither party may 'pre-sign' for future doses.

   b. Document any and all home deliveries of MMT in the patient's record.

   c. Log the home delivery with the address where the delivery was made on the methadone part-fill accountability log.

   d. Document any appropriate follow-up plan in the patient's record.

   e. File the methadone part-fill accountability log with original methadone prescription form.

Background:

Legislation

Federal legislation does not support delivery of narcotics. The Controlled Drugs and Substances Act (CDSA) defines the transport or delivery of narcotics as trafficking, the Narcotic Control Regulations (NCR) limit the transport of narcotics to licensed dealers only.

Controlled Drugs and Substances Act

"Section 2 - Interpretation, Definitions[1]

"traffic" means, in respect of a substance included in any of Schedules I to IV,

(a) to sell, administer, give, transfer, ***transport***, send or ***deliver*** the substance"

Narcotic Control Regulations

"Section 2 - Interpretation, Definitions [2]

"licensed dealer" means the holder of a licence issued under section 9.2.

Dealers' Licenses and Licensed Dealers [3]

8. *(1) Subject to these Regulations, no person* ***except a licensed dealer*** *shall produce, make, assemble, import, export, sell, provide,* ***transport, send or deliver a narcotic.****"*

Pharmacists are required to adhere to the CDSA and its regulations as well as the *Health Professions Act*, *Pharmacy Operations and Drug Scheduling Act* and their *Bylaws*. The College of Pharmacists and the College of Physicians and Surgeons recognize that there are extraordinary circumstances where due to temporary or permanent severe restrictions in mobility patients would require delivery of their methadone for maintenance treatment to ensure best patient health outcomes and continuity of care.

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1 http://laws-lois.justice.gc.ca/eng/acts/C-38.8/page-1.html#h-2

2 http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._1041/page-1.html#docCont

3 http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._1041/page-3.html#docCont

Methadone for Maintenance Controlled Prescription Form Guidelines

Methadone prescriptions can only be accepted when written using an original Methadone Maintenance Controlled Prescription form. When accepting a Methadone Maintenance Controlled Prescription form a pharmacist must ensure that the form is completed by the prescriber as outlined in these guidelines.

Methadone Maintenance Controlled Prescription Form (Example; Figure 1):

These duplicate copy prescriptions are pre-printed with the following information; drug name and strength, prescriber's name, address (optional), College ID number and prescription folio number. These prescription forms are used only for prescribing methadone for maintenance.

Top Section of Form:

Note:

If no 'start day' is indicated in the 'Directions for Use' section of the form the 'prescribing date' becomes the 'start day'.

The prescriber must complete in full, the patient information including; personal health number (PHN), name, address and date of birth. The 'prescribing date' indicates the date that the prescriber saw the patient. The 'Drug Name and Strength' section is preprinted and the prescriber must complete the 'Quantity' section by stating the total quantity of the prescription in numeric and alpha forms.

Under extraordinary circumstances, if the patient has severe restrictions in mobility and if the prescribing physician has provided written authorization on the prescription by signing the declaration, pharmacists may provide home delivery of Methadone Maintenance Treatment (MMT). This practice is the exception to the rule and not normal practice. Refer to *Professional Practice Policy (PPP-71) – Delivery of Methadone Maintenance Treatment.*

Middle Section of Form:

Note:

"DWI except when pharmacy closed" is not an acceptable prescription instruction.

The prescriber must complete the 'Directions for Use' section as follows:

- State the daily dose:
    - the daily dose multiplied by the number of days must equal the total quantity indicated on the prescription, if there is a discrepancy the pharmacist should seek clarification from the prescriber
- Indicate the 'start day' and 'last day':
    - if no 'start day' is indicated, the 'prescribing date' becomes the 'start day'
    - should the 'start day' overlap with, or leave gaps from, an existing prescription the pharmacist should seek clarification from the prescribe
- Indicate any special instructions:
    - may be used to provide special instructions to the pharmacist for example split doses, or special situations for carries.

- Indicate either DWI or CARRIES, if carries are indicated the prescriber must indicate both in numeric and alpha the required number of days per week of witnessed ingestion:
    - if neither of these options are circled the pharmacist is to assume that all doses are DWI
    - if CARRIES has been circled but the specific witnessed ingestion days (ex; Monday and Thursday) have not been noted by the prescriber the pharmacist can determine the days in consultation with the patient. However, the first dose of the prescription and the dose before any carries must be witnessed ingestion. Additionally, the witnessed ingestion doses must be spread evenly throughout the week
    - if CARRIES has been circled but the number of days per week of witnessed ingestion has been left blank the pharmacist must seek clarification from the prescriber
- Authorize the prescription by signing their name in the 'prescriber's signature' box

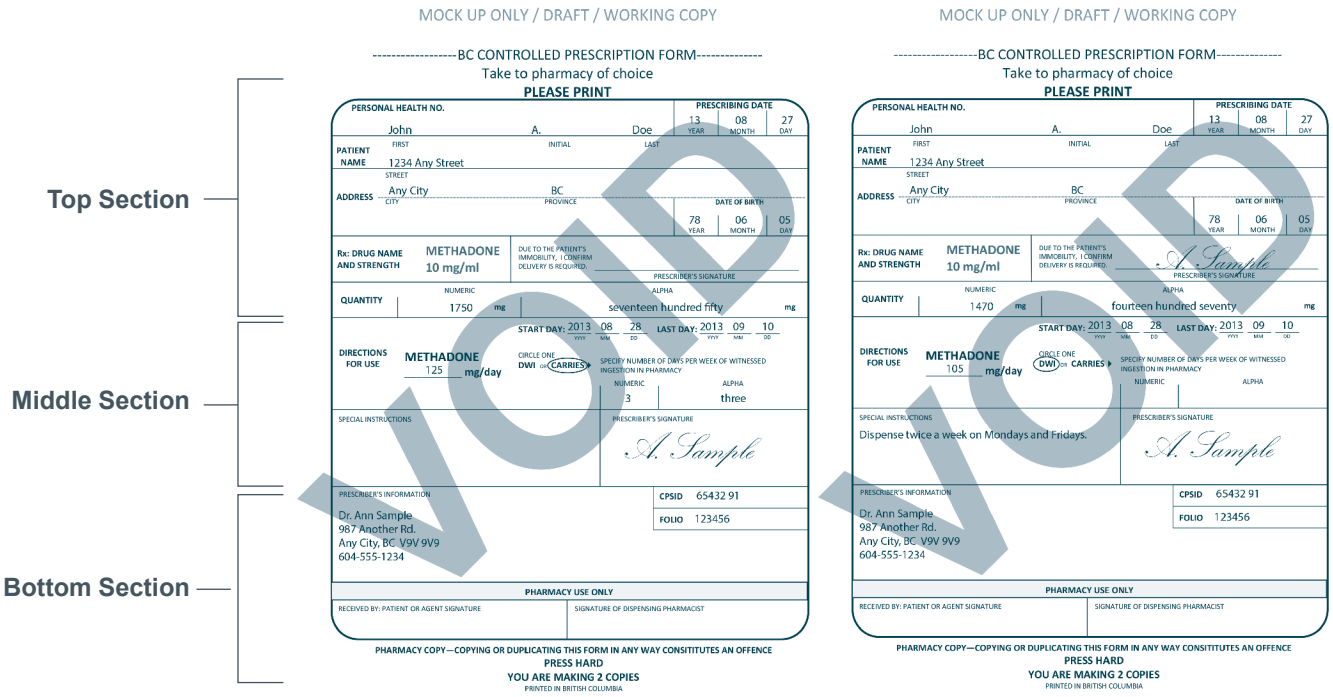
Bottom Section of Form:

Note:

A patient's representative signature is only acceptable with prior written authorization from the prescriber.

As a minimum the prescriber's name, College ID number and prescription folio number will be pre-printed on the form. If the prescribers address is not pre-printed it must be completed by the pharmacist prior to dispensing the prescription. Both the patient and the pharmacist must sign the prescription in the appropriate box.

Figure 1: Methadone Maintenance Controlled Prescription Form



Emergency Fax Methadone Maintenance Controlled Prescription Form Documentation

This form is for the use only in the event of an emergency that requires a faxed Methadone Maintenance Controlled Prescription form which has been initiated following direct consultation between the patient's pharmacist and prescriber.

It is understood that the pharmacist must obtain written documentation from the prescriber prior to dispensing any medication and as such is requesting that the prescriber complete this form and fax back to the pharmacy along with a fax of the Methadone Maintenance Controlled Prescription form as soon as possible.

Prescriber: _____ Patient Name: _____

Pharmacy: _____ Fax Number: _____

Pharmacist: _____ Date: _____

As the prescriber, I request that the above-named pharmacy accept a faxed transmission of the Methadone Maintenance Controlled Prescription form for the above-named patient. I understand that the Methadone Maintenance Controlled Prescription form must be faxed to and received by the pharmacy prior to the pharmacy dispensing methadone. I guarantee that the original Methadone Maintenance Controlled Prescription form will be sent to the pharmacy by the next business day.

Brief description of the emergency situation:

_____

_____

_____

Prescriber's Name: _____

CPSID: _____

Prescriber's Signature: _____

Signature Date: _____

Affix Methadone Maintenance Controlled Prescription form here

Methadone Maintenance Treatment Expectation Form

As your pharmacists, we believe in the principles of the methadone maintenance treatment program, and the valuable role it can play in improving people's lives and their health. We are committed to being an active member of your healthcare team and understand that the success of the program is dependent on ongoing collaboration and communication between yourself, ourselves and your prescriber.

To help you succeed in the program it is important that we both clearly understand the commitment and expectations of each other.

As your pharmacists, you can expect that we will:

- Treat you professionally and respectfully at all times.
- Make ourselves available to discuss any questions or concerns that you may have regarding the program.
- Provide methadone to you exactly as your prescriber has prescribed it and will ensure that they are made aware of any of the following:
    - Missed dose(s) for any reason (ie; failure to pick up, vomited, lost or stolen)
    - Less than full dose consumed (ie; tolerance, self-initiated tapering)
    - Presenting at the pharmacy while intoxicated
    - Prescribing of contraindicated medications (ie; mood-altering drugs)
- Not dispense your methadone (unless directed by your prescriber) to anyone other than you.
- Respect your choice (unless directed by your prescriber) of the pharmacy you wish to have dispense your medication.

As our patient, we can expect that you will:

- Treat all pharmacy staff and other patients respectfully at all times.
- Do your utmost to adhere to the methadone maintenance treatment program as prescribed to you.
- Discuss any concerns you may have regarding your methadone maintenance treatment with us or your prescriber prior to making any adjustments to treatment independently.
- Ensure that any take-home doses of methadone are stored safely and securely.
- Respect the pharmacy's greater community by refraining from loitering or littering.

Pharmacist – Prescriber Communication

Date: _____ Patient Name: _____

To (Prescriber): _____ Patient PHN: _____

Fax: _____ Prescription Form Folio Number: _____

From (Pharmacy): _____ Pharmacy Fax: _____

Pharmacist: _____ Pharmacy Telephone: _____

For Prescriber's Information and Patient Records

☐ This patient missed their methadone dose _____ (dates).

☐ This patient did not take their full daily dose _____ (date) and consumed only ____ mg of the ____ mg prescribed dose.

For Prescriber's Signature and Return of Form to Pharmacy

☐ We require clarity regarding the 'prescribing date' and/or 'start day' for the attached Methadone Maintenance Controlled Prescription form. Please indicate the actual 'prescribing date' (actual date the prescription was written) and dispensing 'start date' or range.

Prescribing Date: _____

Dispensing Start Date or Range: _____

☐ We require clarification and/or a change to the 'Directions for Use' section of the attached Methadone Maintenance Controlled Prescription form.

Description of authorized changes: _____

_____

_____

_____

_____

Prescriber's Name: _____

CPSID: _____

Prescriber's Signature: _____

Signature Date: _____

Affix Methadone Maintenance Controlled Prescription form here

Drug Interactions – General Information

Methadone is extensively metabolized by cytochrome CYP3A4 in liver microsomes. Most drug interactions with methadone are associated with drugs that either induce or inhibit these enzymes.

The sequence of administration of the drugs is the key to evaluating the significance of the interaction. When a patient is stabilized on a drug that affects liver metabolism and methadone is introduced, the interaction may not be observed unless the first drug is discontinued. It is only if a patient is stabilized on methadone and an interacting drug is initiated or discontinued that an interaction may occur.

Drugs that may lower plasma levels (ie; increase the metabolism) of methadone include rifampin, barbiturates, phenytoin and carbamazepine. Drugs that may increase plasma levels (ie; decrease the metabolism) of methadone include ciprofloxacin and fluvoxamine.

Medications that might precipitate a withdrawal syndrome for patients on methadone must be avoided. These are mainly opioid antagonists such as pentazocine, butorphanol, nalbuphine, and naltrexone.

Pharmacists should not rely on PharmaNet to warn of a drug interactions for methadone. The use of PharmaNet is not intended as a substitute for professional judgment. Information on PharmaNet is not exhaustive and cannot be relied upon as complete. The absence of a warning about a drug or drug combination is not an indication that the drug or drug combination is safe, appropriate or effective in any given patient. Health care professionals should confirm information obtained from PharmaNet, and ensure no additional relevant information exists, before making patient care decisions.

Compounding Log

10 mg/ml Stock Solution

Preparation Date	Manufac-turer's Lot Number (Powder)	Manufac-turer's Expiry Date (Powder)	Quantity Used (Powder)	Quantity Prepared (Solution)	Use-By Date (Solution)	Batch Number (Assigned by pharmacy)	Preparer's ID (Initials)	Pharmacist's ID (Initials)

Appendix

9

Methadone Part-Fill Accountability Log

Patient Name: _____

Date Dispensed	Prescription or Transaction Number	Quantity			Delivery Address if Applicable	Pharmacist's Initials	Patient's Signature
		Witnessed	Take Home	Total			

Patient Name: _____

Date Dispensed	Prescription or Transaction Number	Quantity			Delivery Address if Applicable	Pharmacist's Initials	Patient's Signature
		Witnessed	Take Home	Total			

Methadone Information For Patients

What is methadone?

Methadone is a long-acting narcotic medication. Since the mid-1960s methadone has been used as an effective and legal substitute for heroin and other opiates. Methadone maintenance programs help opiate-dependent individuals stabilize their lives and reduce the harm associated with drug use.

How is methadone taken?

Methadone is prepared in a liquid. Doses are usually taken once a day as the effects of a single dose last for about one day. Your physician will write a prescription specifying your dose and how often you need to come to the pharmacy. Initially methadone is prescribed as a daily witnessed dose. As your treatment progresses you may be eligible for take-home doses.

How does methadone work?

Methadone is part of a long-term maintenance program for opiate or heroin dependent people. Drug cravings are reduced without producing a “high.” The goal is to find the dose that will prevent physical withdrawal. The right dose will decrease your drug cravings, and help you to reduce or eliminate heroin use.

How long do I have to stay on methadone?

You should stay on methadone for as long as you experience benefits. Everyone responds differently and methadone can safely be taken for years. If you decide you want to stop taking methadone, you should discuss this with your physician.

Does methadone have side effects?

Methadone is usually tolerated well once the dose is stabilized. Most people experience few, if any, side effects. Please let your pharmacist or physician know if any of these symptoms are bothering you:

- Sweating – This can be due to the methadone itself, or a dose that is too high or too low.
- Constipation – Increasing exercise, fluids and fiber in your diet may decrease this problem.
- Sexual difficulties – This can be either a reduction or an increase in desire.
- Sleepiness or drowsiness – This may be caused by too much methadone. If this occurs consult your doctor to have your dose adjusted. Do not drive a car or participate in activities that require you to be alert when you are drowsy.
- Weight change – An increase in body weight may be due to better health and an improved appetite.

Can methadone interact with other drugs?

Yes. Alcohol and drugs, including prescription, nonprescription, herbal and street drugs, may interfere with the action of methadone in your body. Discuss all medications you are taking with your pharmacist or physician.

Is methadone dangerous?

Methadone is safe to use when it is prescribed and monitored by a physician. It can be very dangerous if used inappropriately. Methadone should never be taken by anybody except the person for whom it is prescribed as overdose and death can occur if the person is not dependent on opiates. Children are especially at risk for overdose and death if they swallow methadone accidentally.

What is my responsibility?

Your responsibility is to drink your methadone dose every day. If you have carries, you must make sure that they are stored safely to prevent possible ingestion by anyone else. If you store your carries in the fridge ensure that they are not accessible. Methadone can be very dangerous if used inappropriately so you must not give or sell your dose to anyone.

Will methadone cure me?

The methadone maintenance program can help you to make positive lifestyle changes. The goal of treatment is to stabilize your body physically and to provide an environment that supports you.

Recommended Reading

Methadone Maintenance Treatment

Provides a general overview of methadone maintenance treatment programs and describes the impact of opioid dependence, methadone pharmacology and benefits. This 16-page document is available at:

http://www.hc-sc.gc.ca/hl-vs/pubs/adp-apd/methadone-treatment-traitement/index_e.html

Literature Review – Methadone Maintenance Treatment

Examines the forty years of accumulated research knowledge and treatment literature about methadone maintenance and reviews the evidence of effectiveness, including cost-effectiveness, the factors that define successful programs, and the program policies associated with the highest success rates. This 86-page document is available at:

http://www.hc-sc.gc.ca/hl-vs/pubs/adp-apd/methadone/index_e.html

Best Practices – Methadone Maintenance Treatment

Provides information on evidence-based best practices in methadone maintenance treatment. It also includes “Insight from the Field” which summarizes comments from experts in the area of methadone maintenance treatment. This 94-page document is available at:

http://www.hc-sc.gc.ca/hl-vs/pubs/adp-apd/methadone-bp-mp/index_e.html

Methadone for Pain Guidelines

http://www.cpso.on.ca/uploadedFiles/policies/guidelines/methadone/Methadone_or_PainGUIDE.pdf

Contact Information

Alberta Health Services Opioid Dependency Program

W: www.albertahealthservices.ca
T: 780-422-1302
F: 780-427-0777

All patients planning to transfer to Alberta should contact the Opioid Dependency Program.

Alcohol & Drug Information and Referral Service

T: 604-660-9382 (24/7)

British Columbia Pharmacy Association

W: www.bcpharmacy.ca
T: 604-261-2092 or 800-663-2840
F: 604-261-2097
E: info@bcpharmacy.ca

British Columbia Centre on Substance Use (BCCSU)

W: www.bccsu.ca
T: 604-806-9142
F: 604-806-9044
E: bccsu@cfenet.ubc.ca

Med Effect Canada (report adverse drug reactions)

Canada Vigilance Regional Office
W: www.healthcanada.gc.ca/medeffect
T: 866-234-2345
F: 866-678-6789
E: CanadaVigilance_BC@hc-sc.gc.ca

College of Pharmacists of British Columbia

W: www.bcpharmacists.org
T: 604-733-2440 or 800-663-1940
F: 604-733-2493 or
E: practicesupport@bcpharmacists.org

College of Physicians and Surgeons of British Columbia

W: www.cpsbc.ca
T: 604-733-7758 or 800-461-3008
F: 604-733-1267

Office of Controlled Substances

T: 613-946-5139 or 866-358-0453 (methadone)
T: 613-954-1541 (thefts or losses)
T: 613-952-2177 (general)
F: 613-957-0110 (thefts or losses)
E: OCS-BSC@hc-sc.gc.ca

Health Protection Branch

Drug diversion of narcotics and controlled drugs

T: 604-666-3350

Non-Insured Health Benefits Program

ESI Canada

W: www.provider.esicanada.ca
W: www.healthcanada.gc.ca/nihb
T: 888-511-4666 (provider claims processing centre)

PharmaCare Help Desk (includes PharmaNet)

www.healthservices.gov.bc.ca/pharme/newsletter/index.html (newsletter)

For Pharmacists

T: 604-682-7120 Lower Mainland
T: 800-554-0250 Elsewhere

For the Public

T: 604-683-7151 Lower Mainland
T: 800-663-7100 Elsewhere

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College of Pharmacists
of British Columbia

Professional Practice Policy #66

Policy Guide

Buprenorphine/Naloxone Maintenance Treatment (2018)

Buprenorphine/Naloxone Maintenance Treatment Policy Guide

All pharmacy managers, staff pharmacists, relief pharmacists and pharmacy technicians employed in a community pharmacy that provides pharmacy services related to buprenorphine/naloxone maintenance treatment (BMT) must know and apply the principles and guidelines outlined here in the College of Pharmacists of BC (CPBC) *Buprenorphine/Naloxone Maintenance Treatment Policy Guide (2018)* and all subsequent revisions.

1.0 Administration

1.1 Pharmacy Operating Hours

Principle 1.1.1 The pharmacy hours of service must be consistent with the dosing requirements of your patient.

Guideline: When a pharmacy accepts a patient who requires daily dispense (i.e., 7 days per week) the pharmacy hours of service need to accommodate this dosing requirement. A pharmacist does not have the independent authority to adapt a prescription for buprenorphine/naloxone maintenance treatment from 'daily dispense' to a 'take-home' dose.

1.2 General Guidance for Pharmacy Professionals

Principle 1.2.1 Provide patient education on how to properly take buprenorphine/naloxone tablets.

Guideline: For example you may instruct the patient to place and hold the tablet(s) under their tongue until it fully dissolves, this may take up to 10 minutes. Avoid swallowing, talking, eating, drinking, and smoking.

Principle 1.2.2 Advise patients to talk to their prescriber and pharmacist about any continuing withdrawal symptoms, cravings, and/or non-medical opioid use. Educate on risks of precipitated withdrawal during buprenorphine/naloxone induction. Educate patients on the inclusion of naloxone in buprenorphine/naloxone formulations and its purpose to deter use in a manner not intended as prescribed.

Principle 1.2.3 Refer colleagues, prescribers, and clinical staff who are unfamiliar with the most recent version of the British Columbia Centre on Substance Use (BCCSU) ~~-~~*A Guideline for the Clinical Management of Opioid Use Disorder*. Recommend completion of online training through the University of British Columbia, Faculty of Medicine~~,~~ Continuing Professional Development's *Provincial Opioid Addiction Treatment Support Program*.

2.0 Receiving Buprenorphine/Naloxone Prescriptions

2.1 Controlled Prescription Program Forms - Overview

Principle 2.1.1 Buprenorphine/naloxone prescriptions can only be accepted when written using an original Controlled Prescription Program form. When accepting buprenorphine/naloxone prescriptions, the pharmacist must ensure that the Controlled Prescription Program Form is completed by the prescriber as outlined in the Controlled Prescription Program.

3.0 Processing (Dispensing) Buprenorphine/Naloxone Prescriptions

3.1 Accepting a Prescription

Principle 3.1.1 Buprenorphine/naloxone for maintenance must be dispensed to patients as an approved, commercially available formulation.

Guideline: Buprenorphine/naloxone is currently available in multiple strengths of sublingual formulations. Tablets can be halved and/or combined to achieve target doses.

Principle 3.1.2 Pharmacists and pharmacy technicians (working within their scope) must review the prescription to ensure that the specific needs of the patient can be accommodated by the pharmacy.

Guideline: Each prescription should be reviewed in detail in consultation with the patient to ensure that the patient's specific needs can be accommodated. For example:

- Evaluate the end date of the prescription to ensure that the authorization for dispensing does not end on a day when the patient will not be able to see a prescriber for a new prescription (e.g., weekends and holidays).
- Review the prescription directions to determine the dosing schedule (daily dispense, take-home doses), including the specific days of the week for each dose or take-home doses, to confirm that the pharmacy operating hours match the dosing schedule.

