College of Pharmacists of British Columbia

Board Meeting
November 26, 2021
Via Video Conference

MINUTES

Members Present:
Steven Hopp, Outgoing Vice-Chair & Incoming Chair, District 4
Andrea Silver, Incoming Vice-Chair, District 3
Alex Dar Santos, District 1
Terri Gibson, District 2
Michael Ortynsky, District 5
Anca Cvaci, District 6
Claire Ishoy, Outgoing Chair, District 7
Eric Sletmoen, District 8
Tracey Hagkull, Government Appointee
Anne Peterson, Government Appointee
Katie Skelton, Government Appointee
Justin Thind, Government Appointee

Staff:
Bob Nakagawa, Registrar and CEO
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 and Board Coordinator
Jon Chen, Digital Communications Lead

Guests:
Michael Coughtrie, Dean, UBC Faculty of Pharmaceutical Sciences
Jeremy Bulatao, Elected UBC Pharmacy Undergraduate Society President

Guests Presenters:
Winnie Lam, Manager, Pharmacy Operations, Geo 3 & 4
Dr. Sean Spina, Director, Special Projects, HaH & MHSU

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1. **WELCOME & CALL TO ORDER**
   Chair Ishoy called the meeting to order at 8:56am on November 26, 2021.

   Chair Ishoy acknowledged the Syilx (pronounced Say-el-ks) Okanagan people on whose unceded traditional territories she is chairing this meeting from.

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She also recognized that attendees of the videoconference are joining the call from different locations across BC, she acknowledged that the Indigenous Peoples are the traditional stewards of the lands and waters from where each of us is attending the meeting from.

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.

- Steven Hopp was nominated

Since no further nominations were made, Steven Hopp was acclaimed as the new Board Chair for a one-year term to conclude at the start of the November 2022 Board meeting.

Steven Hopp assumed the Board Chair position.

3. ELECTION OF VICE-CHAIR

Chair Hopp called for nominations

- Anne Peterson was nominated.
- Andrea Silver was nominated.

After 12 votes were electronically cast and tallied, Andrea Silver was elected as the new Board Vice-Chair for a one-year term to conclude at the start of the November 2022 Board meeting.

Andrea Silver assumed the Board Vice-Chair position.

4. CONSENT AGENDA

a) Items for further discussion

District 5 Board Member, Michael Ortynsky disclosed a perceived conflict of interest to item 7. *Legislation Review Committee: Bylaw Amendments to Officially Adopt the NAPRA Standards for Sterile Compounding* due to his ownership of a compounding pharmacy.

The Board agreed that there is no real conflict and Board member Ortynsky does not need to excuse himself from the discussion.

b) Approval of Consent Items (Appendix 1)

District 3 Board Member and Board Vice-Chair, Andrew Silver requested that item 4b.vii *Approval of 2022 Board Meeting Schedule* be removed from the Consent Agenda and placed onto the regular Agenda for further discussion.

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

CARRIED

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5. CONFIRMATION OF AGENDA (Appendix 2)

It was moved and seconded that the Board:
Approve the November 26, 2021 Draft Board Meeting Agenda as amended.

CARRIED

6. MEDICATION INCIDENT REPORTING UPDATE (Appendix 3)

Ashifa Keshavji, Director of Practice Reviews and Quality Assurance provided an update on the College's work towards implementation of mandatory anonymous medication incident reporting in BC.

The key topics addressed in the presentation includes:

- Current state of community pharmacies;
- Current state of hospital pharmacies;
- Medical incident reporting
- College Strategic Plan;
- College role in the NAPRA working group;
- NAPRA standards;
- National Information Sharing Group; and
- Next steps.

7. LEGISLATION REVIEW COMMITTEE (Appendix 4)

a) Bylaw Amendments to Officially Adopt the NAPRA Standards for Sterile Compounding

Justin Thind, Chair of Legislation Review Committee presented to the Board the proposed amendments to the *Pharmacy Operations and Drug Scheduling Act Bylaws* ("PODSA") to adopt the NAPRA Association of Pharmacy Regulatory Authorities' ("NAPRA") model standards for sterile compounding, for approval for public posting.

It was moved and seconded that the Board:
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 approves the proposed draft bylaws of the College of Pharmacists of British Columbia for public posting, which adopt the National Association of Pharmacy Regulatory Authorities' model standards for sterile compounding, as circulated.

CARRIED

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b) Temporary and Limited Training Requirement Suspension in Professional Practice Policy 66

Justin Thind, Chair of Legislation Review Committee presented to the Board the proposed amendment to Professional Practice Policy-66 Opioid Agonist Treatment ("PPP-66") to temporarily suspend the OAT-Compliance and Management Program for Pharmacy (OAT-CAMPP) training requirement for pharmacists who are only providing the COVID-19 and/or flu immunizations, including boosters, during the COVID-19 public health emergency.