3.2 Assessment of a Prescription

Principle 3.2.1 Should a patient present a prescription for a mood altering drug, including benzodiazepines and opioids, or if the pharmacist discovers that a mood altering drug is also being prescribed to the patient in their review of the PharmaNet patient record, they must contact both the prescriber of buprenorphine/naloxone and, if different, the prescriber of the mood altering drug, prior to dispensing the medication. The pharmacist must document the outcome of the consultation(s) with the prescriber(s) and include it with the original prescription. The purpose of the consultation is to ensure the prescriber(s) are aware that the patient is currently on the buprenorphine/naloxone maintenance program.

Guideline: Mood altering drugs, including benzodiazepines and opioids, should not be prescribed to patients on the buprenorphine/naloxone maintenance program. Co-ingestion of buprenorphine/naloxone with alcohol or benzodiazepines is contraindicated, as combined effects can potentially result in fatal respiratory depression.

4.0 Releasing Buprenorphine/Naloxone Prescriptions

4.1 Releasing a Prescription

Principle 4.1.1 A pharmacist must be present to release the buprenorphine/naloxone prescription to a patient. This function cannot be delegated to a pharmacy technician or any other pharmacy support staff.

Principle 4.1.2 Prior to releasing a buprenorphine/naloxone prescription the pharmacist must assess the patient to ensure that the patient is not intoxicated, including by centrally-acting sedatives and/or stimulants or in any other acute clinical condition that would increase the risk of an adverse event. If the pharmacist believes that it is not safe for the patient to receive their prescription they must consult with the prescriber and document the outcome of the dialogue and include it with the original prescription.

Guideline: Assess patients for symptoms such as slurred speech, ataxia, drowsiness, alcohol smell or unusual behaviour. It is important for the pharmacist to be familiar with each patient's usual behaviour in order to be able to detect significant deviations.

Principle 4.1.3 Prior to releasing a buprenorphine/naloxone prescription, the patient and pharmacist must acknowledge receipt by signing a patient/prescription-specific log. Every part-fill dispensed must be accounted for. The patient/prescription specific log must be included with the original Controlled Prescription Program form. Once complete, it must be filed sequentially by the first prescription or transaction number assigned to the prescription. The pharmacist must be able to review every part-fill dispensed as a complete history on one document.

Guideline: The sample *Buprenorphine/Naloxone Part-Fill Accountability Log* (Appendix 1) can be used for this purpose.

Neither the pharmacist nor the patient is permitted to pre-sign for future doses or backdate signing.

College of Pharmacists of British Columbia

Principle 4.1.4 If a prescriber orders the buprenorphine/naloxone for daily dispense, the pharmacist is not required to observe the patient ingesting the dose. If the prescriber's intentions regarding witnessing are unclear, the pharmacist must consult with the prescriber to clarify, and the outcome of this consultation must be documented and included with the original prescription.

Guideline: If the prescription states daily dispense, the patient may ingest the dose without pharmacist observation.

Patients should be given instructions on how to take the dose. For example you may instruct the patient to place and hold the tablet(s) under their tongue until it fully dissolves, this may take up to 10 minutes. The patient should avoid swallowing, talking, eating, drinking, and smoking.

Principle 4.1.5 If a prescriber orders the buprenorphine/naloxone to be dispensed as a 'Daily Witnessed Ingestion' or 'DWI', the pharmacist must directly observe the patient placing the medication under the tongue. If the prescriber's intentions regarding witnessing are unclear, the pharmacist must consult with the prescriber to clarify, and the outcome of this consultation must be documented and included with the original prescription.

Guideline: Patients should be given instructions on how to take the dose. For example you may instruct the patient to place and hold the tablet(s) under their tongue until it fully dissolves - this may take up to 10 minutes. The patient should avoid swallowing, talking, eating, drinking, and smoking.

The patient is not required to remain in the pharmacy once the pharmacist has directly observed the patient placing the medication under the tongue.

Principle 4.1.6 If take home doses (carries) are prescribed, the first dose does not need to be witnessed, unless ordered by the prescriber. The subsequent take-home doses must be 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. If a pharmacist determines that due to a specific patient circumstance a non-child-resistant container will be used for take-home doses, it must be documented on the patient record.

Guideline: The decision to authorize take-home doses can only be made by the prescriber. However, should a pharmacist believe that a patient is or is not ready to manage take-home doses they should discuss their recommendations or concerns with the prescriber.

Compliance packaging (e.g., blister packaging, pouch packs) may be ordered by the prescriber to discourage diversion and allow for better monitoring during medication call-backs. In these cases, the pharmacy must still ensure that the medications are provided in child-resistant packaging.

Patients should be reminded that buprenorphine/naloxone should be stored out of the reach of children, preferably in a locked cupboard or small lock box.

5.0 Responding to Buprenorphine/Naloxone Dosing Issues

5.1 Missed Doses

Principle 5.1.1 Any buprenorphine/naloxone prescription that has been processed and prepared but is not consumed or picked up by the patient on the prescribed day is considered cancelled and must be reversed on PharmaNet **before the end of the business day**.

Guideline: It is imperative that the PharmaNet patient record reflects accurate and current information in terms of consumed and picked-up buprenorphine/naloxone doses as other healthcare practitioners rely on this information in making treatment decisions.

Principle 5.1.2 If a patient misses a dose, they cannot receive the missed dose at a later date.

Principle 5.1.3 The pharmacist must notify the prescriber of any missed doses before the next scheduled release of medication. The notification document must be retained and filed with the prescription consistent with filing retention requirements.

Guideline: The *Pharmacist-Prescriber Communication* form (Appendix 2) can be used for this purpose.

Principle 5.1.4 If a patient misses 6 or more consecutive days, the prescription must be cancelled.

Guideline: The pharmacist should advise the patient to see the prescriber for a new prescription, as dose adjustment and re-stabilization may be required.

For more information, refer to the BCCSU *A Guideline for the Clinical Management of Opioid Use Disorder* - Appendix 2: Induction and Dosing Guidelines for Buprenorphine/Naloxone.

5.2 Partial Consumption of Doses

Principle 5.2.1 If a patient declines or is unable to consume their full dose, the pharmacist must respect the patient's choice. The unconsumed portion cannot be given as a take-home dose. The patient's partial consumption of a dose and their reason(s) for it must be documented and reported to the prescriber. All patient documentation including the patient-prescription specific log and PharmaNet record must accurately reflect the actual dose consumed by the patient.

Guideline: The *Pharmacist-Prescriber Communication* form (Appendix 2) can be used for the documentation and communication.

The *Buprenorphine/Naloxone Part-Fill Accountability Log* (Appendix 1) can be used for the Part-Fill Accountability Log.

5.3 Lost or Stolen Doses

Principle 5.3.1 If a patient reports that their take-home dose(s) have been lost, stolen or misplaced, a replacement dose(s) cannot be provided. The pharmacist must notify and consult with the prescriber. If the prescriber chooses to authorize a replacement dose, a new original Controlled Prescription Program form must be received by the pharmacy.

5.4 Tapering

Principle 5.4.1 If a patient has decided to initiate a self-tapering regimen by decreasing their daily dose consumption, the pharmacist must record the dose consumed on the patient/prescription specific log (refer to Principle 4.1.3), record the actual dose consumed on the patient's PharmaNet record and notify the prescriber.

Guideline: The *Pharmacist-Prescriber Communication* form (Appendix 2) can be used for the purpose of notifying the prescriber.

Appendix 1

Buprenorphine/Naloxone Part-Fill Accountability Log

Patient Name: _____

Date Dispensed	Prescription or Transaction Number	Quantity				Pharmacist's Initials	Patient's Signature
		Witnessed	Take Home	Total			

Patient Name: _____

Date Dispensed	Prescription or Transaction Number	Quantity				Pharmacist's Initials	Patient's Signature
		Witnessed	Take Home	Total			

Appendix 2

Pharmacist – Prescriber Communication

Date:_____ Patient Name:_____

To (Prescriber):_____ Patient PHN:_____

Fax: _____ Prescription Form Folio Number:_____

From (Pharmacy):_____ Pharmacy Fax:_____

Pharmacist:_____ Pharmacy Telephone:_____

For Prescriber's Information and Patient Records

- ❑ This patient missed their buprenorphine/naloxone dose on _____(date).
- ❑ This patient did not take their full daily dose today _____ (date) and consumed only ____ mg of the ____ mg prescribed dose.
- ❑ This patient's dose has been held due to _____ (reason and date).
- ❑ This patient lost or had their dose(s) stolen _____(dates).
- ❑ This patient's prescription has been cancelled due to _____(number of missed doses).

Additional Information

You May Attach Controlled Prescription Program Form.

College of Pharmacists of British Columbia

College of Pharmacists
of British Columbia

Professional Practice Policy #66

Policy Guide

Slow Release Oral Morphine (SROM) Maintenance Treatment (2018)

Slow Release Oral Morphine (SROM) Maintenance Treatment Policy Guide

All pharmacy managers, staff pharmacists, relief pharmacists and pharmacy technicians employed in a community pharmacy that provides pharmacy services related to SROM maintenance treatment must know and apply the principles and guidelines outlined here in the College of Pharmacists of BC (CPBC) *Slow Release Oral Morphine (SROM) Maintenance Treatment Policy Guide (2018)* and all subsequent revisions.

1.0 Administration

1.1 Pharmacy Operating Hours

Principle 1.1.1 The pharmacy hours of service must be consistent with the dosing requirements of your patient.

Guideline: When a pharmacy accepts a patient who requires daily witness ingestion or daily dispense (i.e., 7 days per week) the pharmacy hours of service need to accommodate this dosing requirement. A pharmacist does not have the independent authority to adapt a prescription for SROM maintenance treatment from 'daily witness' to a 'take-home' dose.

1.2 General Guidance for Pharmacy Professionals

Principle 1.2.1 Provide patient education on how to properly take SROM.

Note: See Principle 4.1.4 for detailed administration requirements.

Principle 1.2.2 Advise patients to talk to their prescriber and pharmacist about any continuing withdrawal symptoms, craving, and/or non-medical opioid use.

Principle 1.2.3 Refer colleagues, prescribers, and clinical staff who are unfamiliar with the most recent version of the British Columbia Centre on Substance Use (BCCSU) *A Guideline for the Clinical Management of Opioid Use Disorder*. Recommend completion of online training through the University of British Columbia Faculty of Medicine~~,~~ Continuing Professional Development's Provincial Opioid Addiction Treatment Support Program.

2.0 Receiving SROM Prescriptions

2.1 Controlled Prescription Program Forms – Overview

Principle 2.1.1 SROM prescriptions can only be accepted when written using an original Controlled Prescription Program form. When accepting SROM prescriptions, the pharmacist must ensure that the Controlled Prescription Program Form is completed by the prescriber as outlined in the Controlled Prescription Program.

3.0 Processing (Dispensing) SROM Prescriptions

3.1 Accepting a Prescription

Principle 3.1.1 SROM for maintenance must be dispensed in approved, commercially available strengths and formulations. Capsule contents cannot be split.

Principle 3.1.2 **Guideline:** Only the once-daily, 24-hour formulation of SROM has been studied in clinical trials for the treatment of opioid use disorder. Other formulations of oral morphine, such as twice-daily, 12-hour sustained- or extended-release formulations, have not been empirically studied in this context and are not recommended. Pharmacists and pharmacy technicians (working within their scope) must review the prescription to ensure that the specific needs of the patient can be accommodated by the pharmacy.

Guideline: Each prescription should be reviewed in detail in consultation with the patient, to ensure that the patient's specific needs can be accommodated. For example:

- Evaluate the end date of the prescription to ensure that the authorization for dispensing does not end on a day when the patient will not be able to see a prescriber for a new prescription (e.g., weekends and holidays).
- Review the prescription directions to determine the dosing schedule (daily witnessed ingestion, take-home doses), including the specific days of the week for each witnessed dose or take-home doses, to confirm that the pharmacy operating hours match the dosing schedule.

3.2 Assessment of a Prescription

Principle 3.2.1 Pharmacists and pharmacy technicians must correctly identify the product as prescribed 'for pain' or 'Opioid Agonist Treatment (OAT)' by using the appropriate Drug Identification Number (DIN) or Product Identification Number (PIN) to ensure patient safety and accurate PharmaNet patient records.

Guideline: Effective June 5, 2017, PharmaCare established PINs for the use of Kadian® SROM as OAT. These PINs are to be used when submitting claims for the various dosing strengths through PharmaNet. Similar to methadone, DINs will be used by pharmacists exclusively for claims for analgesia, and the PINs will be used for claims for OAT.

Prescriptions for Kadian® should specify whether it is designated for analgesia or OAT (i.e., "for OAT" or "for opioid agonist treatment" is to be indicated on the prescription). If there is a question as to whether the prescription is for OAT (i.e., indicated by the dose strength, directions to

"open and sprinkle" capsules for daily witnessed ingestion, or other elements of the prescription), but the prescription lacks the explicit indication "for OAT", the pharmacist should contact the prescriber to confirm the intended use prior to dispensing the medication and properly document any alteration of the prescription.

The claim entered into PharmaNet should match the prescription written by the prescriber. If a claim marked "for OAT" has been entered under the DIN rather than under the PIN for Kadian® for OAT, it must be reversed, following the full standard procedure for reversing a claim entered under the wrong DIN or PIN. Only after a claim has been reversed can it then be re-entered with the correct PIN.

Principle 3.2.2 As with all medications a pharmacist must review each individual PharmaNet patient record, as stated in *HPA Bylaws* (Schedule F Part 1), and resolve any drug-related problems prior to dispensing any SROM prescription. This step is particularly critical for SROM for OAT prescriptions as the automated drug usage evaluation (DUE) built into the PharmaNet system **does not include SROM for OAT**.

Pharmacists providing SROM for OAT maintenance treatment must therefore ensure they maintain their knowledge with respect to potential drug interactions related to SROM.

Guideline: A PharmaNet patient record review should be completed for all prescriptions, including those patients obtaining their prescription on a daily basis or those long-term patients whom the pharmacist may know well.

Principle 3.2.3 Should a patient present a prescription for a mood altering drug, including benzodiazepines and opioids, or if the pharmacist discovers that a mood altering drug is also being prescribed to the patient in their review of the PharmaNet patient record, they must contact both the prescriber of SROM and, if different, the prescriber of the mood altering drug, prior to dispensing the medication. The pharmacist must document the outcome of the consultation(s) with the prescriber(s) and include it with the original prescription. The purpose of the consultation is to ensure the prescriber(s) are aware that the patient is currently on the SROM maintenance program.

Guideline: Mood altering drugs, including benzodiazepines and opioids, should not be prescribed to patients on the SROM maintenance program.

Co-ingestion of SROM with alcohol or benzodiazepines is contraindicated, as combined effects can potentially result in fatal respiratory depression.

4.0 Releasing SROM for OAT Prescriptions

4.1 Releasing a Prescription

Principle 4.1.1 A pharmacist must be present to release the SROM prescription to a patient. This function cannot be delegated to a pharmacy technician or any other pharmacy support staff.

Principle 4.1.2 Prior to releasing a SROM prescription the pharmacist must assess the patient to ensure that the patient is not intoxicated, including by centrally-acting sedatives and/or stimulants or in any other acute clinical condition that would increase the risk of an adverse event. If the pharmacist believes that it is not safe for the patient to receive their prescription they must consult with the prescriber and document the outcome of the dialogue and include it with the original prescription.

Guideline: Assess patients for symptoms such as slurred speech, ataxia, drowsiness, alcohol smell or unusual behaviour. It is important for the pharmacist to be familiar with each patient's usual behaviour in order to be able to detect significant deviations.

Principle 4.1.3 Prior to releasing a SROM prescription, the patient and pharmacist must acknowledge receipt by signing a patient/prescription-specific log. Every part-fill dispensed must be accounted for. The patient/prescription specific log must be included with the original Controlled Prescription Program form. Once complete, it must be filed sequentially by the first prescription or transaction number assigned to the prescription. The pharmacist must be able to review every part-fill dispensed as a complete history on one document.

Guideline: The sample *SROM Part-Fill Accountability Log* (Appendix 1) can be used for this purpose.

Neither the pharmacist nor the patient is permitted to pre-sign for future doses or backdate signing.

Principle 4.1.4 With respect to witnessed ingestion doses, the pharmacist must directly observe the patient ingesting the medication and be assured that the entire dose has been swallowed.

Guideline: SROM has a high risk of diversion, even when administered as witnessed doses (e.g., intact capsules can be 'cheeked' or 'palmed').

To reduce the risk of diversion, daily witnessed ingestion doses should be prepared by opening the capsule(s) and sprinkling the enclosed pellets for immediate ingestion. The patient should be instructed that pellets must not be chewed or crushed.

Pellets may be sprinkled into a 30 mL medicine cup or small cup followed by at least 30 mL of water to ensure that all pellets have been swallowed.

Immediately following observing the patient's ingestion of the medication, the pharmacist should ensure that the entire dose has been swallowed. This may include: engaging the patient in short conversation, asking the patient if there are pellets remaining in their teeth or gums, offering additional water for rinsing, or inspecting the inside of the patient's mouth.

Important Safety Notice: SROM pellets must be swallowed whole. Crushing, chewing, or dissolving slow-release oral morphine capsules or pellets can cause rapid release and absorption of a potentially fatal dose of morphine sulphate.

Principle 4.1.5 If take home doses (carries) are prescribed, the first dose must be a witnessed ingestion. The subsequent take-home doses must be 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. If a pharmacist determines that due to a specific patient circumstance a non-child-resistant container will be used for take-home doses, it must be documented on the patient record.

Guideline: The decision to authorize take-home doses can only be made by the prescriber. However, should a pharmacist believe that a patient is or is

not ready to manage take-home doses they should discuss their recommendations or concerns with the prescriber.
Note that the majority of prescriptions for SROM will be for daily witnessed ingestion (DWI). In exceptional cases, patients may be transitioned to take-home dosing schedules. If a patient's prescription indicates transition to a take-home dosing schedule for SROM, it is best practice to call and confirm with the prescriber.

Compliance packaging (e.g., blister packaging, pouch packs) may be ordered by the prescriber to discourage diversion and allow for better monitoring during medication call-backs. In these cases, the pharmacy still needs to ensure that the medications are provided in child-resistant packaging.

Patients should be reminded that SROM should be stored out of the reach of children, preferably in a locked cupboard or small lock box.

5.0 Responding to SROM Dosing Issues

5.1 Missed Doses

Principle 5.1.1 Any SROM prescription that has been processed and prepared but is not consumed or picked up by the patient on the prescribed day is considered cancelled and must be reversed on PharmaNet **before the end of the business day**.

Guideline: It is imperative that the PharmaNet patient record reflects accurate and current information in terms of consumed and picked-up SROM doses as other healthcare practitioners rely on this information in making treatment decisions.

Principle 5.1.2 If a patient misses a dose, they cannot receive the missed dose at a later date.

Principle 5.1.3 The pharmacist must notify the prescriber of any missed doses before the next scheduled release of medication. The notification document must be retained and filed with the prescription consistent with filing retention requirements.

Guideline: The *Pharmacist-Prescriber Communication* form (Appendix 2) can be used for this purpose.

Principle 5.1.4 If a patient misses 2 or more consecutive doses, the prescription must be cancelled.

Guideline: The pharmacist should advise the patient to see the prescriber for a new prescription, as dose adjustment and re-stabilization may be required.

For more information, refer to the BCCSU *A Guideline for the Clinical Management of Opioid Use Disorder* - Appendix 3: Induction and Dosing Guidelines for Slow Release Oral Morphine.

5.2 Partial Consumption of Doses

Principle 5.2.1 If a patient declines or is unable to consume their full dose, the pharmacist must respect the patient's choice. The unconsumed portion cannot be given as a take-home dose. The patient's partial consumption of a dose and their reason(s) for it must be documented and reported to the prescriber. All patient documentation including the patient-prescription specific log and PharmaNet record must accurately reflect the actual dose consumed by the patient.

Guideline: The *Pharmacist-Prescriber Communication* form (Appendix 2) can be used for the documentation and communication.

The *SROM Part-Fill Accountability Log* (Appendix 1) can be used for the Part-Fill Accountability Log.

5.3 Vomited Doses

Principle 5.3.1 If a patient reports that they vomited their dose, a replacement dose cannot be provided. The pharmacist must notify the prescriber and provide them with information about the incident (time the dose was taken, time of vomiting, and other relevant points). If the prescriber chooses to authorize a replacement dose, a new original Controlled Prescription Program form must be received by the pharmacy.

5.4 Lost or Stolen Doses

Principle 5.4.1 If a patient reports that their take-home dose(s) have been lost, stolen or misplaced, a replacement dose(s) cannot be provided. The pharmacist must notify and consult with the prescriber. If the prescriber chooses to authorize a replacement dose, a new original Controlled Prescription Program form must be received by the pharmacy.

5.5 Tapering

Principle 5.5.1 If a patient has decided to initiate a self-tapering regimen by decreasing their daily dose consumption, the pharmacist must record the dose consumed on the patient/prescription specific log (refer to Principle 4.1.3), record the actual dose consumed on the patient's PharmaNet record and notify the prescriber.

Guideline: The *Pharmacist-Prescriber Communication* form (Appendix 2) can be used for the purpose of notifying the prescriber.

Appendix 1

SROM Part-Fill Accountability Log

Patient Name: _____

Date Dispensed	Prescription or Transaction Number	Quantity				Pharmacist's Initials	Patient's Signature
		Witnessed	Take Home	Total			

Patient Name: _____

Date Dispensed	Prescription or Transaction Number	Quantity				Pharmacist's Initials	Patient's Signature
		Witnessed	Take Home	Total			

Appendix 2

Pharmacist – Prescriber Communication

Date:_____ Patient Name:_____

To (Prescriber):_____ Patient PHN:_____

Fax: _____ Prescription Form Folio Number:_____

From (Pharmacy):_____ Pharmacy Fax:_____

Pharmacist:_____ Pharmacy Telephone:_____

For Prescriber's Information and Patient Records

- ❑ This patient missed their slow release oral morphine dose on _____(date).
- ❑ This patient did not take their full daily dose today _____ (date) and consumed only ____ mg of the ____ mg prescribed dose.
- ❑ This patient's dose has been held due to _____ (reason and date).
- ❑ This patient lost or had their dose(s) stolen _____(dates).
- ❑ This patient's prescription has been cancelled due to _____(number of missed doses).

Additional Information

You May Attach Controlled Prescription Program Form.

College of Pharmacists of British Columbia

11. Legislation Review Committee

Jeremy Walden

Chair of Legislation Review Committee

College of Pharmacists of British Columbia

11 a) Committee Update

College of Pharmacists of British Columbia

Committee Update

October 24, 2018 Meeting

- Consent Agenda Items:
  - DSR amendments
  - Minor amendments to telepharmacy application requirements (removal of Schedules “C” and “E”)

- Regular Agenda Items:
  - DSR Scheduling by Reference Initiative
  - Amendments to PPP-66 training requirements

College of Pharmacists of British Columbia

Committee Update, continued

Key Upcoming Committee Work

- Amendments to the Drug Schedules Regulation

College of Pharmacists of British Columbia

11 b) Drug Schedules Regulation - Scheduling By Reference

College of Pharmacists of British Columbia

Background

- Drugs are scheduled on the Drugs Schedules Regulation (DSR), as follows:

Schedule	Description
Schedule I	Prescription drugs
Schedule IA	Prescription drugs that are part of the Controlled Prescription Program.
Schedule II	Non-prescription drugs retained within the Professional Service Area.
Schedule III	Non-prescription drugs available from the self-selection Professional Products Area
Schedule IV	Drugs that may be prescribed by a pharmacist.

College of Pharmacists of British Columbia

Background, continued

- Health Canada determines whether a drug must be sold by prescription only.
- The CPBC can:
  - Further restrict the conditions of sale of non-prescription products (i.e., Schedule II and III drugs); and,
  - Determine which drugs should be scheduled as IA.

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What Is Scheduling By Reference?

Rather than listing each drug and the schedule it has been assigned, the DSR could just reference the drug schedules established by external organizations – e.g. Health Canada and NAPRA.

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Background, continued

- Prescription drugs: Most PRAs schedule by reference to federal legislation.
- Non-prescription drugs: Most PRAs schedule by reference to recommendations made by NDSAC, a NAPRA committee.
- B.C. is one of the only provinces that maintains its own list of drugs in the DSR. Most amendments are based on NAPRA recommendations.
- The College has the authority to adopt drug scheduling decisions by reference. It has never used that authority.

College of Pharmacists of British Columbia

Issues With Current System

- DSR is not a complete list of scheduled drugs.
- Unintentional inconsistencies between the DSR and national schedules.
- The DSR creates an unintentional barrier to prescribing by other regulated health professionals.
- Under the *Pharmacists Regulation*, registrants may only compound and dispense a drug specified in the DSR.
- Conducting a meaningful independent review of each drug scheduling decision is costly, time-consuming and duplicative.

College of Pharmacists of British Columbia

Example of Scheduling By Reference

- Different provinces have slightly different models for scheduling by reference:
- Alberta example:
  - **Schedule 1 drugs**
    - Drugs on the federal Prescription Drug List
    - Drugs on a schedule to the Controlled Drugs and Substances Act
    - Subject to exceptions determined by the College
  - **Schedule 2 drugs**
    - Drugs designated as Schedule 2 by NAPRA
    - Subject to exceptions determined by the College
  - **Schedule 3 drugs**
    - Drugs designated as Schedule 3 by NAPRA
    - Subject to exceptions determined by the College

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Potential Benefits of Scheduling By Reference

- The DSR will be a complete list of scheduled drugs.
- Federal prescription drug amendments and NAPRA recommendations would be automatically incorporated, creating significant efficiencies.
- If desired, the College can retain its authority to create exceptions to NAPRA's recommendations.
- The DSR will no longer be a barrier to prescribing by other regulated health professionals.
- The College will not be required to duplicate NDSAC's work.

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Potential Issues with Scheduling By Reference

- Drug scheduling decisions would be adopted automatically, unless the College actively decides to make an exception:
  - The College might inadvertently adopt decisions that it does not agree with.

- The College might be seen to be abdicating its authority for drug scheduling:
  - However, Alberta's approach is an example where the College retains their authority.

College of Pharmacists of British Columbia

Recommendation and Next Steps

Recommendation:

- It is recommended that the College pursue drug scheduling by reference.

Next Steps:

- College staff to conduct research on a go-forward approach, consult with legal counsel, liaise with government, and begin drafting an amended regulation, etc.
- Draft DSR amendments will be presented to the Board for approval at their June 2019 meeting.
- If approved, amendments will be filed with the Ministry of Health, and expected to come into force by September 2019.

College of Pharmacists of British Columbia

11 b) Drug Schedules Regulation – Scheduling by Reference

MOTION:

Direct the Registrar to pursue drug scheduling by reference to federal legislation and the National Drug Schedules established by the National Association of Pharmacy Regulatory Authorities (NAPRA), with respect to the Drug Schedules Regulation.

College of Pharmacists of British Columbia

11 c) Professional Practice Policy-66: Amendment to Training Requirements

College of Pharmacists of British Columbia

Background

- PPP 66 requires pharmacists and pharmacy technicians working in a pharmacy that dispenses methadone maintenance treatment (MMT) to complete the College's online MMT training program.
- It does not require completion of a specific training program related to the other OAT drugs (i.e., buprenorphine/naloxone and slow release oral morphine) in PPP-66.
- To date, there has been no identified comprehensive OAT training program tailored to pharmacies.

College of Pharmacists of British Columbia

Background, continued

- In conjunction with the Ministry of Health, BCPhA developed an OAT training program for pharmacy that covers all three OAT medications outlined in PPP-66.
- *Opioid Agonist Treatment Compliance and Management Program for Pharmacy* (OAT-CAMPP) fully launches in January 2019.
- It is comprised of both online and in-person workshop components.

College of Pharmacists of British Columbia

Background, continued

- The intent is to:
  - Train one pharmacist from each pharmacy within six months; and,
  - Phase in a training requirement for all pharmacists dispensing OAT over a two-year period (ending March 31, 2021).
  - This transition time provides flexibility so that pharmacists throughout the province to access the in-person training component.

College of Pharmacists of British Columbia

Proposed PPP-66 Amendment

- Align PPP-66 with the new BCPhA OAT-CAMPP training program.
- OAT-CAMPP would be required for any pharmacist or pharmacy technician working in a pharmacy that dispenses buprenorphine/ naloxone, methadone or slow release oral morphine.
- Pharmacy technicians would only required to complete the online component.
    - The in-person workshop focuses on clinical cases that are not as relevant for pharmacy technicians.
- This will better equip registrants with the tools needed to provide the best care for patients with opioid use disorder.

College of Pharmacists of British Columbia

Proposed PPP-66 Amendment, continued

- Between January 1, 2019 and March 31, 2021:
  - Require either the CPBC MMT training program **or** the OAT-CAMPP for pharmacists or pharmacy technicians working in a pharmacy that dispenses buprenorphine/naloxone, methadone or slow release oral morphine.

- After March 31, 2021:
  - The CPBC MMT training program will sunset.
  - OAT-CAMPP will continue to be required.

College of Pharmacists of British Columbia

Consequential and House-keeping Amendments

- Consequential and housekeeping (e.g., style consistency, formatting, etc.) amendments are proposed to three policy guides under PPP-66:
  - PPP 66-Policy Guide – Methadone Maintenance Treatment (2013);
  - PPP 66-Policy Guide – Buprenorphine/Naloxone Maintenance Treatment (2018); and
  - PPP 66-Policy Guide – Slow Release Oral Morphine Maintenance Treatment (2018).

College of Pharmacists of British Columbia

11 c) Professional Practice Policy-66: Amendment to Training Requirements

MOTION 1:

Approve amendments to Professional Practice Policy-66 Opioid Agonist Treatment (PPP-66) to align with a new opioid agonist treatment training program for pharmacy, as circulated, effective on January 1, 2019.

College of Pharmacists of British Columbia

11 c) Professional Practice Policy-66: Amendment to Training Requirements

MOTION 2:

Amend the following policy guides to incorporate consequential and housekeeping amendments, as circulated, effective on January 1, 2019.

- PPP-66 Policy Guide – Methadone Maintenance Treatment (2013)
- PPP-66 Policy Guide – Buprenorphine/Naloxone Maintenance Treatment (2018)
- PPP-66 Policy Guide – Slow Release Oral Morphine Maintenance Treatment (2018)

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

12. Developing a Pharmacy Professional Master's Degree Program in a Changing Educational Landscape

INFORMATION ONLY

Presenter's Biography

Dr. Patricia Gerber obtained her Pharmacy degree from UBC in 1993. She completed a Pharmacy Practice Residency Program at the Children's & Women's Health Centre of BC in 1994, and obtained her Doctor of Pharmacy (PharmD) degree from UBC in 1997.

Between 1994 and 2008 Dr. Gerber served in various roles at the Children's & Women's Health Centre of BC: as Clinical Pharmacist, Preceptor, Education Coordinator, and Residency Coordinator. Since 2008, Dr. Gerber has served in several educational leadership and scholarly roles at the UBC Faculty of Pharmaceutical Sciences including as Clinical Coordinator and, most recently, as Director of the Graduate PharmD Program.

She has been teaching, designing and developing pedagogical initiatives, and providing leadership in entry-topractice and graduate programs since 1994. She is currently the Director of Degree Programs for Pharmacists at the Faculty.

Dr. Gerber has served as Vice Chair and Acting Chair of the College's Discipline Committee, and is currently a member of the College's Ethics Advisory Committee. She also serves as Faculty in the international Professional Problem-Based Ethics

Presentation Synopsis

Amid the expansion of pharmacists' roles and the advancement of practice, the pharmacy education landscape has seen significant changes marked primarily by the replacement of the B.Sc. Pharm entry-to practice degree with the PharmD degree. Within BC, these changes occurred at a time of evolution of residency programs and the closure of the UBC Graduate PharmD Program. The closure of the latter, which was a major source of professional leaders for over two decades, represents a loss of a path that was meeting some but not all of the profession's needs for individuals equipped to continue to advance the profession.
Although some pharmacists pursue residency training or non-pharmacy-specific programs (e.g. MBA), there is no longer a pharmacy-specific educational path for pharmacists to become professional leaders. This gap presents a new opportunity for developing a different kind of degree program, one that will graduate leaders, innovators, and advocates equipped with knowledge and skills relevant to the advancement of the profession via legislative and regulatory changes, expansion of integrated health teams, and evolving practice models. In this

presentation Dr. Gerber will describe the current efforts to develop a new Pharmacy Professional Master's degree program at the UBC Faculty of Pharmaceutical Sciences.

a place of mind
THE UNIVERSITY OF BRITISH COLUMBIA
Faculty of Pharmaceutical Sciences

Development of a Pharmacy Professional Master's Degree Program In a Changing Educational Landscape

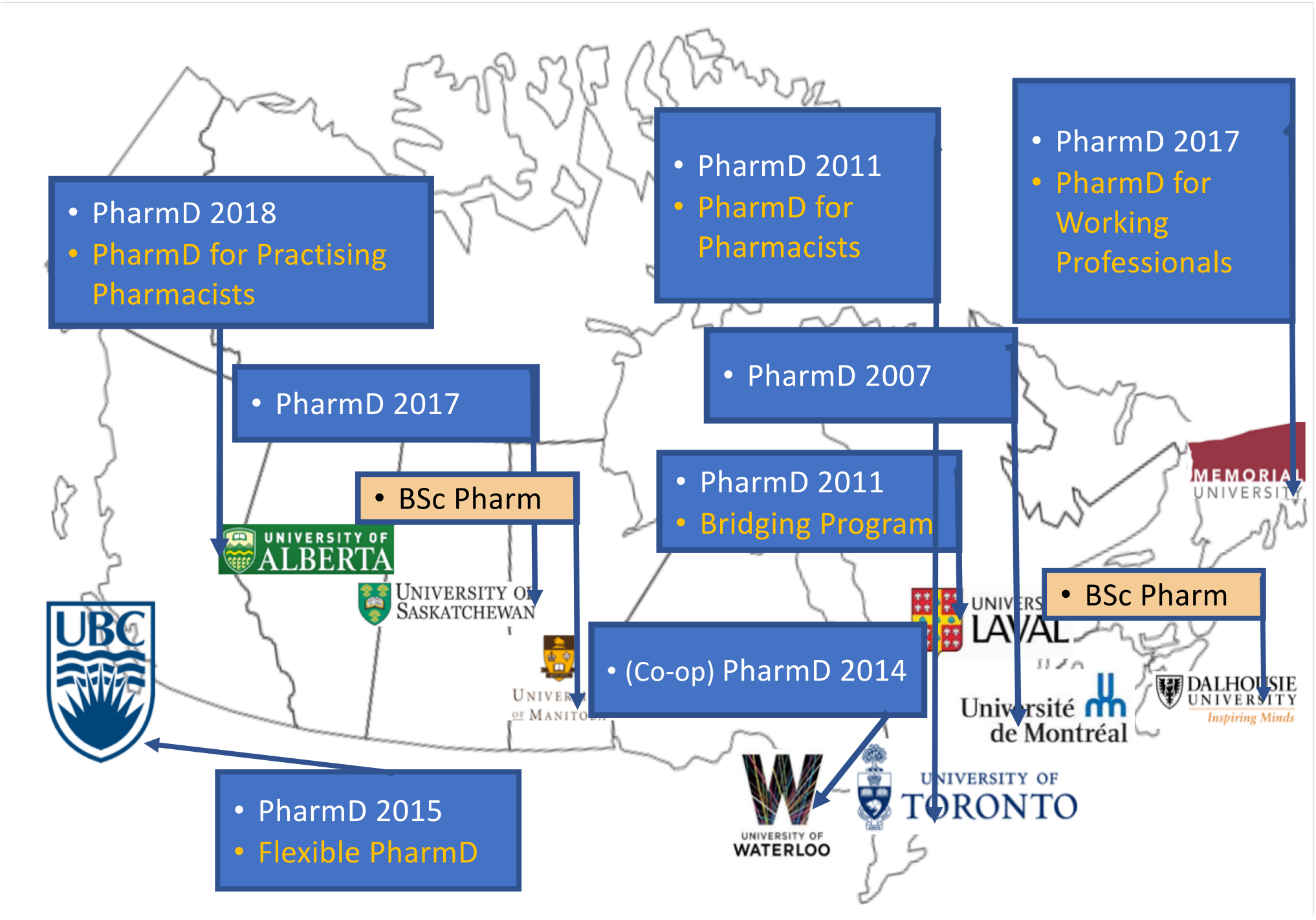
College of Pharmacists of BC
Patricia Gerber, B.Sc.(Pharm), ACPR, Pharm.D., FCSHP
Director, Degree Programs for Pharmacists
November 23, 2018

Agenda

- Evolving pharmacy educational landscape
- Right conditions for developing a new program
- Progress to-date in the development of a Professional Master's degree program
- Your questions

Changes in Pharmacy Education in Canada

1. **Replacement of the BSc with the PharmD as the entry-to-practice degree. Emergence of “bridging” programs.**

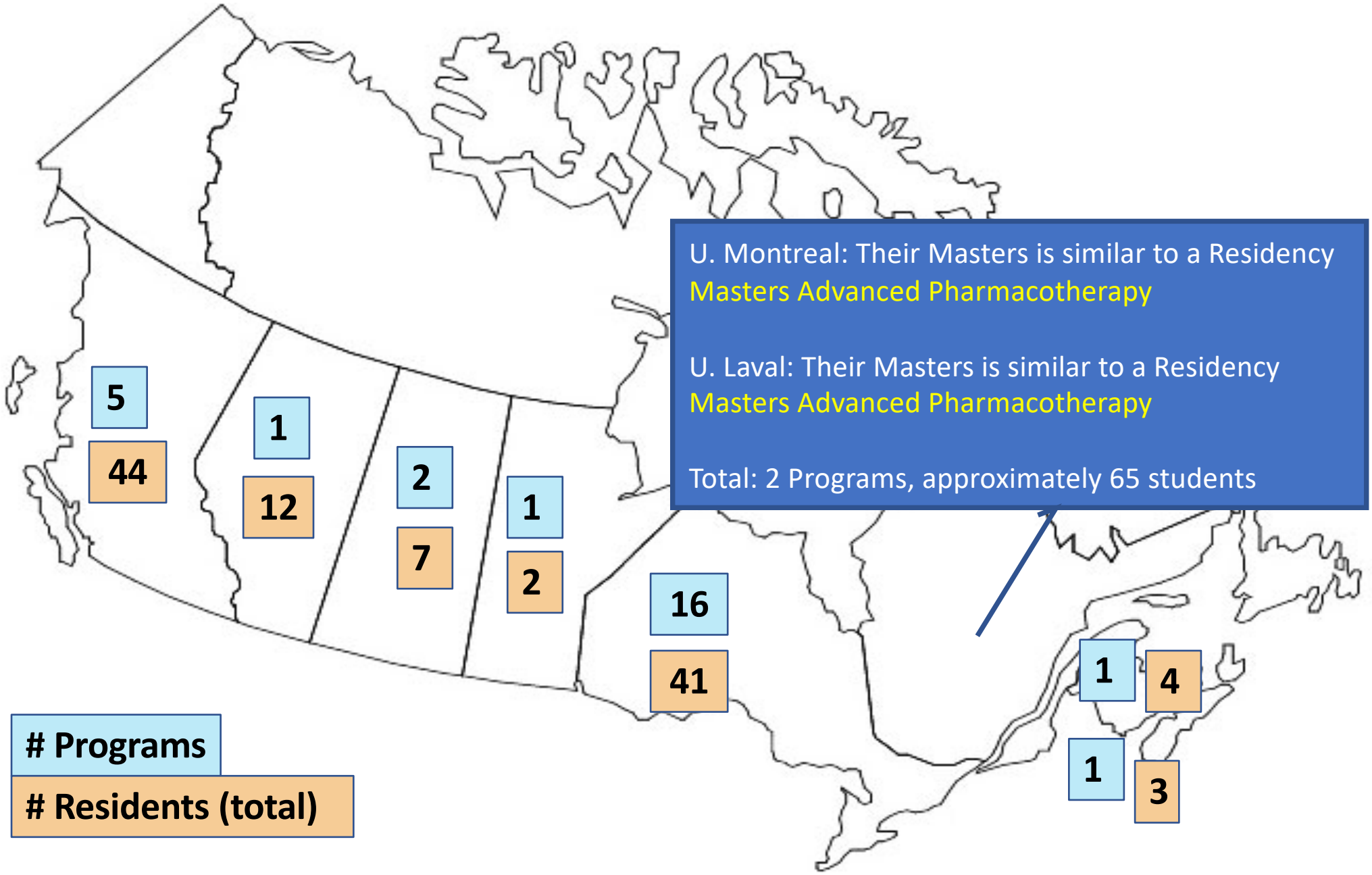

• PharmD 2018
• PharmD for Practising Pharmacists
• PharmD 2011
• PharmD for Pharmacists
• PharmD 2017
• PharmD for Working Professionals
• PharmD 2017
• PharmD 2007
• BSc Pharm
• PharmD 2011
• Bridging Program
• BSc Pharm
• (Co-op) PharmD 2014
• PharmD 2015
• Flexible PharmD
UBC
UNIVERSITY OF ALBERTA
UNIVERSITY OF SASKATCHEWAN
UNIVERSITY OF MANITOBA
LAVAL
MEMORIAL UNIVERSITY
Université de Montréal
DALHOUSIE UNIVERSITY
Inspiring Minds
UNIVERSITY OF WATERLOO
UNIVERSITY OF TORONTO

Changes in Pharmacy Education in Canada

1. The replacement of the BSc with the PharmD as the entry-to-practice degree. Emergence of “bridging” programs.
2. **In BC, evolving Pharmacy Practice Residency Programs.**
    1. **Increased number of residents**
    2. **Advanced (specialized) Residency (Critical Care)**

Residency (ACPR) Programs in Canada

Source: CSHP 2018-2019 Matches for accredited programs

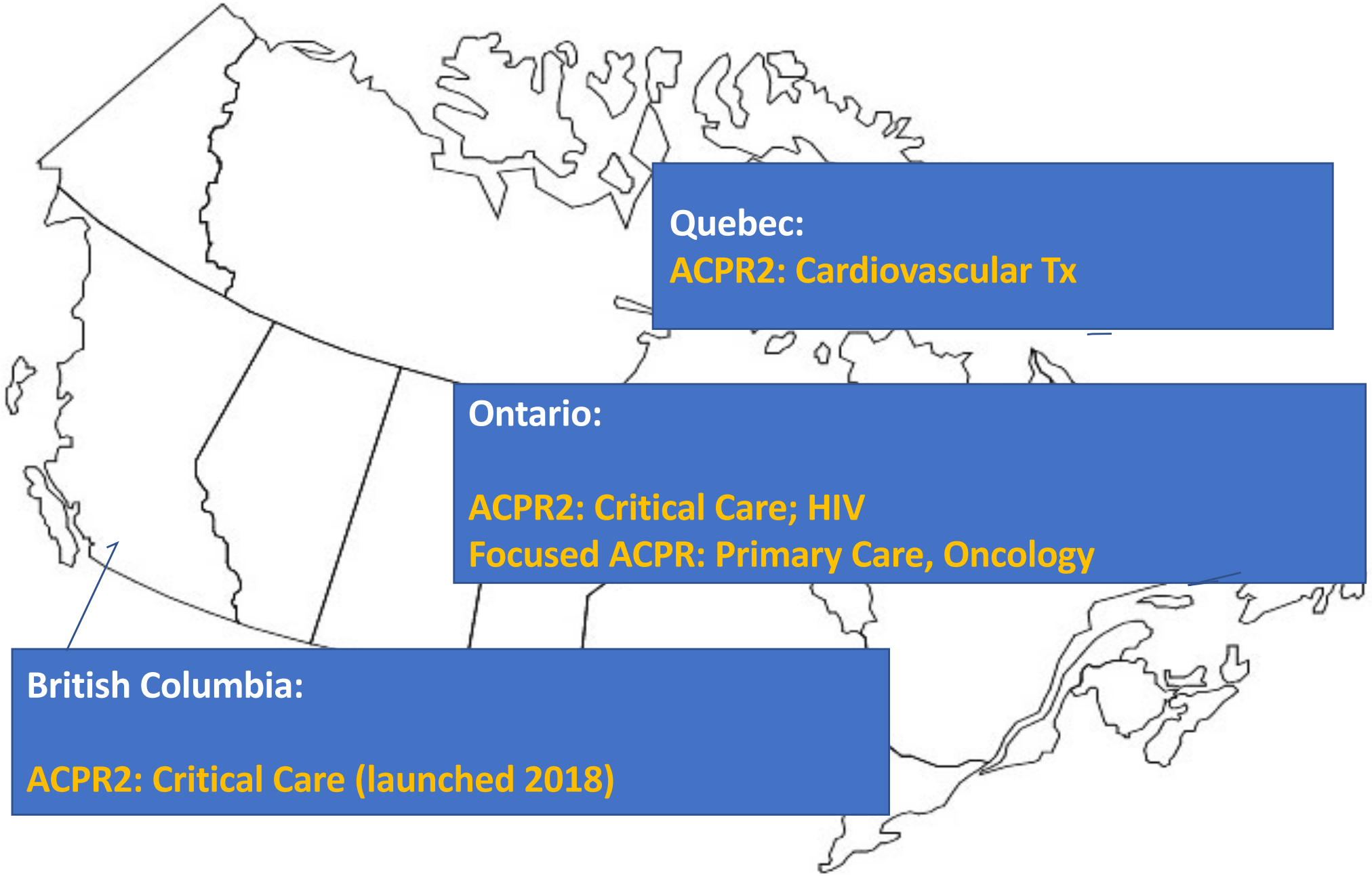


U. Montreal: Their Masters is similar to a Residency Masters Advanced Pharmacotherapy

U. Laval: Their Masters is similar to a Residency Masters Advanced Pharmacotherapy

Total: 2 Programs, approximately 65 students

Beyond ACPR Education in Canada



Quebec:
ACPR2: Cardiovascular Tx

Ontario:

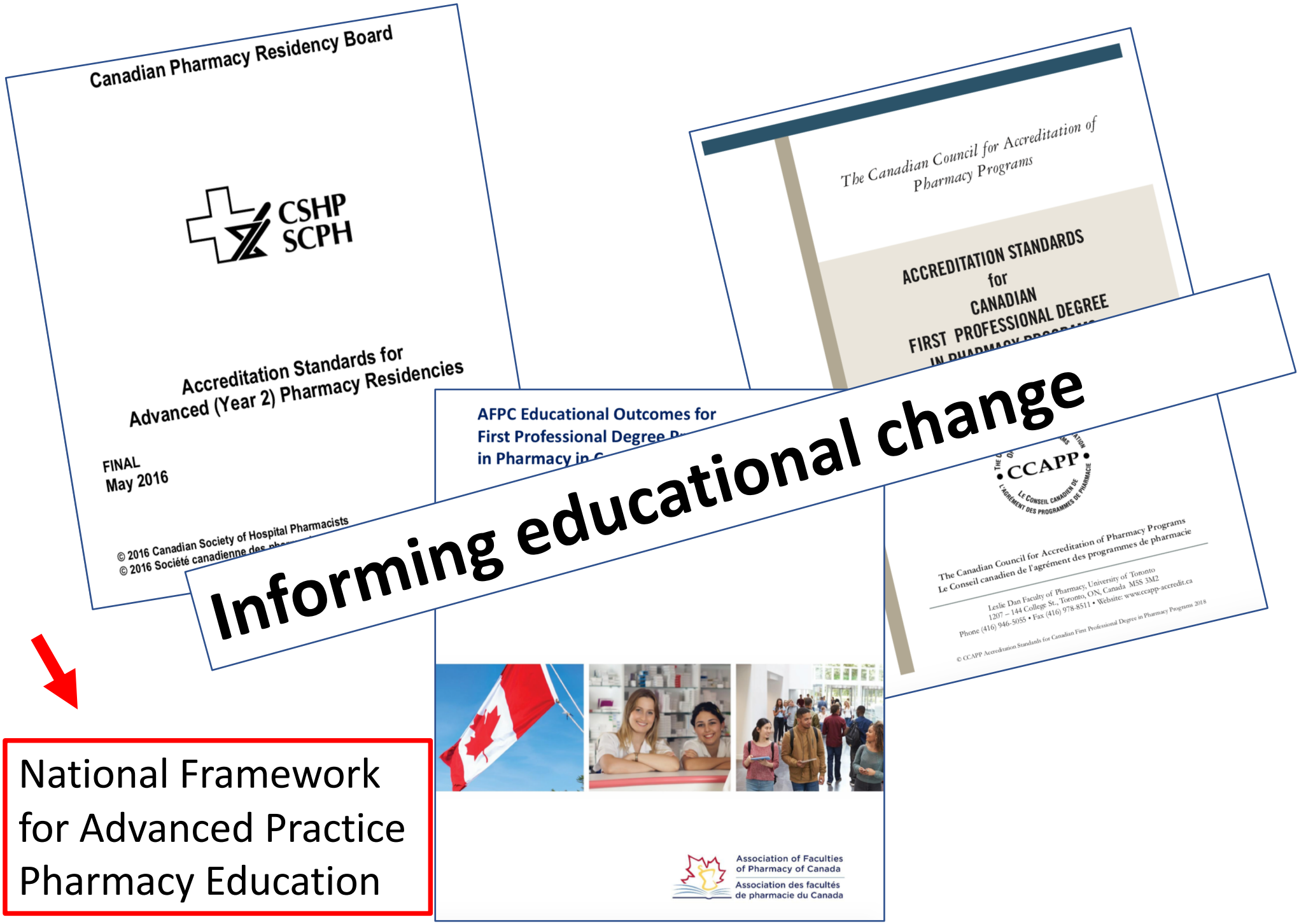
ACPR2: Critical Care; HIV
Focused ACPR: Primary Care, Oncology

British Columbia:

ACPR2: Critical Care (launched 2018)

Changes in Pharmacy Education in Canada

1. The replacement of the BSc with the PharmD as the entry-to-practice degree. Emergence of “bridging” programs
2. In BC, evolving Pharmacy Practice Residency Programs.
    1. Increased number of residents
    2. Advanced (specialized) Residency (Critical Care)
3. **Closure of the UBC Graduate PharmD Program**
    - A major source of professional leadership for > 25 years
    - A loss of a path that was meeting *some* but not all of the profession’s needs for pharmacy leaders



National Framework for Advanced Practice Pharmacy Education

National Framework for Advanced Practice Pharmacy Education in Canada (2018)

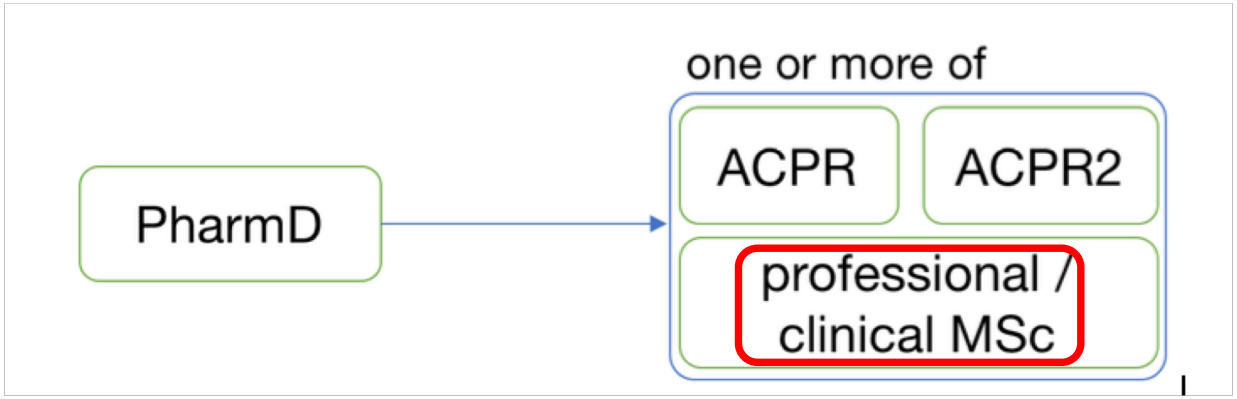
- Discussion document developed by thought-leaders from across the country.

- To develop advanced practice definitions, career identities, and educational pathways.

- To provide clarity about the roles of pharmacists that are attainable through education beyond the entry-to-practice degree.

“Advanced Practice Clinician”

- Practice covers **complex health care issues**.
- **Higher levels of knowledge and skill** over extended period of practice
- Applies **expertise** to assess complex and dynamic situations.
- **Assesses clinical situations** in the absence of evidence/data
- Makes **autonomous decisions** about patient care
- Interprets relevant health care **policy and strategy** to establish policies
- **Role model; leader.**



Spend most of their time:

- Patient care, educating, research

Potential employers:

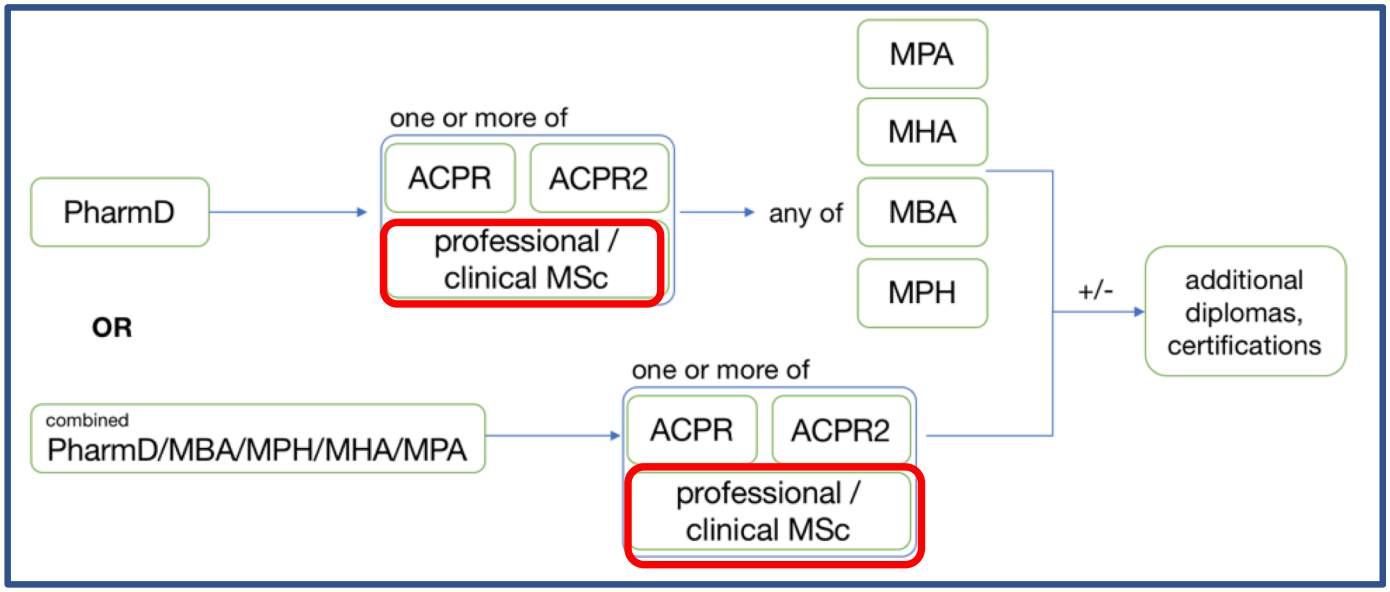
- Hospital, community pharmacy, primary/ambulatory care clinic, academia

“Clinician Leader”

- Participates in **development of policy/ strategy/priorities**; leads integration into strategy.
- Shapes and contributes to the **clinical governance** of the workplace/ organization.
- Influences colleagues, clinicians, managers to share **vision for professional services**.
- Leads efforts to ensure **innovation produces and improvement in service delivery**.
- **Assesses and reassigns resources** to improve effectiveness of use.
- Does **performance management** of the team.
- **Plans and supervises** the implementation of a project.
- **Leads change**

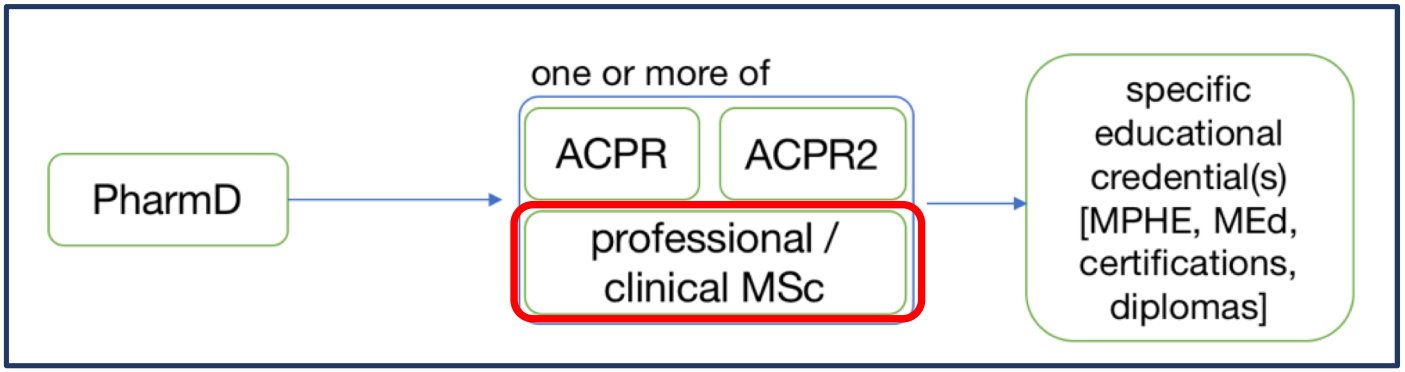
Spend most of their time:
- Administration time

Potential employers:
- Hospital, community/ ambulatory/ primary care, academia, regulatory body, government.



“Clinician Educator”

- **Designs and manages a course** and strives for **excellence in teaching**.
- Engages in **faculty development and/or mentorship** around teaching, **educational leadership**, and/or scholarship.
- Shapes and contributes to **institutional and/or national education policy.**
- Shapes, contributes to the **development of academic programming**
- Conducts or collaborates on **educational research or scholarly activity**.

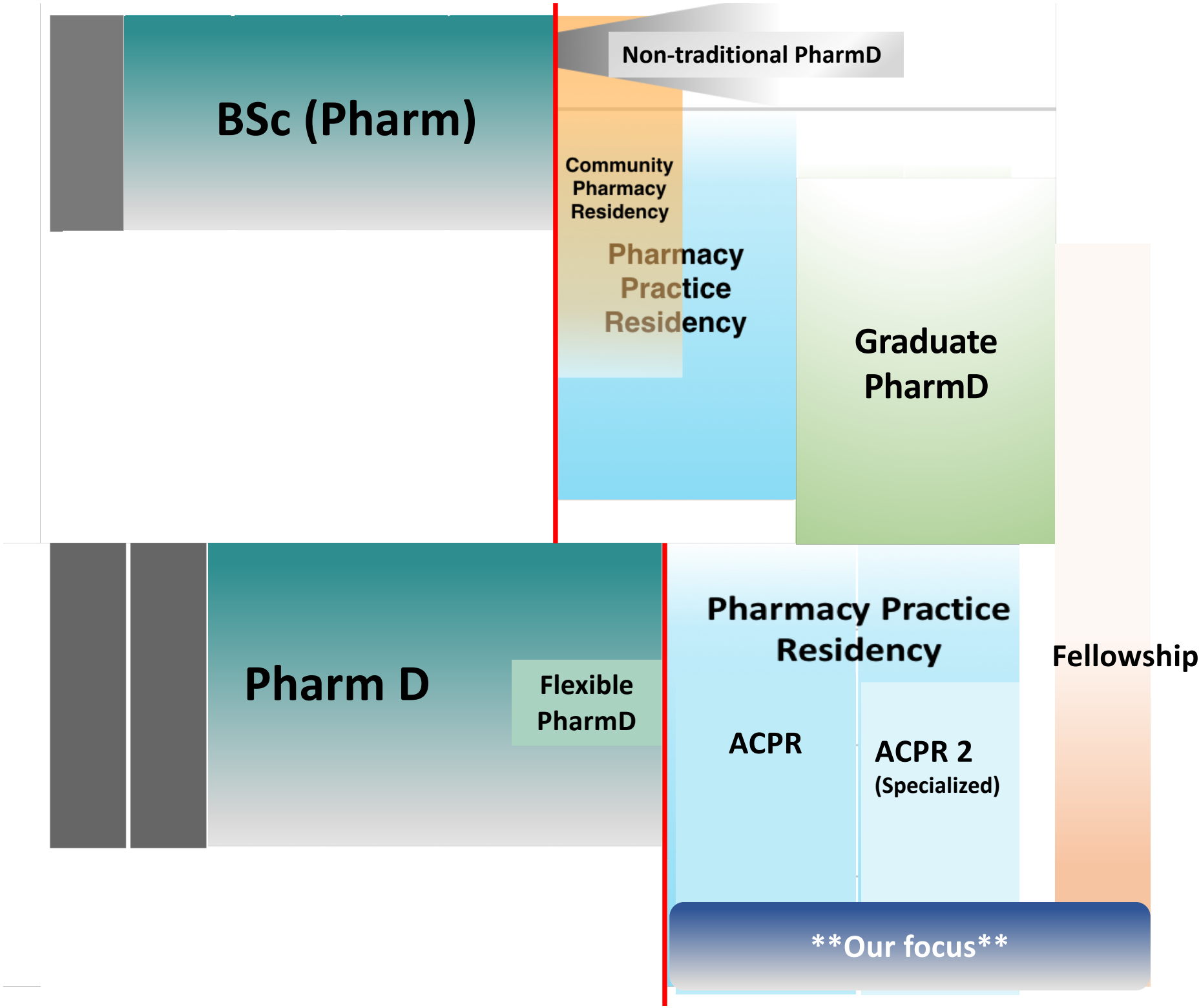


Spend most of their time:

- Protected time teaching/precepting.

Potential employers:

- Hospital, academia, corporate/community pharmacy, primary /ambulatory care.


BSc (Pharm)
Non-traditional PharmD
Community Pharmacy Residency
Pharmacy Practice Residency
Graduate PharmD
Pharm D
Flexible PharmD
Pharmacy Practice Residency
ACPR
ACPR 2 (Specialized)
Fellowship
Our focus

Changes in Pharmacy Education in Canada

1. The replacement of the BSc with the PharmD as the entry-to-practice degree. Emergence of “bridging” programs
2. In BC, evolving Pharmacy P… Programs.
   1. Increased…
   2. Advanced… Care)
3. Closure of the… m
   - A major sour… s
   - A loss of a pa… e profession’s n…

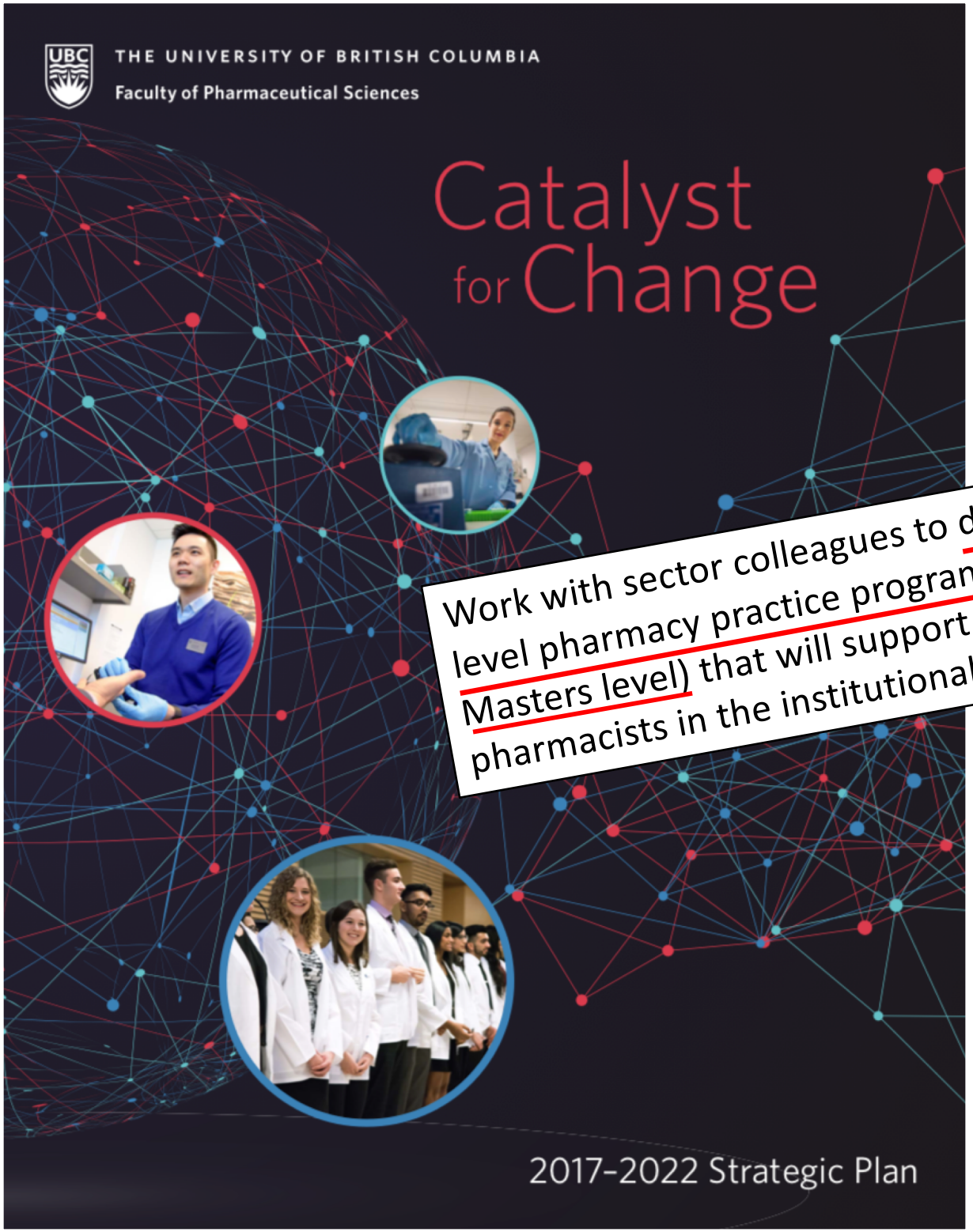
- Some pharmacists pursue residency training or non-pharmacy-specific master's programs (e.g. MBA, MHA)

- There no longer is a ***pharmacy-specific*** **educational path** for pharmacists to become **professional leaders**.

- This gap results in a *new* need:
  - Leaders in the profession
  - Succession planning for stakeholders who hired graduates of the Grad PharmD Program (within in-patient, ambulatory/outpatient care, academia, government settings)

A Gap = A Need = An Opportunity

…not a new idea



Work with sector colleagues to develop and implement advanced level pharmacy practice program(s) (e.g. at the Professional Masters level) that will support career development of pharmacists in the institutional sector and in other high skill areas

Phase 1: Exploratory phase

Consultation process

College of Pharmacists of BC	March 6, 2018
Community Pharmacy Leaders + BCPhA	April 6, 2018
BC Health Authorities Clinical Coordinators	April 10, 2018
Ministry of Advanced Education	May 1, 2018
Primary Care Pharmacists	May 15, 2018
BC Pharmacy Practice Residency Coordinators	May 17, 2018
BC Health Authorities Directors of Pharmacy	May 17, 2018
LMPS Pharmacy Leadership Team	May 22, 2018
UBC Faculty of Pharmaceutical Sciences	May 24, 2018
MOH Pharmaceutical Services Division	June 15, 2018

We asked…

1. What are needs/opportunities for advanced pharmacy education?

2. What could collaboration & partnerships look like?
   - What role could/should the Faculty play?
   - What role could/should other stakeholders play?

Community pharmacy

- ✓ Running a business
- ✓ Collaborating with industry
- ✓ Government affairs
- ✓ Practice design

Health Authorities

- ✓ Advanced clinical skills
- ✓ Teaching and precepting
- ✓ Informatics
- ✓ Medication use evaluation

Primary Care

- ✓ Health technology literacy
- ✓ Medication reconciliation
- ✓ Chronic disease management
- ✓ Basics of cognitive behavior Tx

People
- Managing people
- Conflict management
- Coaching, mentoring
- Difficult conversations

Communication & Teaching
- Motivational interviewing
- Patient interviewing
- Technical writing

Workplace, Context, Culture
- Project management
- Risk management
- Leadership

Pharmacy Practice
- Critical thinking skills
- Collaboration, team-based skills
- Shared decision-making
- Critical appraisal of the literature, application of therapeutic guidelines

Health Systems
- Health policy
- Advocacy
- Public relations
- Quality improvement

Research
- Practice-based research
- Statistics
- Study design
- Ethics approval process

Government

- ✓ Ph'economics
- ✓ Legislation
- ✓ Accounting basics

Academia

- ✓ Teaching
- ✓ Curriculum design
- ✓ SoTL

Other Professional Master's Degree Programs in Canada

Other Pharmacy Professional Master's Programs in Canada

University of Toronto:

Proposed **M. Science in Pharmacy (Clinical)**

University of Waterloo

Proposed **M. Pharmacy in Advanced Pharmacy Practice (Clinical)**

Opportunity to design a program:

- Unique within the Canadian landscape.
- Focused on the the areas identified by stakeholders during the consultative phase.
- Expanding the thinking about “advanced”, to domains *not* traditionally explored
    - In- and out-patient care practice domain…
    - Leadership/management/business domain…
    - Government/regulatory domain…
    - Academic domain….

To graduate pharmacists who are: **leaders, innovators, advocates** equipped with knowledge and skills relevant to the advancement of healthcare.

- Legislative and regulatory changes, expansion of integrated health teams, evolving practice models.