It was moved and seconded that the Board:
Amend Professional Practice Policy – 66 Opioid Agonist Treatment to temporarily suspend the OAT-Compliance and Management Program for Pharmacy training requirement for pharmacists who are only providing the COVID-19 and/or flu immunizations, including boosters, during the COVID-19 public health emergency.

CARRIED

8. HOSPITAL AT HOME – HOW CURIOUSITY AND COLLABORATION ARE TRANSFORMING ACUTE CARE IN BC (Appendix 5)

Winnie Lam and Dr. Sean Spina presented to the Board an overview of the Hospital at Home Program.

The key topics addressed in the presentation includes:

- Patient oriented research;
- Government partnership;
- A Canadian approach to developing, implementing and evaluating Hospital at Home;
- Medication distributions dilemma and medication documentation dilemma;
- Medication systems collaboration and medication distribution collaboration;
- Medication administration creativity and medication systems creativity;
- Role of Clinical Pharmacists;
- A new role of acute-care delivery;
- Public / stakeholder engagement on Hospital at Home; and
- Results and implementation evaluation.

9. DRUG ADMINISTRATION COMMITTEE: AMENDMENTS TO PHARMACIST DRUG ADMINISTRATION AGE LIMIT (Appendix 6)

Alex Dar Santos, Member of the Drug Administration Committee presented to the Board the proposed amendment to the *Health Professions Act* Bylaws to lower the patient age limit for drug administration by pharmacists by injection to 4 years of age.

It was moved and seconded that the Board:
The Board tabled a motion to amend the Health Professions Act Bylaws to lower the patient age limit for drug administration by pharmacists by injection to 4 years of age. The proposed amendments will be brought back to the Board at the February 2022 Board meeting together with additional information requested by the Board.

CARRIED

Abstention from District 1 Board Member, Alex Dar Santos recorded

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10. GOVERNANCE COMMITTEE: APPOINTMENT OF BOARD MEMBERS TO BOARD COMMITTEES (Appendix 7)

Anne Peterson, Chair of the Governance Committee presented to the Board the final recommendation of committee appointments.

a) Appointment of Board Members to Committees

Audit and Finance Committee

- Reappoint Steven Hopp as a Committee Chair
- Reappoint Alex Dar Santos as Committee Vice-Chair
- Reappoint Steven Hopp, newly elected Board Chair as a Member
- Appoint Andrea Silver, newly elected Board Vice-Chair as a Member
- Reappoint Alex Dar Santos as a Member
- Reappoint Anca Cvaci as a Member
- Reappoint Tracey Hagkull as a Member

Governance Committee

- Appoint Claire Ishoy as a Member, for a 3-year term
- Appoint Alex Dar Santos as a Member, for a 3-year term
- Appoint Anca Cvaci as a Committee Vice-Chair

Legislation Review Committee

- Appoint Eric Sletmoen as a Member, for a 3-year term

Past Chairs Advisory Committee

- Appoint Claire Ishoy as a Member, for a 3-year term

Registrar Evaluation & Succession Planning Committee

- Appoint Steven Hopp as Committee Chair
- Reappoint Steven Hopp, newly elected Board Chair as a Member
- Appoint Andrea Silver, newly elected Board Vice-Chair as a Member
- Reappoint Terri Gibson as Member
- Reappoint Justin Thind as a Member
- Reappoint Claire Ishoy as Member

It was moved and seconded that the Board:

Approve College committee member appointments for terms beginning on November 26, 2021, as circulated.

CARRIED

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b) Board Meeting Guidelines: Robert's Rules to BCCNM Meeting Guidelines

Anne Peterson, Chair of the Governance Committee presented to the Board its recommendation to replace the current procedures of the College Board meetings, Robert's Rules of Order with meeting guidelines, based on those from the British Columbia College of Nurses and Midwives, and associated bylaw amendments, for the February 2022 Board meeting.

It was moved and seconded that the Board:
Direct the Registrar to bring forward Board meeting guidelines, based on those from the British Columbia College of Nurses and Midwives, and associated bylaw amendments for the February 2022 meeting.

CARRIED

11. REGISTRAR AND CEO LAST REPORT

Registrar Nakagawa reflected on his tenure at the College as he prepares for retirement.

12. ITEMS BROUGHT FORWARD FROM CONSENT AGENDA

4b.vii *Approval of 2022 Board Meeting Schedule*
The Board discussed about the option of an in-person Board meeting in April 2022. The Board would like to meet April 28, 2022 for the Committee of the Whole meeting and April 29, 2022 for the Board meeting.

It was moved and seconded that the Board:
Approve the 2022 Board Meeting Schedule, as amended.

CARRIED

ADJOURNMENT

Chair Hopp adjourned the meeting at 2:33pm on November 26, 2021.

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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 2021 (Updated Format)
    c. Action Items & Business Arising
    d. 2021/22 to 2025/26 Strategic Plan Update
iii. Approval of September 24, 2021 Draft Board Meeting Minutes **[DECISION]**
iv. Committee Updates
v. Audit and Finance Committee: Finance Report (September Financials)
vi. Approval of September 17, 2021 Draft Committee of the Whole Meeting Minutes **[DECISION]**
vii. Approval of 2022 Board Meeting Schedule **[DECISION]**

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4b.i. Chair's Report

INFORMATION ONLY

It is my pleasure to provide this report for the November 2021 meeting. Since the previous Board Meeting report (September 2021), I have been involved in the following activities as Board Chair:

General:

- Liaised with Registrar, Vice Chair and Board to plan November 2021 Board meeting
- Reviewed draft September 2021 board meeting and Committee of the Whole meeting minutes
- Attended regular videoconferences with Registrar and Vice-Chair to discuss College and Board business
- Prepared and chaired an Emergency Board Meeting
- Planned and attended Long and Shortlist interviews for registrar candidates
- Connected with board members regarding board activities and agenda planning
- Met and oriented two new board members

Events:

- Attended staff meeting to update staff on the registrar search process

Committees:

- Registrar Search Committee
- Legislative Review Committee
- Governance Committee
- Audit and Finance Committee

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 28, 2021

Non-profit Tax Return – Filed August 11, 2021

Non-profit Information Return – Filed August 11, 2021

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.

Employer Health Tax 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:

Registrar and CEO

Chief Operating Officer

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

INFORMATION ONLY

	MOTIONS/ACTION ITEMS	RELEVANT BOARD MEETING	STATUS
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: At their September 2020 meeting, in light of the COVID-19 State of Emergency, the Board approved extending the implementation plan to adopt the Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations and the Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations from May 2021 to July 2022.** **This item is proceeding to the November 2022 Board Meeting for consideration of public posting approval.**	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: At the October 2019 Legislation Review Committee meeting, the committee discussed that these standards of practice should be included in the HPA Modernization Project, which began in 2021. This project is underway.**	06-2017	IN PROGRESS
3.	Motion: Direct the Registrar to explore the development of new requirements for the security of information in local pharmacy computer systems. **Status: The Policy & Legislation Department has addressed some of the issues in the new electronic record keeping PPP. Work is being done by the Ministry of Health addressing this issue with**	02-2018	IN PROGRESS

	MOTIONS/ACTION ITEMS	RELEVANT BOARD MEETING	STATUS
	PRIME and updated SCS document No further update at this point. The current status is still in effect.		
4.	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. **Status: Research and analysis has begun. Further, the College has engaged the Ministry of Health on the topic of amending the Drug Schedules Regulation to allow for scheduling by reference. No further update at this point. The current status is still in effect.**	11-2018	IN PROGRESS
5.	Motion: Direct the Registrar to remove current restrictions on pharmacist injection and intranasal administration of medications, while restricting the administration of injections for Schedule 1A drugs and drugs for cosmetic purposes and retaining current age limit restrictions. **Status: At the November Board meeting, the Board accepted the amendments, in principle to the Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions, as circulated. Registrar Nakagawa reported to the Board on his meeting with Mark Armitage, Assistant Deputy Minister, Health Sector Workforce and Beneficiary Services Division, Mitch Moneo, Assistant Deputy Minister, Pharmaceutical, Laboratory & Blood Services Division and David Byres, Associate Deputy Minister, Clinical Leadership on November 16, 2020. He expressed the Board's desire to collaborate with the Ministry in this matter. The Board asked Registrar Nakagawa to follow-up with another conversation with the Ministry and keep the Board appraised of the progress.** **Registrar Nakagawa had a subsequent discussion with Ministry of Health executives on December 10, 2020, who requested a more fulsome report addressing the rationale for removing the restrictions on drug administration. The College has drafted a "Drug Administration by Pharmacists" document to be discussed with the Ministry tentatively planned for February 2021.** **The "Drug Administration by Pharmacists" document was emailed to Mark Armitage, Assistant Deputy Minister Health Sector Workforce and Beneficiary Services Division, and to Mitch Moneo, Assistant Deputy Minister**	02-2019	IN PROGRESS