- Equipped for advanced roles within a range of sectors: practice, corporate, government, regulatory

Leveraging partnerships on- and off-campus

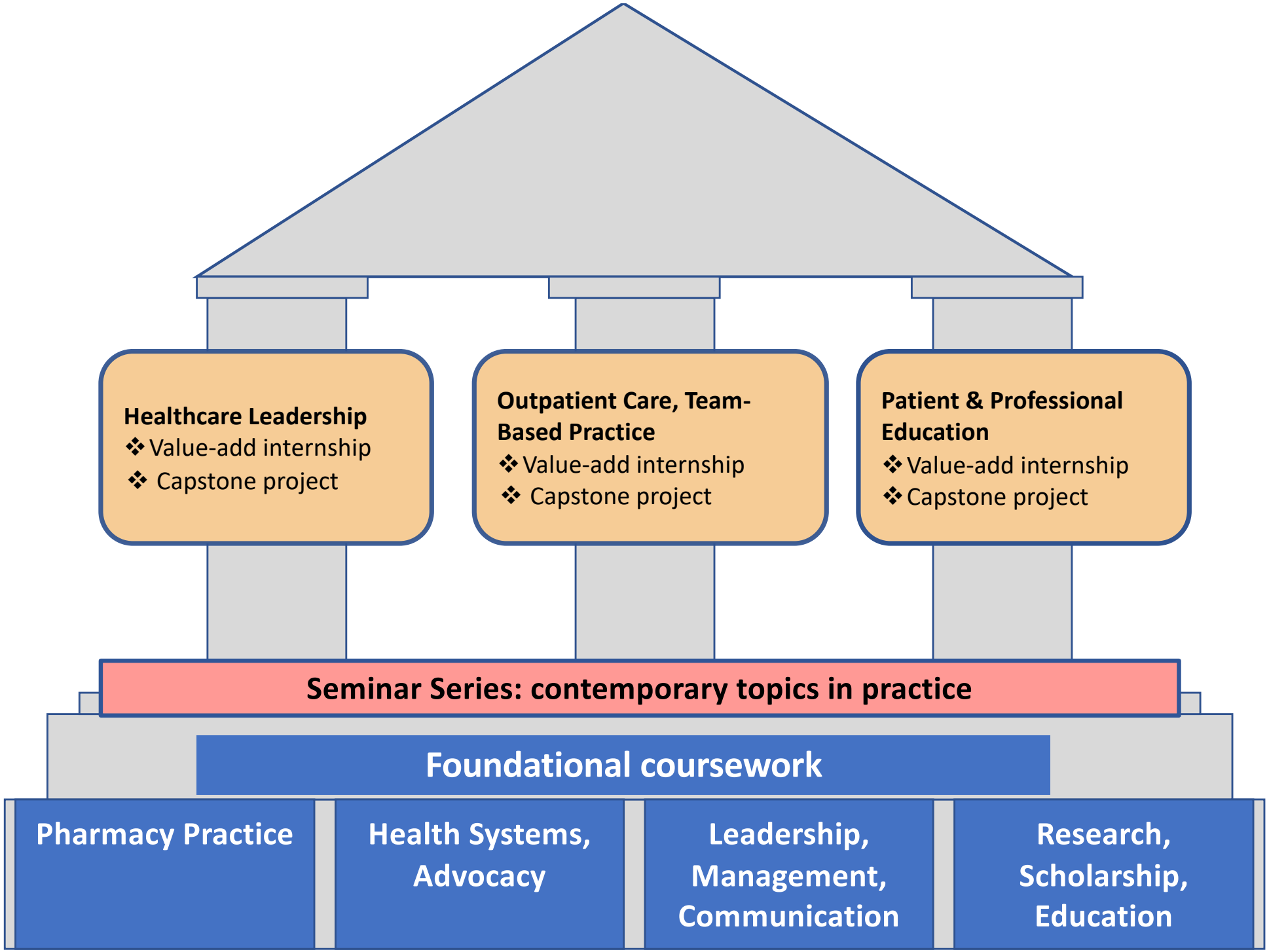

College of Pharmacists of BC
March 6, 2018
Community Pharmacy Leaders + BCPhA
April 6, 2018
BC Health Authorities Clinical
ordinators
April 10, 2018
Ministry of Advan
May 1, 2018
Primary Care Pha
May 15, 2018
BC Pharmacy
May 17, 2018
BC Health Author
cy
May 17, 2018
LMPS Pharmacy Leadership
May 22, 2018
UBC Faculty of Pharmaceutical Sciences
May 24, 2018
MOH Pharmaceutical Services Division
June 15, 2018
June 19, 2018
Large Final Town
Hall

Large Town Hall:

- In attendance: representatives from in-patient care, community practice, health authorities, primary care, regulatory, government, and academia.

Outcome:

- Unanimous in-principle support for development of professional master's degree program


Healthcare Leadership
❖ Value-add internship
❖ Capstone project
Outpatient Care, Team-Based Practice
❖ Value-add internship
❖ Capstone project
Patient & Professional Education
❖ Value-add internship
❖ Capstone project
Seminar Series: contemporary topics in practice
Foundational coursework
Pharmacy Practice
Health Systems, Advocacy
Leadership, Management, Communication
Research, Scholarship, Education

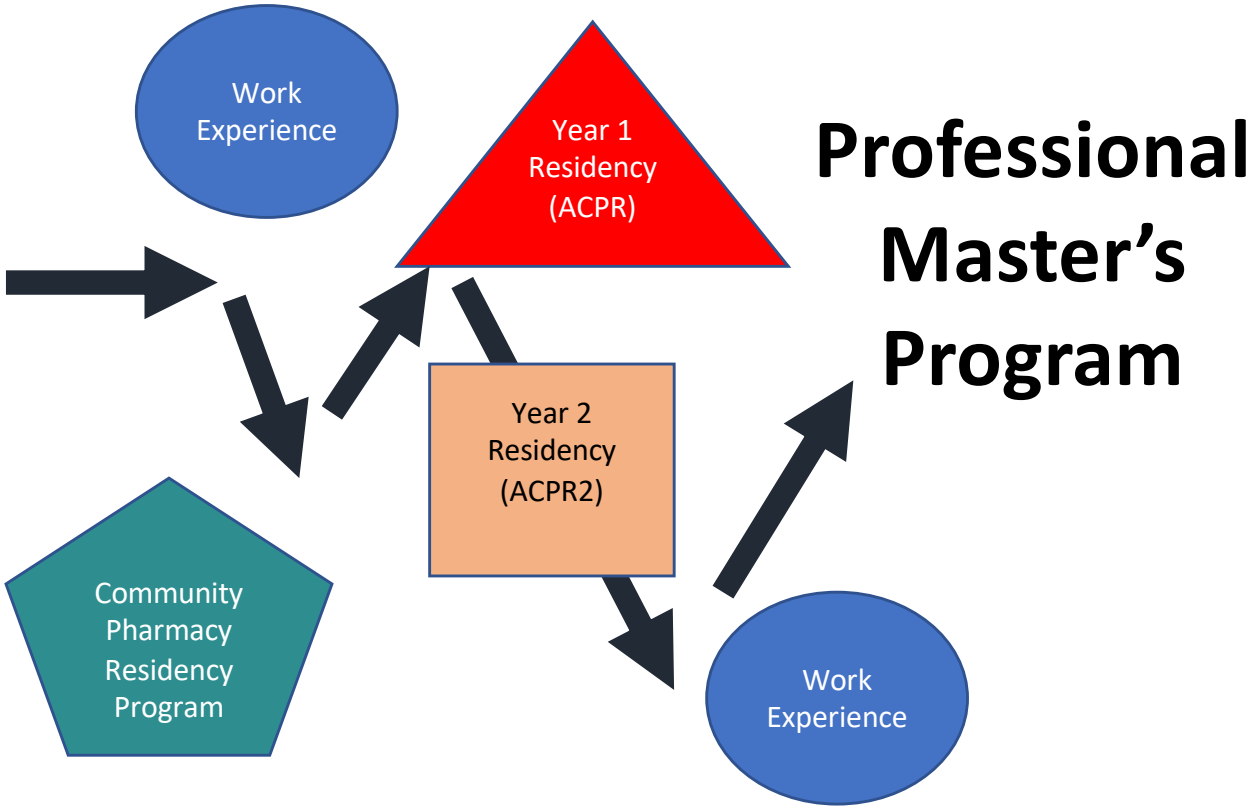
Undergraduate Program

Master's Program

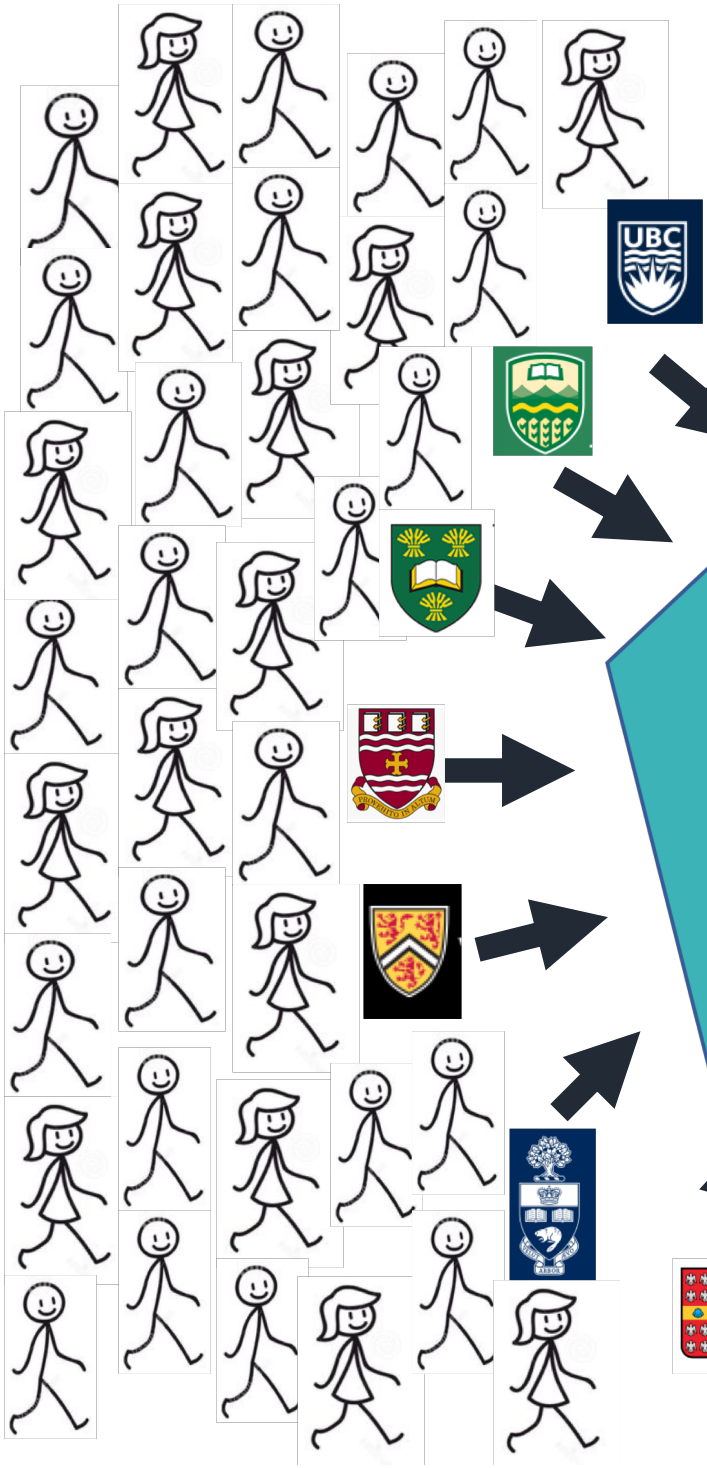
Finding relevance and depth within a focused context

PhD Program

Discovering, inventing, or designing something new

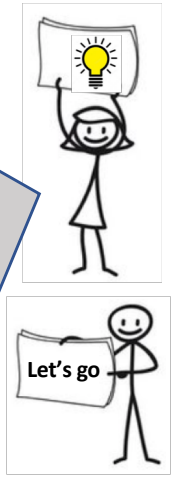


Professional Master's Program



~ 1,200 PharmD graduates per year: **SYSTEM-LEVEL** CHANGE

INDIVIDUAL - LEVEL CHANGE



Professional Master's Program

New generation of leaders who will take on advanced practice roles in evolving and challenging health care environments

Phase 2: Summer 2018

- **Meetings with UBC supporting units**
  - Office of the Vice President Academic
  - Extended Learning
  - Centre for Teaching and Learning Technologies
  - Strategy and Decision Support

- **Market surveys**
  - Feedback from BC pharmacists
    - Assistance: College of Pharmacists of BC, BCPhA, CSHP
  - Feedback from 4th year E2P PharmD students

Market Surveys

Pharmacists: 177 responses

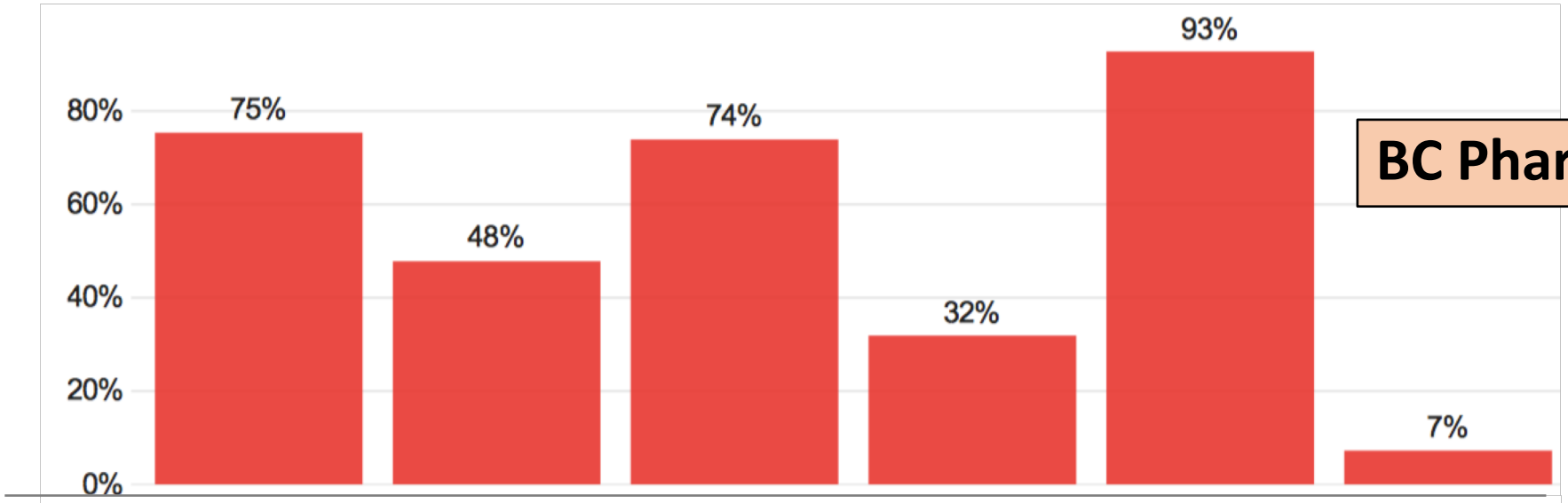
Metropolitan Vancouver	44.8%
Vancouver Island/Coastal	25.9%
Fraser Valley	11.2%
Kootenay/Okanagan	11.2%
Northern BC	2.6%

Health Authority-Based Care	29.9%
Independent Pharmacy	21.4%
General Inpatient Care	20.5%
Chain Pharmacy	17.9%
Long-Term Care	9.4%
Ambulatory Care/Clinic	9.4%
Banner Pharmacy	6.0%
Primary Care	5.1%
Consulting	4.3%
Residential Care	3.4%
Academia	3.4%
Home Care	2.6%
Government	2.6%
Research and Development	0.9%

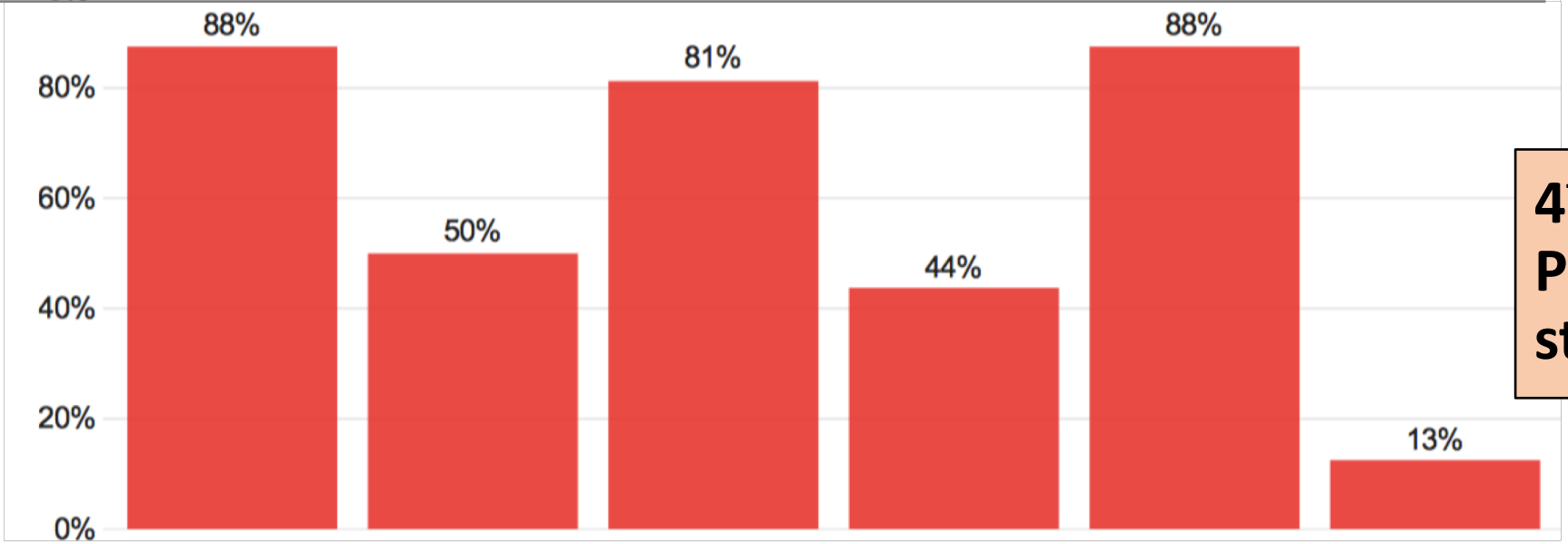
Pharmacy Practice (Hospital Pharmacy) Residency	32.2%
Doctor of Pharmacy degree (Pharm.D.), post-graduate/post-baccalaureate	16.1%
Certified Diabetes Educator	7.6%
Board Certified Pharmacotherapy Specialist	6.8%
Doctor of Pharmacy degree (Pharm.D.), non-traditional/flexible	5.9%
International Pharmacy graduate	5.1%
Master of Business Administration	3.4%
Community Practice Residency	2.5%
Executive Master of Business Administration in Healthcare Management	0.8%
Master of Health Administration	0.8%
Master of Public Health	0.8%
Post-degree Diploma in Mental Health and Addictions	0.8%
MSc in Benchtop Research or Clinical Pharmacy	0.8%

4th Year PharmD Students: 46 responses

This program could present new opportunities for you with regard to...



BC Pharmacists



4th year PharmD students

Career advancement | Higher salary | Personal fulfilment | Marketability | Professional growth | Other, please specify:

BC Pharmacists:

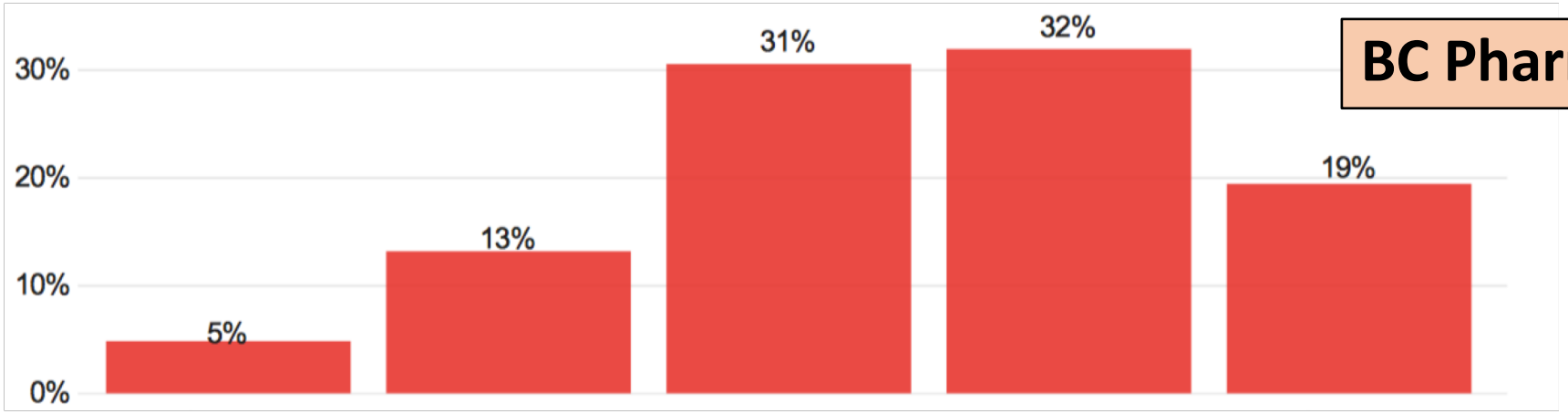
- “Movement towards a ‘second career’ in community practice after clinical work in hospital”

- “Expanding scope of practice for all pharmacists”

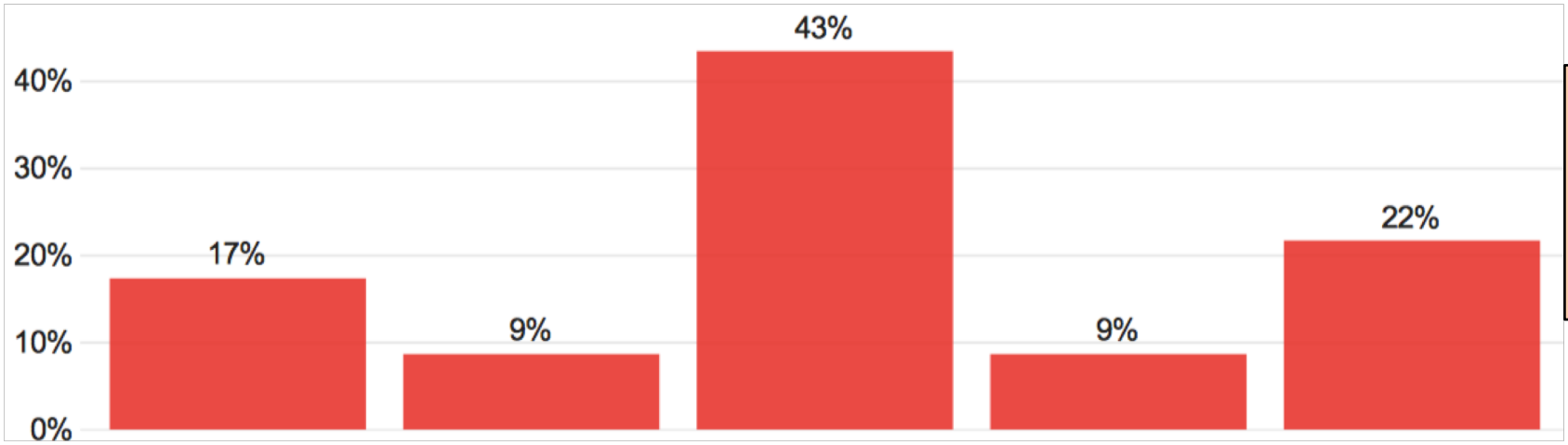
Pharmacy Students:

- “Provide a non-residency advancement”

Would you consider enrolling in the future?



BC Pharmacists



4th year PharmD students

Definitely	Probably Yes	Might or might Not	Probably Not	Definitely Not

Phase 3: September 2018 - Present

- Establishment of a Task Force
- Design and development of the program
- Second phase of consultations with stakeholders

Task Force Membership

- **Dana Cole** - Regional Director, Pharmacy Services, Northern Health
- **Dorothy Cram** - Pharmacist, Pure Integrative Pharmacy
- **Curtis Harder** - Clinical Coordinator, VGH, VIHA
- **Gary Jung** - Manager, Professional Services/Managed Care, Save on Foods
- **Mike Legal** - Clinical Manager, Tertiary Care Sites, Providence Health, Vancouver Acute, RCH, LMPS
- **Walton Pang** - Director, Therapeutic Review & Optimal Use, Drug Intelligence and Optimization Branch, Medical Beneficiary & Pharmaceutical Services Division, BC Ministry of Health
- **Richard Slavik** - Manager, Professional Practice - Pharmacy Services, Clinical Support Services, IH
- **Greg Wheeler** – Pharmacist, Oliver Pharmacy, Westbank Pharmacy
- **Arden Barry**
- **Roxane Carr**
- **Patricia Gerber**
- **Michael Guimond**
- **Sandra Jarvis-Selinger**
- **Peter Loewen**
- **Larry Lynd**
- **George Pachev**
- **Ginette Vallée**
- **Janice Yeung**
- **Peter Zed**

- **Jordan Ho** - Pharmacy Practice Resident
- **Jenah Alibhai** – E2P PharmD Student

GOAL: To provide pharmacists with **a foundation of knowledge and skills** that, ***augmented with experience in challenging health care environments***, will enable them to take on advanced practice roles.