	MOTIONS/ACTION ITEMS	RELEVANT BOARD MEETING	STATUS
	Pharmaceutical, Laboratory and Blood Services Division, of the Ministry of Health on March 9, 2021. **A briefing note on the document is included for the consent agenda for the April 2021 Board meeting.** **Registrar Nakagawa met with Sheila Malcolmson, Minister of Mental Health and Addictions and updated her on this file to see how this fits into her portfolio and the coordinated network of mental health and addictions services.**		
6.	Motion: Direct the Registrar to require mandatory anonymous medication incident reporting in all pharmacies using any medication incident reporting platform of the pharmacy's choosing that meets the College's criteria. **Status: The NAPRA Medication Incident Working Group resumed work in August 2020 and met in February 2021 to continue work on the Draft Model Standards for Continuous Quality Improvement and Medication Incident Reporting. The final draft was completed and approved by NAPRA Board in May 2021. An update will be presented to the Board at their November 2021 meeting.**	09-2019	IN PROGRESS
7.	Direct the Registrar to engage with the Ministry of Health to move the amendments to the Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions forward. **Status: See update under: "Motion: Direct the Registrar to remove current restrictions on pharmacist injection and intranasal administration of medications, while restricting the administration of injections for Schedule 1A drugs and drugs for cosmetic purposes and retaining current age limit restrictions."**	09-2020	IN PROGRESS
8.	Direct the Registrar to remove natural health products from the Drug Schedules Regulation in a step-wise manner to align with the removal of natural health products from the National Association of Pharmacy Regulatory Authorities' National Drug Schedules. **Status: The Board approved the initial set of relevant DSR changes at their September 2021 meeting. The next set is expected to proceed to the Board for their February 2022 meeting.**	09-2020	IN PROGRESS.

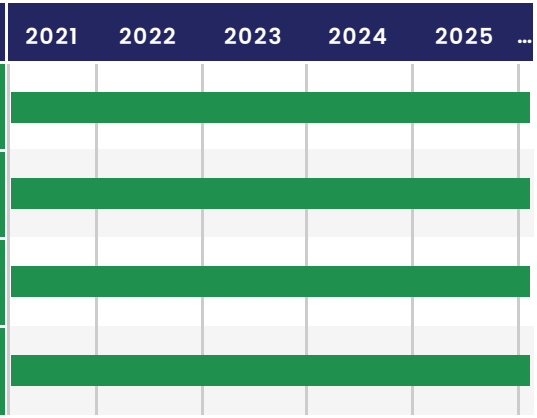
17
ACTION ITEMS

2%
ACTION ITEM COMPLETION

COLLEGE OF PHARMACISTS OF BC STRATEGIC PLAN

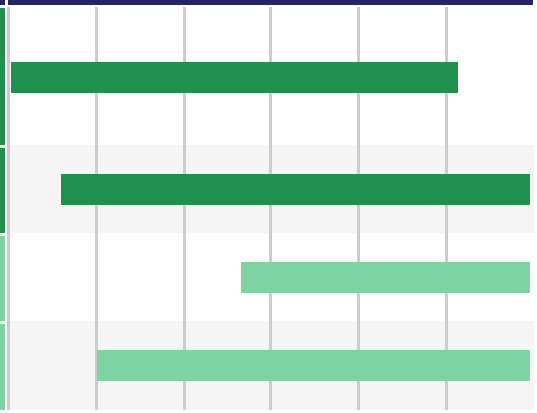
THE PUBLIC IS GIVEN EVIDENCE-INFORMED, PATIENT-CENTRED, TEAM BASED CARE

Action Item	Owner	Current Completion
To support the provision of evidence-informed, person-centred, team-based care: 100%		**7%** **7 / 100%** 7% ahead
Modernize the Standards of Practice to support this objective: 100%	Director of Practice Reviews & Quality Assurance	**10%** **10 / 100%** 10% ahead
Enhance practice reviews to include a focus area that reflects this objective: 100%	Director of Practice Reviews & Quality Assurance	**0%** **0 / 100%** -
Enhance Medication Incident Reporting: 100%	Director of Practice Reviews & Quality Assurance	**11%** **11 / 100%** 11% ahead



TO ENABLE PRACTICE INNOVATION THROUGH REGULATION THAT ENHANCES HEALTH AND WELLNESS OF THE PUBLIC

Action Item	Owner	Current Completion
Ensure patient safety and health and wellness of the public by implementing a plan that engages registrants and the public in identifying practice innovations and determining the College's role: 100%		0% 0 / 100% -
Review practice innovation impact on the public and consider ongoing opportunities for innovation: 100%	Deputy Registrar	0% 0 / 100% -
Define the regulatory approach to practice innovation: 100%	Director of Policy & Legislation	0% 0 / 100% -
Develop a framework to engage registrants and the public: 100%	Director of Communications & Engagement	0% 0 / 100% -