Four Program "themes"

1. Pharmacy Practice
2. Health Systems and Advocacy
3. Leadership, Management, and Communication
4. Research, Scholarship, and Education

Proposed *Principles* for Program Development

- Responsive and committed to serving the needs of patients, the public, and the profession
- In partnership and collaboration with stakeholders
- Transparent communication
- Building on our strengths
- Constructive alignment in curriculum design
- Apply evidence-based approach to curriculum design
- Considering “ideal vs. attainable”
- Sustainable

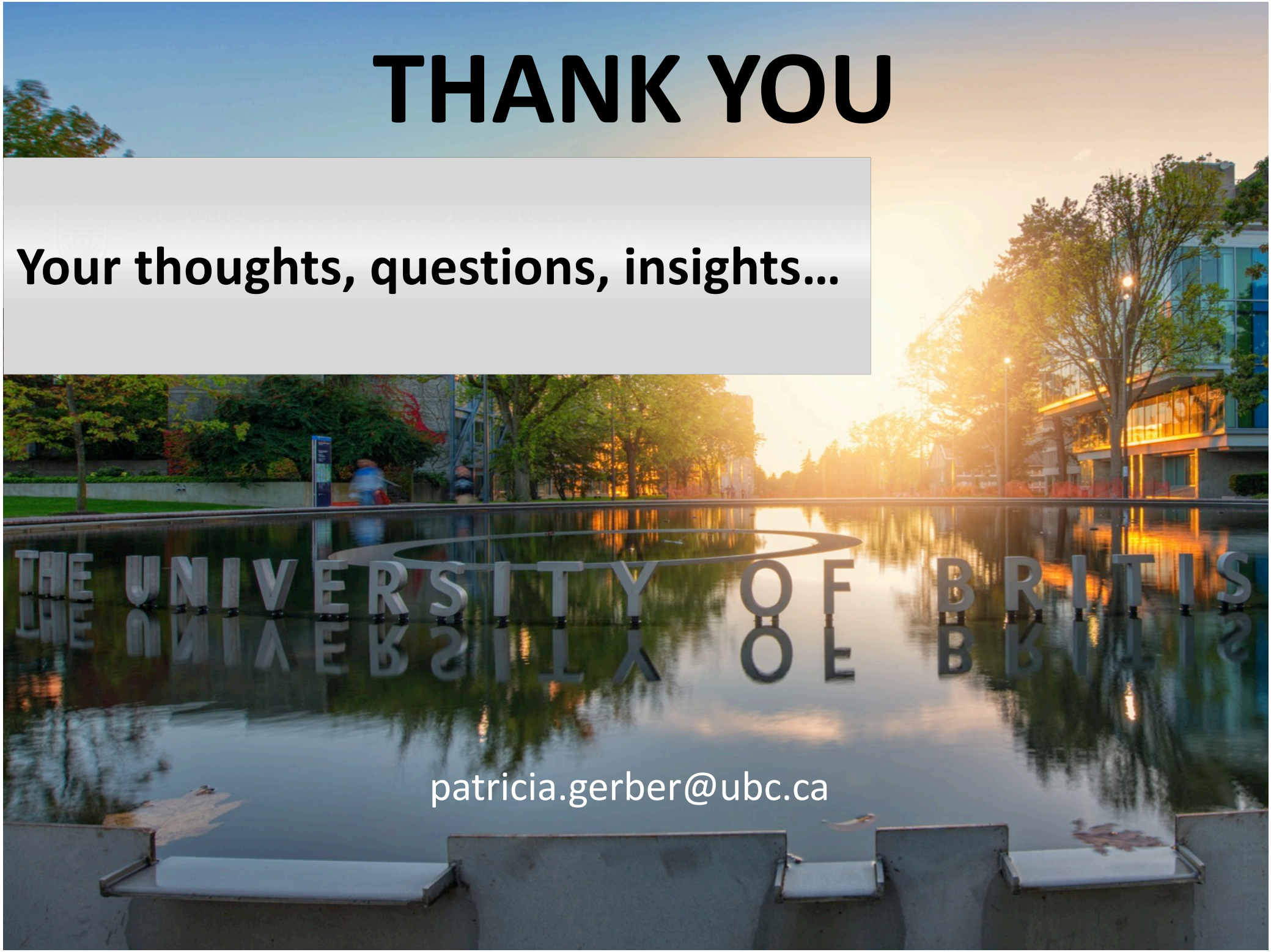
Phase 4: By summer 2019

Submission to:

- ✓ Faculty
- ✓ UBC Curriculum Committee
- ✓ UBC Senate, UBC Board of Governors
- ✓ Ministry of Advanced Education

THANK YOU

Your thoughts, questions, insights…



patricia.gerber@ubc.ca

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

13. Health Canada's Problematic Prescription Drug Use Initiative

INFORMATION ONLY

Presenter's Biography

Angela Lina

Compliance and Enforcement Officer and acting Team Lead, Western Region Problematic Prescription Drug Use (PPDU), Controlled Substances Program, Health Canada.

She has been conducting pharmacy inspections since the launch of this program in 2015.

Prior to this, worked for the Canadian Food Inspection Agency as a microbiologist and a laboratory auditor under ISO 17025 and in the private sector as a Quality Assurance Officer and auditor.

Health Canada Santé Canada

Canada

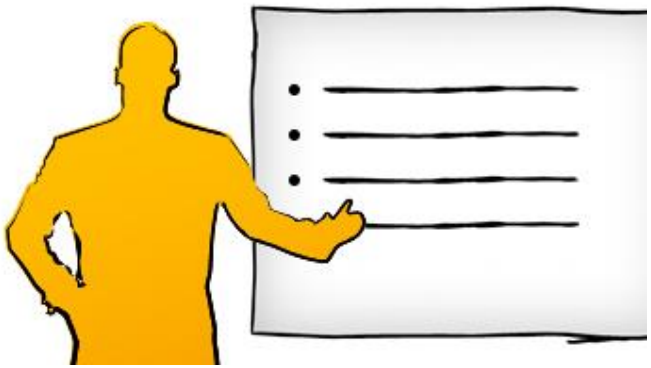
Health Canada's Problematic Prescription Drug Use (PPDU) Initiative

Angela Lina, A/ Team Lead,
Problematic Prescription Drug Use Division,
Western Canada, Controlled Substances Program

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Outline

- CSP Western Mandate/Background
- Problematic Prescription Drug Use Initiative
- Community Pharmacy Inspections
- Expected Results



Health Canada Mission and Vision

- **Health Canada** is the federal department responsible for helping the people of Canada maintain and improve their health.

- **Health Canada** is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity lifestyle and effective use of the public health care system.

Health Canada Santé Canada

Canada's Drugs and Substances Strategy

- Prevention
- Enforcement
- Evidence
- Treatment
- Harm Reduction
- Funding

Health Canada has launched a public consultation on potential next steps in the Canadian Drugs and Substances Strategy (CDSS)

Canada.ca/substance-use-consultation

Health Canada Santé Canada

Your health and safety... our priority. *Votre santé et votre sécurité... notre priorité.*

Canada

Controlled Substances Program

www.hc-sc.gc.ca

Programme des substances contrôlées

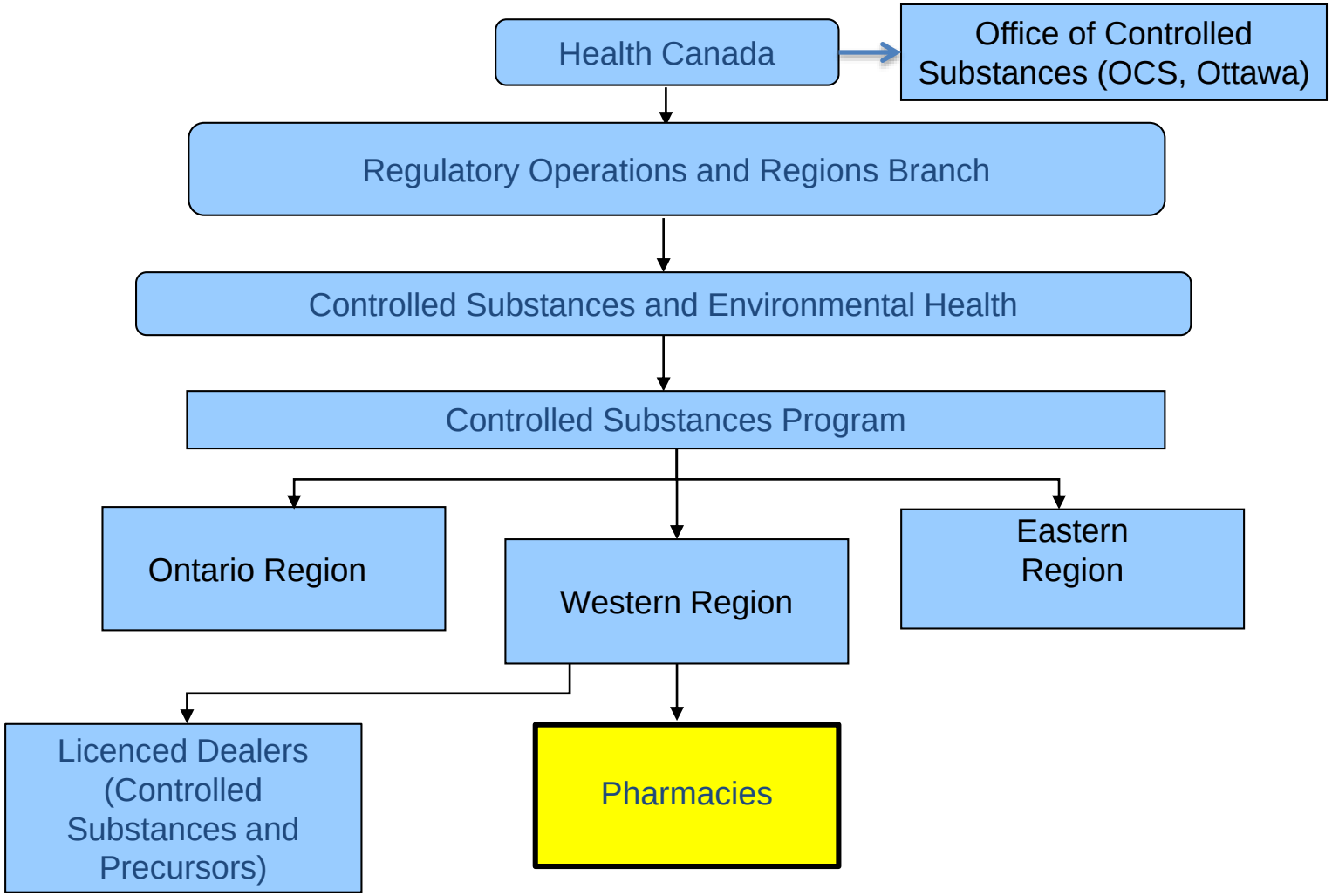
www.sc-hc.gc.ca

Controlled Drugs and Substances Act

Benzodiazepines	Controlled Drugs	Medicinal Marihuana	Narcotics	Precursors	Restricted Drugs
					
Benzodiazépines	Drogues contrôlées	Marihuana à des fins médicales	Stupéfiants	Précurseurs	Drogues d'usage restreint

Loi réglementant certaines drogues et autres substances

Who are we??


Health Canada
Office of Controlled Substances (OCS, Ottawa)
Regulatory Operations and Regions Branch
Controlled Substances and Environmental Health
Controlled Substances Program
Ontario Region
Western Region
Eastern Region
Licenced Dealers (Controlled Substances and Precursors)
Pharmacies

Mandate of the Controlled Substances Program

- Ensuring controlled substances and precursor chemicals are available for recognized medical, scientific and industrial purposes while minimizing the risk of diversion of these substances to illicit markets

- This involves the development of laws, regulations, policies and operations that support the control of illicit drugs and other substances

The Problematic Prescription Drug Use (PPDU) Initiative Objectives:

- To verify, promote and improve pharmacists' compliance with the Controlled Drugs and Substances Act and its regulations
- To strengthen cooperation and communication between Health Canada, pharmacists and their provincial authorities and associations
- To facilitate the exchange of information at the national level to address diversion of prescription drugs and problems related to their problematic use

Canadian Legislative Framework

CDSA

- Narcotic Control Regulations (NCR)
- Food and Drug Regulations-Part G (FDR-G)
- Food and Drug Regulations-Part J (FDR-J)
- Benzodiazepines and Other Targeted Substances Regulations
- Precursor Control Regulations (PCR)

Inspector's Powers - CDSA

- open and examine any receptacle or package
- examine anything found on site
- examine any labels or advertising material or records, books, electronic data
- use or cause to be used any computer system
- reproduce any document from any electronic data
- take labels or advertising material or records, books or other documents
- use or cause to be used any copying equipment
- take photographs and make recordings/sketches
- examine substances and for purposes of analysis obtain samples
- seize & detain any controlled substance, precursor, conveyance or device
- order any person on site to establish their identity
- order any person on site to refrain from, or engage in, a CDSA regulated activity

Pharmacist Obligations – CDSA Regulations

A Pharmacist shall:

- Furnish such information respecting the dealings of the pharmacist in any controlled substance in such form and at such times as the Minister may require;
- Make available and produce to an inspector upon request his special narcotic prescription file together with any books, records or documents which he is required to keep;
- Permit an inspector to make copies of or to take extracts from such files, books, records or documents;
- Permit an inspector to check all stocks of controlled substances on his premises

Compliance and Enforcement Tools

- Compliance Letter
- Targeted Inspections
- Inspection Blitzes (i.e. high opiate purchasers, northern & border communities)
- Import Alerts
- Seizures, Retention, Voluntary Forfeiture
- Warning Letters / Prosecution
- Referral to RCMP or Competent Authority
- Licence Suspension (Licensed Dealers)
- Restricted List (Pharmacists)

What is Problematic Prescription Drug Use

Taking someone else's prescription drugs to self- medicate

X

Taking prescription medication in a way other than prescribed

Taking medication to get high

Problematic Prescription Drugs

Most common types of problematic prescription drugs include:

Opioids: Fentanyl, Oxycodone, Hydromorphone (CDSA Schedule I)

Benzodiazepines: Diazepam, Alprazolam, Lorazepam (CDSA Schedule IV)

Stimulants: Amphetamine, Methylphenidate (CDSA Schedule III)

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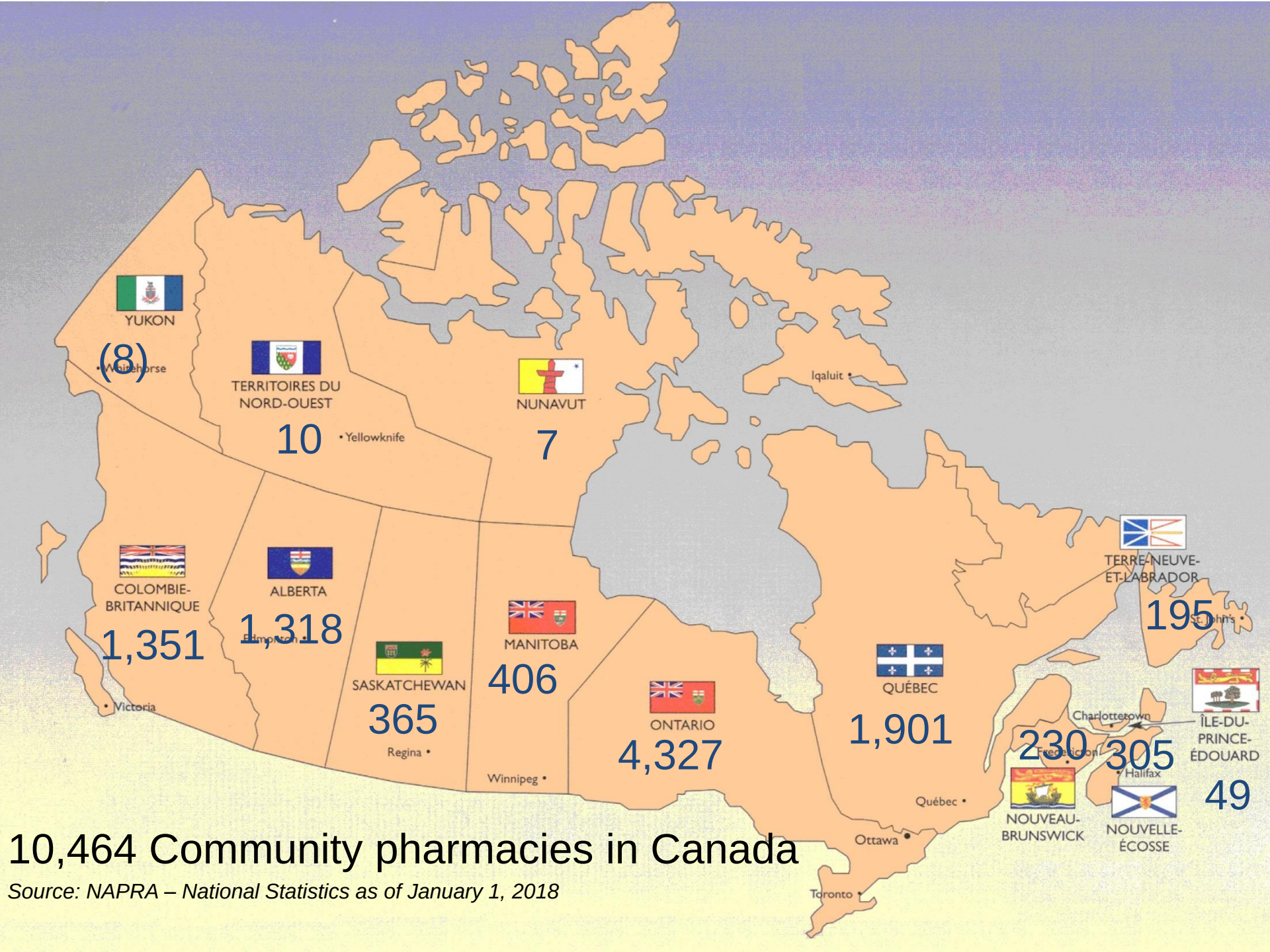
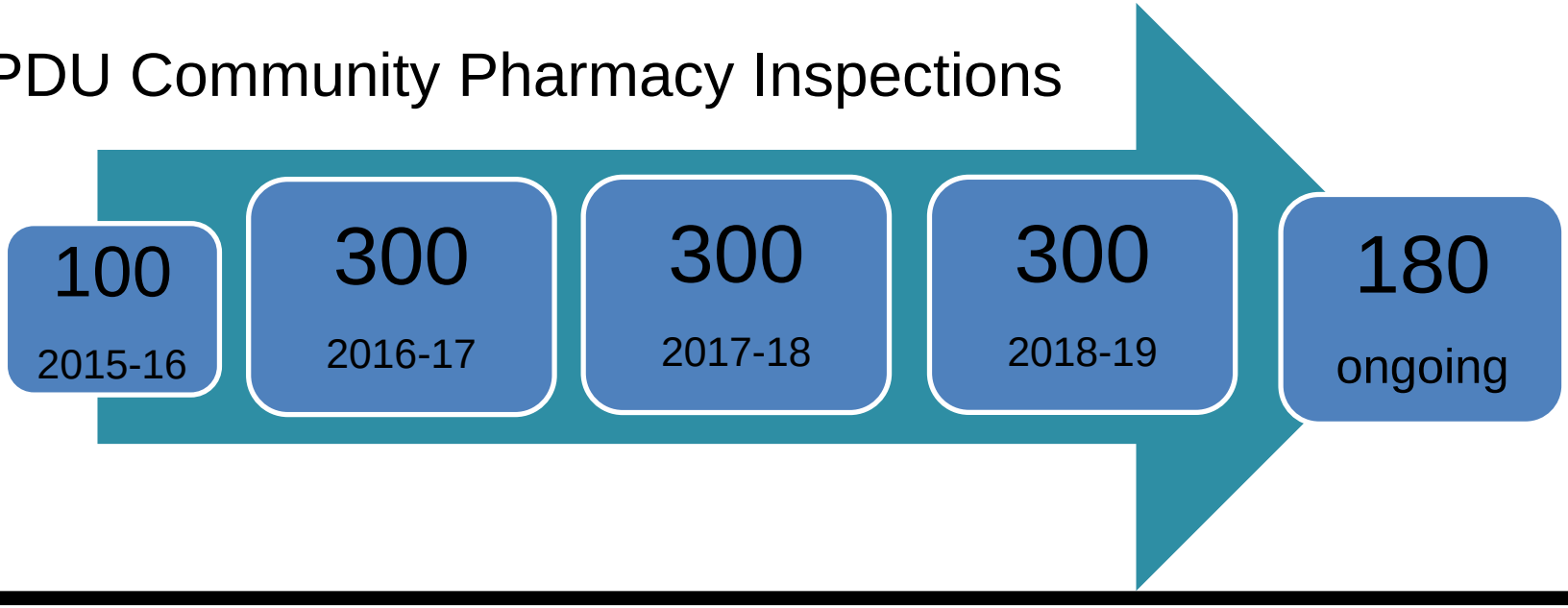


10,464 Community pharmacies in Canada

Source: NAPRA – National Statistics as of January 1, 2018

PPDU Community Pharmacy Inspections



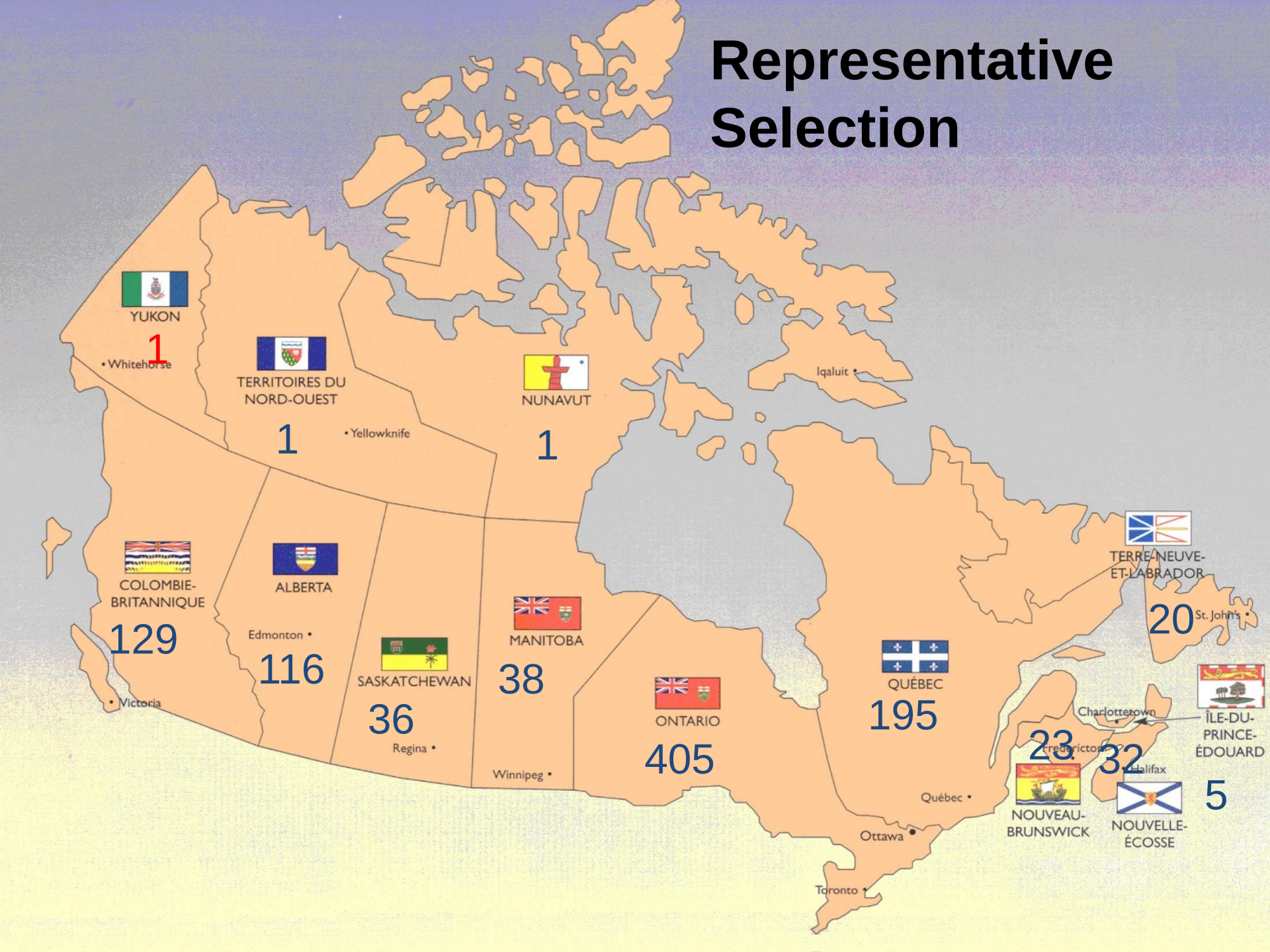
Targeted inspections

(i.e. regional issues, cases referred by our partners, loss or theft, complaints from the public, etc ...)

- All applicable requirements of the *Controlled Drugs and Substances Act* and its *Regulations* will be assessed
- 50% unannounced and 50% announced
- Selection of controlled substances
- Selection of pharmacies

Please note: targeted inspections continue as part of other Compliance and Enforcement activities outside this initiative

Representative Selection



Inspection of a Community Pharmacy

Assess all applicable requirements of the *Controlled Drugs and Substances Act* and its *Regulations*

Areas of review:

- Security measures
- Inventory count / reconciliation
- Purchase & dispensing records
- Prescription files
- Reports: Loss or Theft , Forgeries
- Destruction

Inspection phases

- Introductory meeting
- Pharmacy tour
- Inventory reconciliation
- Records review
- Interview with pharmacist
- Exit meeting

- On average, an inspection takes 6 hours

Pharmacy Tour

The pharmacy tour is focused on security.

Pharmacist must take all reasonable steps that are necessary to protect narcotics on premises against loss or theft

Ways to help accomplish this requirement:

- Proper storage: safe, locked cupboards, on shelves, etc
- Frequent inventory counts **and reconciliations**
- Security systems/alarms
- Properly placed video surveillance, etc.

Inventory Reconciliation

- Health Canada expects a pharmacist to record and report all negative inventory adjustments including but not limited to loss or thefts, controlled substances dispensed in error, the destruction of damaged or expired products.

Inventory Reconciliation

- As a first step, the Inspector will ask the pharmacist to complete a physical inventory count of the selected controlled substances.
- **Inspectors defer to onsite personnel to physically manipulate or count the controlled substances**
- Note the prescription number of the last controlled substance recorded by the community pharmacy (indicates the audit cut-off point).

Inventory Reconciliation

- When a starting inventory count is available, the following accountability reconciliation formula will be used:

Starting Inventory + Purchases = Disbursements + Physical Inventory

- When starting inventory count is not available, a modified accountability reconciliation formula should be used:

Purchases < Disbursements + Physical Inventory

- If any discrepancies (overage or shortage) are noted, the Inspector will confirm these findings before notifying the pharmacist of the apparent discrepancy

Inventory Reconciliation

Why do a reconciliation for controlled substances?

- To protect your inventory from internal diversion
- Inventory counts do not by themselves prevent diversion from occurring
- Perpetual (theoretical) inventories represent a good tool to monitor the inventory, that said they are not fool-proof and can be manipulated
- Never depend on perpetual inventory alone – always double check the quantities with a true manual count

Records Review

- Purchase records,
- Transaction records,
- Prescription files,
- Narcotic and controlled drug prescription “special” file,
- Destruction Records

Exit Meeting and Report

- Inspectors conduct an interview with the pharmacist and explain the findings that will appear in the report.

- Reports are typically sent within 10 business days of the inspection, and require response within 30 business days

Common Inspection Findings

1. Insufficient or lack of inventory control
   a) Discrepancies found during reconciliation
   b) Inability to state what on-hand quantity should be
2. Loss/theft reporting (must be submitted within 10 days of discovery: OCS_Reporting_Rapporteur_BSC@hc-sc.gc.ca)
3. The federal forgery report is submitted on a voluntary basis and is meant to capture both filled and unfilled prescriptions. Should the prescription be filled, submission of a loss or theft form is required.
4. Destruction records and procedures
5. Record keeping
6. Advertising (i.e. displaying of exempted codeine products or promotion of methadone delivery services).

Preparation for a PPDU Inspection

- Increase the number of physical inventory checks for all controlled substances.
- Keep all relevant records on site for at least 2 years.
- Ensure that purchase and sales reports are auditable i.e. they can be easily provided for any controlled substance requested.
- Have records of previous inventory checks handy.
- Document reasons for all inventory adjustments.
- Become familiar with reconciliation calculations.

Expected Results

Pharmacies are aware of CDSA and its regulations

Improve communication with stakeholders

Data analysis will be shared by the Office of Controlled Substances (OCS)

Pharmacies are compliant with the CDSA and its regulations

Compliance Promotion

Health Canada | Santé Canada

Your health and safety... our priority. | *Votre santé et votre sécurité... notre priorité.*

Pharmacy Inspections

Problematic Drug Use
Problematic drug use has been identified as a growing problem around the world and Canada is no exception. In its last report, the International Narcotic Control Board identified Canada as being the second largest user of opioids after the USA.

In Canada, problematic prescription drug use represents a complex and growing problem having negative impacts on public health and public safety in many communities. Similarly, the illegal use of pharmaceuticals such as opioids has become an issue of increasing concern with impacts on public safety and community well-being.

Government of Canada
The Government of Canada is taking a multilateral approach to minimizing the risk of diversion of prescription drugs from the supply chain and increasing intelligence regarding the incidence and nature of problematic prescription drug use in Canada.

Health Canada
Health Canada is increasing the numbers of inspections at retail pharmacies that dispense narcotics, controlled drugs and targeted substances.

Inspections
Health Canada intends to conduct approximately 1000 inspections across the country from 2015 to 2019. Starting in 2019-2020, approximately 180 inspections will be carried out on an ongoing annual basis.

The selection of community pharmacies to be inspected will be random but representative of the distribution of pharmacies across Canada.

The inspections aim to promote and improve compliance with the *Controlled Drugs and Substances Act* and its relevant regulations and strengthen communication between Health Canada, pharmacy provincial licensing authorities, professional associations, and pharmacists by ensuring the availability of updated guidance documents and new educational tools such as information bulletins.

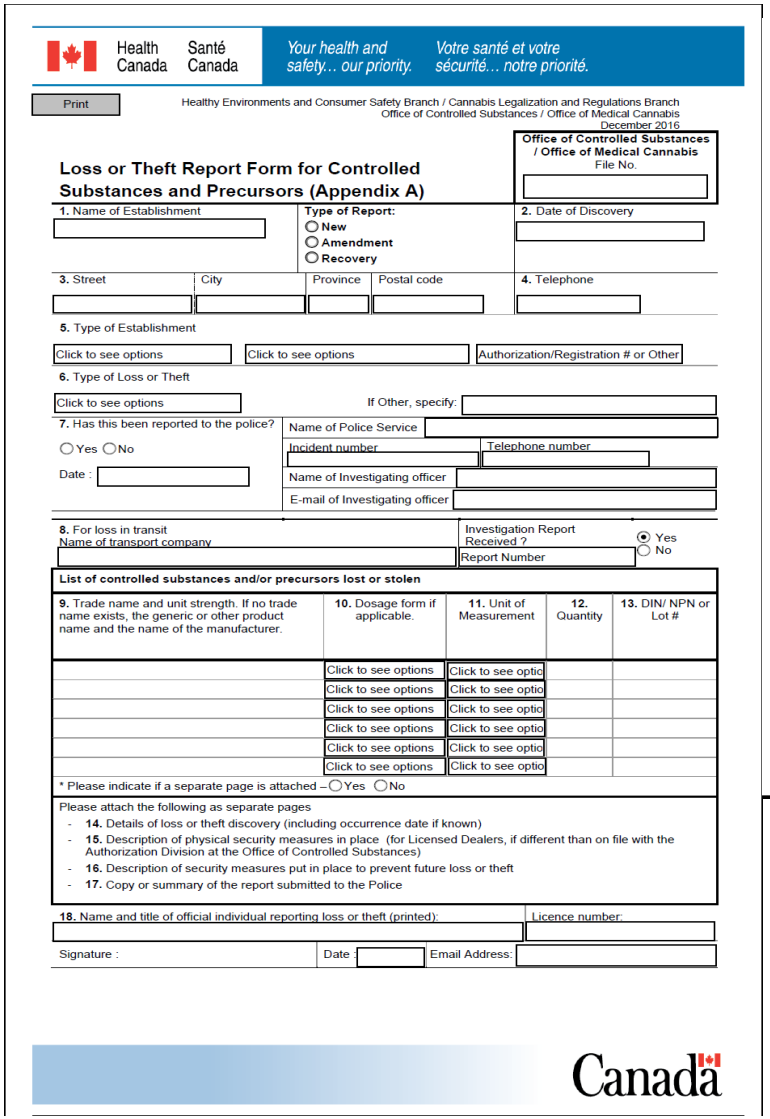
The inspections also aim to verify pharmacy compliance against applicable regulations, as well as assess purchase records, prescription records, loss and theft reports, destruction protocols, inventory reconciliation, security measures and any other information relevant to the act of dispensing controlled substances.

For more information about the community pharmacy inspection program, please do not hesitate to contact the National Compliance Section of the Office of Controlled Substances.

Email: hc.compliance-conformite.sc@canada.ca
Phone: 1-866-569-2560
Address: Health Canada
Office of Controlled Substances
National Compliance Section
AL 0300B
Ottawa ON K1A 0K9

Canada

Compliance Promotion



Health Canada / Santé Canada

Your health and safety... our priority. / *Votre santé et votre sécurité... notre priorité.*

Print

Healthy Environments and Consumer Safety Branch / Cannabis Legalization and Regulations Branch
Office of Controlled Substances / Office of Medical Cannabis
December 2016

Office of Controlled Substances / Office of Medical Cannabis
File No.

Loss or Theft Report Form for Controlled Substances and Precursors (Appendix A)

1. Name of Establishment

Type of Report:
- ○ New
- ○ Amendment
- ○ Recovery

2. Date of Discovery

3. Street | City | Province | Postal code

4. Telephone

5. Type of Establishment

Click to see options | Click to see options | Authorization/Registration # or Other

6. Type of Loss or Theft

Click to see options | If Other, specify:

7. Has this been reported to the police? ○ Yes ○ No

Date :

Name of Police Service

Incident number | Telephone number

Name of Investigating officer

E-mail of Investigating officer

8. For loss in transit
Name of transport company

Investigation Report Received ? ◉ Yes ○ No

Report Number

List of controlled substances and/or precursors lost or stolen

9. Trade name and unit strength. If no trade name exists, the generic or other product name and the name of the manufacturer.	10. Dosage form if applicable.	11. Unit of Measurement	12. Quantity	13. DIN/ NPN or Lot #
	Click to see options	Click to see optio		
	Click to see options	Click to see optio		
	Click to see options	Click to see optio		
	Click to see options	Click to see optio		
	Click to see options	Click to see optio		
	Click to see options	Click to see optio		

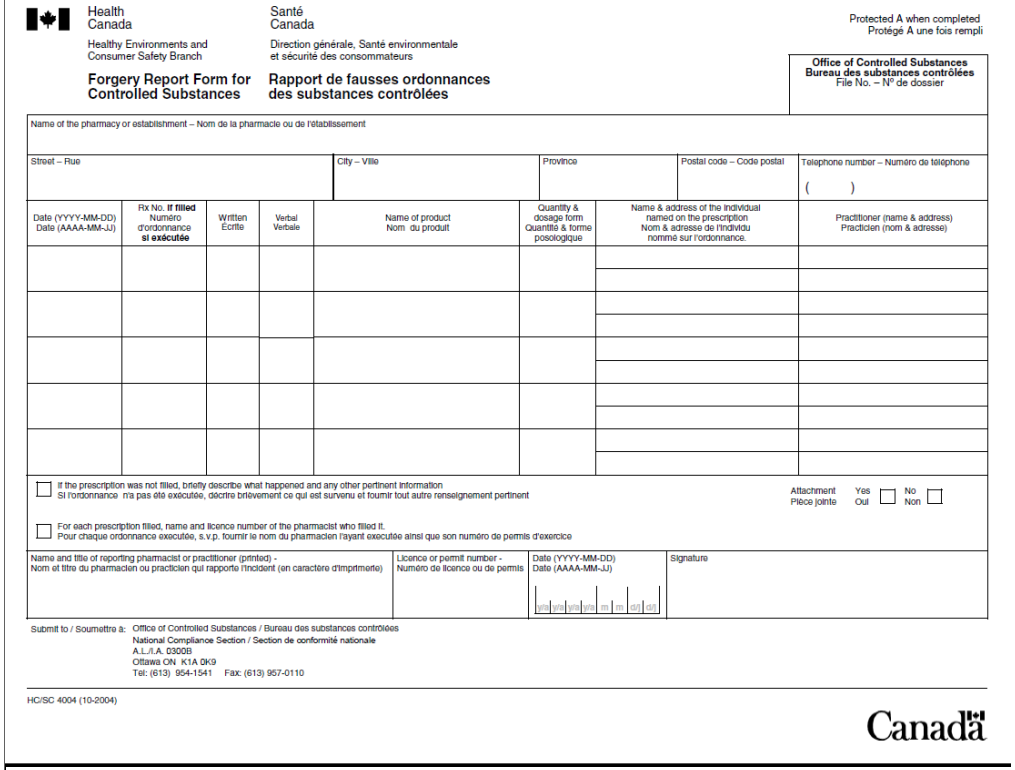
* Please indicate if a separate page is attached – ○ Yes ○ No

Please attach the following as separate pages
- **14.** Details of loss or theft discovery (including occurrence date if known)
- **15.** Description of physical security measures in place (for Licensed Dealers, if different than on file with the Authorization Division at the Office of Controlled Substances)
- **16.** Description of security measures put in place to prevent future loss or theft
- **17.** Copy or summary of the report submitted to the Police

18. Name and title of official individual reporting loss or theft (printed): | Licence number:

Signature : | Date : | Email Address:

Canada



Health Canada / Santé Canada

Healthy Environments and Consumer Safety Branch / Direction générale, Santé environnementale et sécurité des consommateurs

Protected A when completed
Protégé A une fois rempli

Forgery Report Form for Controlled Substances / **Rapport de fausses ordonnances des substances contrôlées**

Office of Controlled Substances
Bureau des substances contrôlées
File No. – N° de dossier

Name of the pharmacy or establishment – Nom de la pharmacie ou de l'établissement

Street – Rue | City – Ville | Province | Postal code – Code postal | Telephone number – Numéro de téléphone ( )

Date (YYYY-MM-DD) Date (AAAA-MM-JJ)	Rx No. **If filled** Numéro d'ordonnance **si exécutée**	Written Ecrite	Verbal Verbale	Name of product Nom du produit	Quantity & dosage form Quantité & forme posologique	Name & address of the individual named on the prescription Nom & adresse de l'individu nommé sur l'ordonnance.	Practitioner (name & address) Praticien (nom & adresse)

☐ If the prescription was not filled, briefly describe what happened and any other pertinent information
Si l'ordonnance n'a pas été exécutée, décrire brièvement ce qui est survenu et fournir tout autre renseignement pertinent

Attachment / Pièce jointe Yes / Oui ☐ No / Non ☐

☐ For each prescription filled, name and licence number of the pharmacist who filled it.
Pour chaque ordonnance exécutée, s.v.p. fournir le nom du pharmacien l'ayant exécutée ainsi que son numéro de permis d'exercice

Name and title of reporting pharmacist or practitioner (printed) - Nom et titre du pharmacien ou praticien qui rapporte l'incident (en caractère d'imprimerie) | Licence or permit number - Numéro de licence ou de permis | Date (YYYY-MM-DD) Date (AAAA-MM-JJ) | Signature

Submit to / Soumettre à: Office of Controlled Substances / Bureau des substances contrôlées
National Compliance Section / Section de conformité nationale
A.L./I.A. 0300B
Ottawa ON K1A 0K9
Tel: (613) 954-1541 Fax: (613) 957-0110

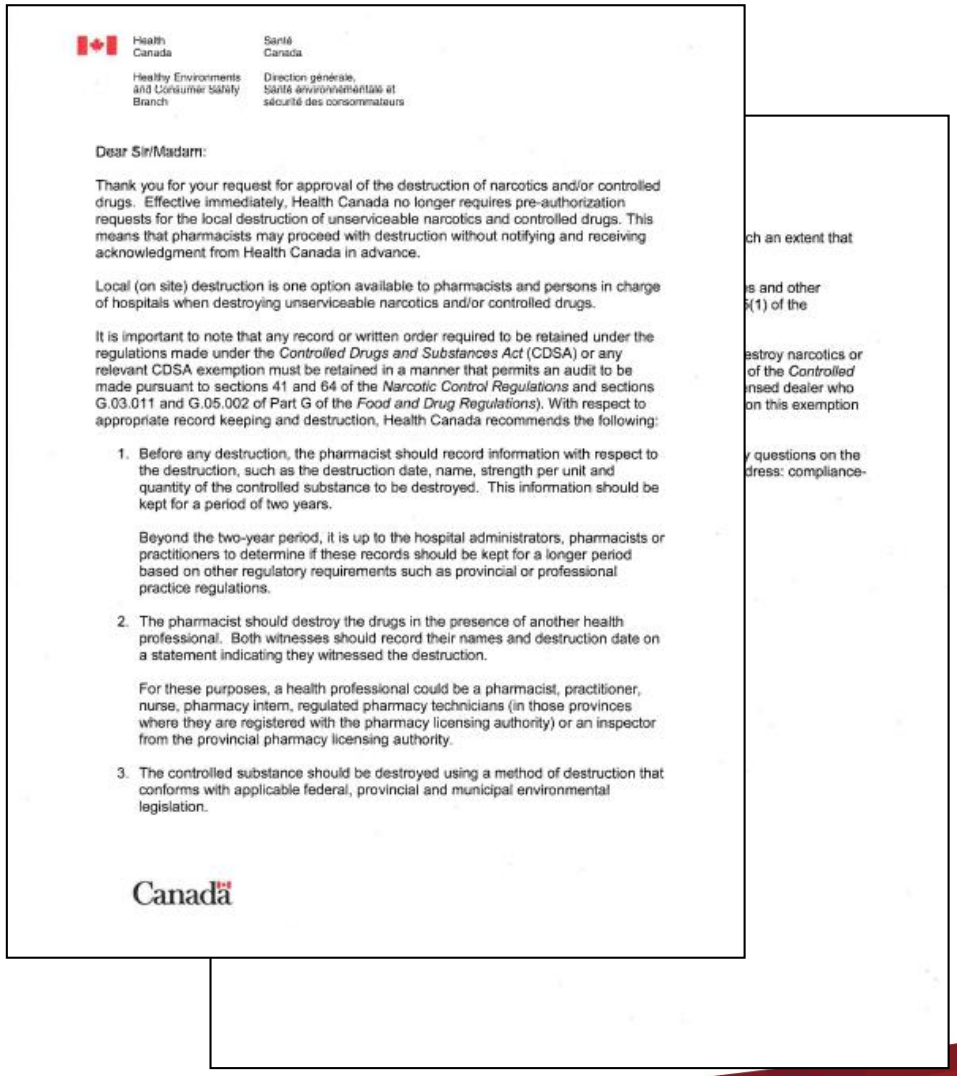
HC/SC 4004 (10-2004)

Canada

New Destruction Guidance

Requirements:

- ✓ A destruction protocol was published in January 2018. Distinctions are now made between pharmacy stock versus post consumer returns.
- ✓ Pharmacy stock destruction still requires an approved witness (i.e. practitioner, pharmacist, a pharmacy intern, pharmacy technician, or HC inspector) attestation.
- ✓ The selected destruction method must meet all applicable federal, provincial, and municipal requirements (e.g. consumption rendered impossible or improbable; environmental legislations).
- ✓ Record all pertinent information with respect to the destruction.
- ✓ Retain destruction records for at least 2 years.



Health Canada
Healthy Environments and Consumer Safety Branch

Santé Canada
Direction générale, Santé environnementale et sécurité des consommateurs

Dear Sir/Madam:

Thank you for your request for approval of the destruction of narcotics and/or controlled drugs. Effective immediately, Health Canada no longer requires pre-authorization requests for the local destruction of unserviceable narcotics and controlled drugs. This means that pharmacists may proceed with destruction without notifying and receiving acknowledgment from Health Canada in advance.

Local (on site) destruction is one option available to pharmacists and persons in charge of hospitals when destroying unserviceable narcotics and/or controlled drugs.

It is important to note that any record or written order required to be retained under the regulations made under the *Controlled Drugs and Substances Act* (CDSA) or any relevant CDSA exemption must be retained in a manner that permits an audit to be made pursuant to sections 41 and 64 of the *Narcotic Control Regulations* and sections G.03.011 and G.05.002 of Part G of the *Food and Drug Regulations*). With respect to appropriate record keeping and destruction, Health Canada recommends the following:

1. Before any destruction, the pharmacist should record information with respect to the destruction, such as the destruction date, name, strength per unit and quantity of the controlled substance to be destroyed. This information should be kept for a period of two years.

   Beyond the two-year period, it is up to the hospital administrators, pharmacists or practitioners to determine if these records should be kept for a longer period based on other regulatory requirements such as provincial or professional practice regulations.

2. The pharmacist should destroy the drugs in the presence of another health professional. Both witnesses should record their names and destruction date on a statement indicating they witnessed the destruction.

   For these purposes, a health professional could be a pharmacist, practitioner, nurse, pharmacy intern, regulated pharmacy technicians (in those provinces where they are registered with the pharmacy licensing authority) or an inspector from the provincial pharmacy licensing authority.

3. The controlled substance should be destroyed using a method of destruction that conforms with applicable federal, provincial and municipal environmental legislation.

Canada

New Destruction Guidance

Post consumer returns:

- ✓ As a matter of policy, Health Canada has been recommending that pharmacists record the name of the drug products, strength and quantity for post-consumer returns. Effective April 1, 2018, Health Canada no longer requires this information to be recorded for post-consumer returns. Consequently, there is no requirement to separate post-consumer returned controlled substances from other post-consumer returned prescription or non-prescription medications.

- ✓ Pharmacists working in a retail or community pharmacy pharmacists are responsible for securing the post-consumer returns that a pharmacy accepts until they are destroyed locally or are sent off-site for destruction purposes.

- ✓ Post-consumer returns must be received by a pharmacist, pharmacy intern, or pharmacy technician, and deposited in a tamper-evident, single-use, one-way entry container with a unique identifier number.

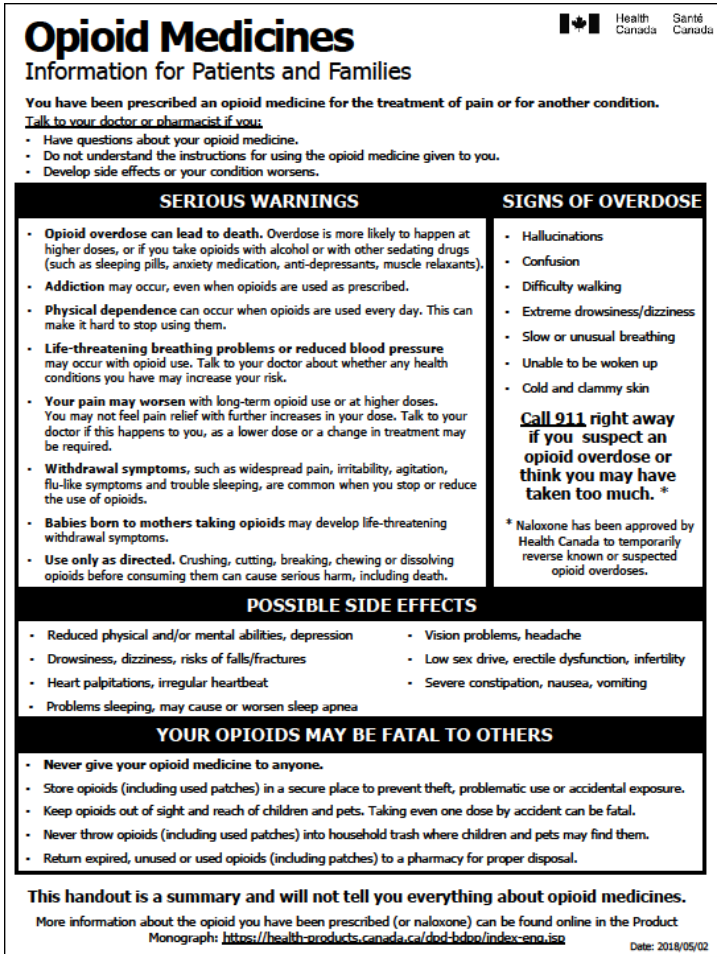
- ✓ Records concerning these products and their final disposition must be retained in an auditable format for a period of 2 years.

- ✓ Guidance can be found at: https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/controlled-substances/compliance-monitoring/compliance-monitoring-controlled-substances/unserviceable-stock.html

New Opioid Labelling Requirements

Requirements:

- ✓ On October 20, 2018 a new opioid sticker and handout requirement came into effect .
- ✓ The warning sticker states that the medication can cause dependence, addiction and overdose; it must be applied to the container each time it is dispensed to the patient (exemptions apply for dependence treatment)
- ✓ The handout is to be provided to the patient at the same time and contains key messages on the safe use of opioids, and on the risks associated with their use.
- ✓ Q&A Guidance (including a PDF version): https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/policies/opioids-questions-answers.html
- ✓ Notice re: Updated Part A List of Opioids: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/opioids-a-buprenorphine-methadone.html.



Opioid Medicines

Health Canada / Santé Canada

Information for Patients and Families

You have been prescribed an opioid medicine for the treatment of pain or for another condition.

Talk to your doctor or pharmacist if you:

- Have questions about your opioid medicine.
- Do not understand the instructions for using the opioid medicine given to you.
- Develop side effects or your condition worsens.

SERIOUS WARNINGS

- **Opioid overdose can lead to death.** Overdose is more likely to happen at higher doses, or if you take opioids with alcohol or with other sedating drugs (such as sleeping pills, anxiety medication, anti-depressants, muscle relaxants).
- **Addiction** may occur, even when opioids are used as prescribed.
- **Physical dependence** can occur when opioids are used every day. This can make it hard to stop using them.
- **Life-threatening breathing problems or reduced blood pressure** may occur with opioid use. Talk to your doctor about whether any health conditions you have may increase your risk.
- **Your pain may worsen** with long-term opioid use or at higher doses. You may not feel pain relief with further increases in your dose. Talk to your doctor if this happens to you, as a lower dose or a change in treatment may be required.
- **Withdrawal symptoms**, such as widespread pain, irritability, agitation, flu-like symptoms and trouble sleeping, are common when you stop or reduce the use of opioids.
- **Babies born to mothers taking opioids** may develop life-threatening withdrawal symptoms.
- **Use only as directed.** Crushing, cutting, breaking, chewing or dissolving opioids before consuming them can cause serious harm, including death.

SIGNS OF OVERDOSE

- Hallucinations
- Confusion
- Difficulty walking
- Extreme drowsiness/dizziness
- Slow or unusual breathing
- Unable to be woken up
- Cold and clammy skin

Call 911 right away if you suspect an opioid overdose or think you may have taken too much. *

* Naloxone has been approved by Health Canada to temporarily reverse known or suspected opioid overdoses.

POSSIBLE SIDE EFFECTS

- Reduced physical and/or mental abilities, depression
- Drowsiness, dizziness, risks of falls/fractures
- Heart palpitations, irregular heartbeat
- Problems sleeping, may cause or worsen sleep apnea
- Vision problems, headache
- Low sex drive, erectile dysfunction, infertility
- Severe constipation, nausea, vomiting

YOUR OPIOIDS MAY BE FATAL TO OTHERS

- **Never give your opioid medicine to anyone.**
- Store opioids (including used patches) in a secure place to prevent theft, problematic use or accidental exposure.
- Keep opioids out of sight and reach of children and pets. Taking even one dose by accident can be fatal.
- Never throw opioids (including used patches) into household trash where children and pets may find them.
- Return expired, unused or used opioids (including patches) to a pharmacy for proper disposal.

This handout is a summary and will not tell you everything about opioid medicines.

More information about the opioid you have been prescribed (or naloxone) can be found online in the Product Monograph: https://health-products.canada.ca/dpd-bdpp/index-eng.jsp

Date: 2018/05/02

New Opioid Labelling Requirements

Part A — Opioids subject to the prescription labelling provisions - (Please note that Tramadol is also subject to the requirements)

Drugs intended for human use containing any of the following active ingredients	Including (but not limited to)	Qualifier
Buprenorphine	Buprenorphine Hydrochloride	Except when authorized and used for the treatment of an opioid use disorder.
Butorphanol	Butorphanol Tartrate	n/a
Codeine	Codeine Phosphate	Except for those products referred to in subsection 36(1) of the Narcotic Control Regulations.
Fentanyl	Fentanyl Citrate	n/a
Hydrocodone	Hydrocodone Bitartrate	n/a
Hydromorphone	Hydromorphone Hydrochloride	n/a
Meperidine	Meperidine Hydrochloride	n/a
Methadone	Methadone Hydrochloride	Except when authorized and used for the treatment of an opioid use disorder.
Morphine	Morphine Hydrochloride; Morphine Sulfate	n/a
Normethadone	Normethadone Hydrochloride	n/a
Opium	Opium and Belladonna	n/a
Oxycodone	Oxycodone Hydrochloride	n/a
Oxymorphone	Oxymorphone Hydrochloride	n/a
Pentazocine	Pentazocine Hydrochloride; Pentazocine Lactate	n/a
Tapentadol	Tapentadol Hydrochloride	n/a
Tramadol	Tramadol Hydrochloride	n/a

Methadone Prescribing Changes

- ✓ In the past, practitioners were required to obtain an exemption from Health Canada before they could prescribe, sell, provide or administer methadone.

- ✓ As of May 19, 2018, the Government of Canada removed this unique regulatory constraint imposed on methadone. Exemptions are no longer required from Health Canada for practitioners to prescribe, administer, sell or provide methadone to their patients.

- ✓ Pharmacists will no longer need to contact Health Canada in order to verify if a practitioner holds a valid subsection 56(1) exemption to prescribe methadone. Methadone is permitted to be prescribed in the same manner as other narcotics under the NCR. As such, pharmacists may sell or provide a narcotic, such as methadone, to a person if the pharmacist has a written order or prescription, signed and dated, by a practitioner.

- ✓ Please note that practitioners and pharmacists are still required to meet all other applicable provisions of the Narcotic Control Regulations, as well as the requirements established by their province or territory or the licensing authority (i.e. College of Physician and Surgeons or Nurses, Medical Councils, etc.) governing their practice when dealing with controlled substances. Examples of such requirements include, but are not limited to, additional courses or training.

Information Sharing and Engagement

- Report on the PPDU initiative will be shared with NAPRA and the Colleges
  - Agregated data
  - Observed trends
- This information has been shared via a summary report published on the Health Canada website starting in 2017

Resources for pharmacists

- Loss/theft report and forgery forms
- Policy documents/CDSA section 56 exemptions
- Stakeholder Registry (Consultations)

- Adverse reaction reporting
- Adverse reaction database
- Health Product InfoWatch publications

- Drug Product Database (DIN products)
- Natural Health Product Database (NPN, DIN-HM)

- Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051)

Contact information

Controlled Substance Program, Western Region
Regulatory Operations and Regions Branch, Health Canada
400 – 4595 Canada Way
Burnaby, British Columbia V5G 1J9

Email: CSP.Western@canada.ca
Telephone: 604-653-6512
Fax: 604-666-5741

Questions?

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

14. Pharmacists Providing Antipsychotic Depot Injections

DECISION REQUIRED

Recommended Board Motion:

Approve the delegation request to authorize pharmacists from Pro-Health Pharmacy to administer antipsychotic depot injections.

Purpose

To seek Board approval for a delegation of a medical act to authorize pharmacists from Pro-Health Pharmacy to administer antipsychotic depot injections.

Background

Request to Delegate the Authority for Administering Depot Injections

The College was recently approached regarding a request to delegate the authority to administer antipsychotic depot injections[1] from a medical practitioner to pharmacists from Pro-Health Pharmacy in Chilliwack B.C.

The aim of this request is to help address a gap in mental health care in the Chilliwack area. The requestor, Pharmacy Manager Christian Mitchell, has noted that Chilliwack's mental health services are over-capacity and not able to effectively address the demand for services. Added to this is the complexity of Chilliwack's changing population. Chilliwack's homeless population increased by 203% from 2014 to 2017, which was the largest increase in the Fraser Valley Regional District (FVRD) over that period[2]. During a 2017 homelessness survey in the FVRD, when asked to report on their health problems, almost half of the respondents in Chilliwack (46.3%) noted experiencing mental illness, but only 17.3% reported receiving treatment[3]. One of the conclusions from a report on that survey called for new ways of thinking of and providing treatment that can facilitate community integration[4].

[1] In general terms, a depot injection is an injection, usually subcutaneous or intramuscular, of a drug that releases its active compound in a consistent way over a long period of time.
[2] http://www.fvrd.ca/assets/Government/Documents/2017%20FVRD%20Homelessness%20Survey%20Report.pdf
[3] http://www.fvrd.ca/assets/Government/Documents/2017%20FVRD%20Homelessness%20Survey%20Report.pdf
[4] http://www.fvrd.ca/assets/Government/Documents/2017%20FVRD%20Homelessness%20Survey%20Report.pdf

Pro-Health Pharmacy, a licensed community pharmacy, is located nearby Chilliwack General Hospital (CGH) and Chilliwack Mental Health and Substance Use Centre. Mr. Mitchell works closely with Dr. Naveed Almas, Head of Psychiatry for CGH and Chilliwack Mental Health. Mr. Mitchell and Dr. Almas believe that by authorizing pharmacists from Pro-Health Pharmacy to administer antipsychotic depot injections, via a Delegation of a Medical Act, they will be able to provide better mental health care in the Chilliwack area (see Appendix 1 for a letter from Dr. Almas on this issue).

The proposed delegation would involve administering the following medications via depot injection: Aripiprazole, Paliperidone, Olanzapine, Haloperidol, Risperidone, Zuclopenthixol and Flupentixol. Pharmacists will administer the injection in the pharmacy's private patient exam room. The pharmacists will also provide medication counselling and medication reviews when necessary and appropriate. These medication reviews will be transmitted to Chilliwack Mental Health for collaboration with a psychiatrist and the nursing team. This will allow the pharmacists to work in collaboration with Chilliwack Mental Health.

Initially, Mr. Mitchell will be the only pharmacist providing depot injections, and he is authorized by the CPBC to administer injections. The number of pharmacists administering depot injections under this delegation is expected to increase. Pharmacists employed by Pro-Health Pharmacy will be selected to administer these injections based on their clinical inclination, injection certification with the College, and competency with depot administration. Pro-Health Pharmacy will ensure that any pharmacists selected undergo training and supervision with Dr. Almas. Pharmacists will need demonstrate a minimum of 10 successful injections under direct supervision of Dr. Almas to be listed as a delegate.

Approval Process for Delegating the Authority for Administering Depot Injections

Currently, the administration of depot injections for antipsychotic medications is beyond the scope of practice of B.C. pharmacists. Section 4(1)(c.1) of the "Pharmacists Regulation" under the *Health Professions Act* permits pharmacists to administer Schedule I, IA, or II drugs or substances by intradermal, intramuscular or subcutaneous injection. However, section 4.1 of that regulation states that a pharmacist may only perform injections of drugs or substances if associated standards, limits, and conditions have been established for them. At this time, the CPBC has only developed standards, limits and conditions about providing immunizations by injection. The College's Drug Administration Committee is exploring amending these standards, limits and conditions to broaden the types of drugs that may be administered by injection.

Pharmacists involved in the above-noted request will be permitted to administer depot injections via a Delegation of a Medical Act by the College of Physicians and Surgeons of B.C. (CPSBC). The CPSBC allows persons other than physicians to be entrusted with performing a medical act, in certain circumstances. According to CPSBC guidelines, when a medical act that is outside the accepted scope of practice of another discipline is delegated, the responsibility for that act is shared. The physician who delegates the act still has a responsibility to the patient,

and the person who carries out the act must do so with care and diligence and is legally liable if negligent.

In order to finalize this delegation, the Boards of both Colleges involved need to approve it. The CPSBC notified Dr. Almas that his request for delegation was approved on October 19, 2018 (see Appendix 2 for a copy of CPSBC letter confirming approval of the delegation). The final step of the approval process is for the CPBC Board to consider approval of the initiative.

Recommendation

The Registrar recommends that the Board approve the delegation of a medical act to allow pharmacists from Pro-Health Pharmacy to administer antipsychotic depot injections, for the following reasons:

- The healthcare professionals involved in the initiative will be able to provide needed health care in the Chilliwack area, with appropriate patient safeguards in place (e.g., injection certification, training and supervision).
- The initiative may help inform future amendments to pharmacists' scope of practice with respect to injection authorities.
- Corresponds with the October 5, 2018 CPSBC approval of the initiative.

Appendix	
1	Letter from Dr. Almas Requesting Approval of the Delegation
2	October 19, 2018 Letter from CPSBC Confirming Approval of the Delegation

fraserhealth
Better health. Best in health care.

To Whom It May Concern:

My name is Naveed Almas and I am the head Psychiatrist in Chilliwack British Columbia.

For years now, the city of Chilliwack has had an outcry for mental health and addictions services. Being outside of the Greater Vancouver Area, we do not receive the same funding for mental health services as other metropolis areas. This gap in mental health has been identified by the community, city council and local physicians. In May of 2017 there was 221 people deemed homeless in Chilliwack, of this, 49% struggle with a mental illness and 68% struggle with addiction.

As a result of this unmet need, Chilliwack's emergency department and acute care ward have been overrun by people of this nature. This overload causes a large financial and time strains on our hospital system.

I have recently implemented a Transition Outreach Team at Chilliwack General Hospital Psychiatry which works with admitted psychiatric inpatients being discharged from CGH who require intensive short term follow-up support immediately after discharge. Although we have seen great success with this team, I believe that through partnership with a clinical focused community Pharmacy we can better manage mental health in Chilliwack.

The team at Pro-Health Pharmacy has a high clinical capacity and will be involved in working closely alongside myself at the Transition Outreach Team and Chilliwack Mental Health. These depot-injection services are absolutely essential for the managing mental health in Chilliwack. By allowing pharmacists at Pro-Health Pharmacy to administer depot-injections under my training and supervision I believe that we will see better patient outcomes and reduction in emergency room visits and hospital resources.

Through the Delegation of a Medical Act I wish to partner with the Pro-Health Pharmacy team, to administer Depot injections using their clinically trained pharmacists to bridge the gap of mental health care in Chilliwack. We will adhere to specified practice protocols and a high level of training.

Yours truly,

Dr. Naveed Almas

College of Physicians and Surgeons of British Columbia
300–669 Howe Street
Vancouver BC V6C 0B4
www.cpsbc.ca
Telephone: 604-733-7758
Toll Free: 1-800-461-3008 (in BC)
Fax: 604-733-3503

October 19, 2018

College File No.: 33164

VIA EMAIL

Dr. Naveed Almas
2659- Eagle Mountain Drive
Abbotsford, BC

Dear Dr. Almas:

Re: Depo psychiatric medications – delegation request

We acknowledge receipt of and thank you for your fax letter of October 5, 2018 requesting authority to delegate the administration of antipsychotic depo injections to the Pro-Health Pharmacy team.

At a recent meeting, the Executive Committee had an opportunity to review your request. We are pleased to inform you that the committee passed the following resolution:

RESOLUTION 18-830
RESOLVED that the Executive Committee approves the request of Dr. Naveed Almas (CPSID #33164) to delegate administration of antipsychotic depo injections to the Pro-Health Pharmacy team.

We thank you for your inquiry and if you have any questions regarding this correspondence, please do not hesitate to contact the undersigned.

Yours truly,

Heidi M. Oetter, MD
Registrar and CEO

HMO/js

College of Pharmacists of British Columbia

14. Pharmacists Providing Anti-psychotic Depot Injections

Bob Nakagawa

Registrar

College of Pharmacists of British Columbia

Background

- Administering depot injections for anti-psychotic medications is beyond the scope of practice of B.C. pharmacists.
  - The “Pharmacists Regulation” under the HPA allows pharmacists to administer Schedule I, IA, or II drugs or substances by injection.
  - That regulation also states that a pharmacist *may only* perform injections of drugs or substances if associated standards, limits, and conditions have been established for them.
- The CPBC has only established standards, limits and conditions about providing *immunizations* by injection or intranasal route.

College of Pharmacists of British Columbia

Background, continued

- Pharmacists may be permitted to administer depot injections via a Delegation of a Medical Act by the CPSBC.
- Key aspects of a Delegation of a Medical Act are:
  - Requires approval by the Boards of both Colleges involved.
  - The responsibility for the act is shared.
  - The physician who delegates the act still has a responsibility to the patient, and the person who carries out the act must do so with care and diligence and is legally liable if negligent.

College of Pharmacists of British Columbia

Delegation Request

- The College recently received a delegation request.
- Authority would be delegated to administer anti-psychotic depot injections from a medical practitioner to pharmacists from Pro-Health Pharmacy in Chilliwack B.C.
- Pro-Health Pharmacy is a licensed community pharmacy in Chilliwack.
- The aim of the proposal is to address the following in that community:
  - A gap in mental health care, and;
  - Demand for mental health services.

College of Pharmacists of British Columbia

Delegation Request, continued

- involves administering the following medications via depot injection: aripiprazole, paliperidone, olanzapine, haloperidol, risperidone, zuclopenthixol and flupentixol.
- Pharmacists would administer injections in the pharmacy's private patient exam room, and provide medication counselling and medication reviews, as appropriate.
- Pharmacists would work in collaboration with Chilliwack Mental Health: medication reviews would be transmitted to Chilliwack Mental Health for collaboration with a psychiatrist and the nursing team.

College of Pharmacists of British Columbia

Delegation Request, continued

- Initially, the pharmacy manager would be the only pharmacist providing depot injections. He is certified by the CPBC to administer injections.
- There will be an increase of pharmacists at Pro-Health Pharmacy administering depot injections under this delegation:
  - Pharmacists will be selected based on their clinical indication, injection certification with the CPBC, and competency with depot administration.
  - Pharmacists selected will undergo training and supervision with the medical practitioner involved in the delegation: they will need to demonstrate a minimum of 10 successful injections under direct supervision of the medical practitioner.

College of Pharmacists of British Columbia

Delegation Request, continued

- The CPSBC approved this delegation on October 19, 2018.
- The final step of the approval process is for the CPBC Board to consider approval of the initiative.

Next Steps:

- College staff will communicate the Board's decision with the requestor.
- The Drug Administration Committee is currently exploring amending the College's standards, limits and conditions to broaden the types of drugs that may be administered by injection.

College of Pharmacists of British Columbia

Pharmacists Providing Anti-psychotic Depot Injections

MOTION:

Approve the delegation request to authorize pharmacists from Pro-Health Pharmacy to administer antipsychotic depot injections.

College of Pharmacists of British Columbia

BOARD MEETING
November 23, 2018

15. CLEAR Regulatory Excellence Award – College of Pharmacists of BC

INFORMATION ONLY

Purpose

To advise the Board that that the College recently won a regulatory excellence award from the Council on Licensure, Enforcement and Regulation (CLEAR).

Background

CLEAR is US-based, international association for professional and occupational regulators, and an international resource for professional regulation. Every year, CLEAR offers a limited number of awards, one of which is for regulatory excellence.

The CLEAR Regulatory Excellence Award recognizes an individual, team, program or agency demonstrating an outstanding contribution to the enhancement of occupational or professional regulation, regulatory processes, or consumer and public protection. The individual, team, program or agency must have demonstrated exceptional leadership, vision, creativity, results and outcomes above and beyond the regular functions of the job or expectations, and beyond what is normally achieved.

On September 28, 2018, CLEAR presented the College with the 2018 Regulatory Excellence Award for a team for our work on pharmacy security measures. Photos and videos of the award presentation can be accessed via the following link: https://www.clearhq.org/awards

Discussion

The College's Pharmacy Security Measures Initiative

From 2012 to 2013, pharmacies in Vancouver experienced a 160% increase in community pharmacy robberies, often targeted for their prescription opioid medications. After being contacted by the Vancouver Police Department about the distressing number of pharmacy robberies, the College formed a working group to examine the issue comprised of representatives from law enforcement, pharmacies, CPBC staff and the BC Pharmacy Association. The working group developed a set of pharmacy security requirements aimed at reducing pharmacy robberies and protecting confidential patient health information. The cornerstone was a requirement that all community pharmacies store their narcotic drugs in a time-delayed safe. The measures were first introduced via policy in 2015, and transitioned to bylaw in 2017.

The College commissioned and received an evaluation of the pharmacy security measures by Dr. Martin Andresen, Professor of Criminology and Director of the Institute for Canadian Urban Research Studies at Simon Fraser University. Dr. Andresen analyzed changes in trends in the number of pharmacy robberies before and after the measures came into effect.

The evaluation found strong evidence supporting the notion that the measures had their intended effect across the province[1]. Notably in Vancouver where the majority of pharmacy robberies occurred, there was an immediate and substantial drop (94%) in pharmacy robberies after the College's pharmacy security requirements took effect.

[1] Dr. Andresen presented his findings to the Board at their April 2018 meeting.

College of Pharmacists of British Columbia

15. CLEAR Regulatory Excellence Award - College of Pharmacists of BC

Bob Nakagawa

Registrar

College of Pharmacists of British Columbia

Background

Council on Licensure, Enforcement & Regulation

Promoting Regulatory Excellence

- CLEAR is US-based, international association for professional and occupational regulators, and an international resource for professional regulation.
- The CLEAR Regulatory Excellence Award recognizes an individual, team, program or agency demonstrating an outstanding contribution to the enhancement of occupational or professional regulation, regulatory processes, or consumer and public protection.
- The individual, team, program or agency must have demonstrated exceptional leadership, vision, creativity, results and outcomes above and beyond the regular functions of the job or expectations, and beyond what is normally achieved.

College of Pharmacists of British Columbia

Background cont.

On September 28, 2018, CLEAR presented the College with the 2018 Regulatory Excellence Award for a team for our work on pharmacy security measures. Photos and videos of the award presentation can be accessed via the following link:

https://www.clearhq.org/awards