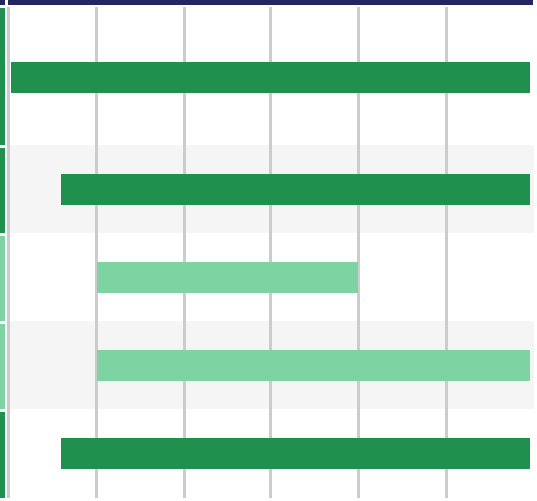


TO HAVE THE PUBLIC AND HEALTH PROFESSIONALS TRUST PHARMACY PROFESSIONALS AS VALUABLE RESOURCES

Action Item	Owner	Current Completion	2021	2022	2023	2024	2025	2026
To communicate what the public and health professionals can expect from pharmacy professionals, including services provided during provincial emergencies for example the COVID-19 pandemic and the overdose crisis: 100%		0% 0 / 100% -						
Support greater collaboration within the healthcare system, including team-based care, by building awareness of how pharmacy professionals can help ensure all British Columbians receive high quality person-centred care: 100%	Director of Practice Reviews & Quality Assurance	0% 0 / 100% -						
Hear from British Columbians on their expectations of pharmacy professionals, and the pharmacy care they provide: 100%	Director of Communications & Engagement	0% 0 / 100% -						
Develop a Bill of Rights to increase the transparency and awareness of what British Columbians should expect from pharmacy professionals: 100%	Deputy Registrar	0% 0 / 100% -						

TO ALIGN WITH GOVERNMENT PRIORITIES AND HAVE STRONG, COLLABORATIVE ENGAGEMENT WITH ALL PROVIDERS

Action Item	Owner	Current Completion
Enhance patient health and wellness and align with the new health profession regulatory framework through collaborative engagement with Government and all healthcare providers: 100%		0% 0 / 100% -
Develop a position statement on regulation of pharmacy practice in interdisciplinary care: 100%	Deputy Registrar	0% 0 / 100% -
Review and implement the new health profession regulatory framework: 100%	Director of Policy & Legislation	0% 0 / 100% -
Demonstrate existing front-line collaboration across healthcare providers: 100%	Director of Communications & Engagement	0% 0 / 100% -
Support healthcare provider access to PharmaNet: 100%	Deputy Registrar	0% 0 / 100% -



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4b.iii Approval of September 24, 2021 Draft Board Meeting Minutes

DECISION REQUIRED

Recommended Board Motion:

Approve the September 24, 2021 draft Board meeting minutes as circulated.

Appendix	
1	https://library.bcpharmacists.org/2_About_Us/2-1_Board/Board_Videoconference_Minutes-20210924.pdf

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4b.iv Committee Updates

INFORMATION ONLY

Purpose

To provide updates of committee activities since the last Board meeting.

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 and will not be submitting minutes.

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i. Application Committee
The Application Committee has met six times since the last Board meeting. The committee reviewed twelve pharmacy files. Five files were incomplete renewals, and seven pharmacy files were eligibility-related cases. Please note, as this update was submitted on November 5, 2021 the number of pharmacy files reviewed may increase dependent on the number of cases reviewed in November. (E.g., late renewals and any new eligibility cases.)

ii. Audit and Finance Committee
The Audit and Finance Committee will be meeting before the Board meeting to review the latest financial report and discuss the 2022/23 budget process as well as an update re the Joint Venture curtain wall project.

iii. Discipline Committee
The Discipline Committee did not have any hearing for the period of August 2021 to September 2021. There are currently five pending files and one file in progress.

iv. Drug Administration Committee
The Drug Administration Committee (DAC) has met once since the June Board meeting. The recommendation from the DAC will be presented at the November 2021 Board meeting.

v. Ethics Advisory Committee
The Ethics Advisory Committee has not met since the September Board meeting.

vi. Governance Committee

The Governance Committee ("The Committee") met on November 1, 2021 via videoconference and discussed four items.

1) The Committee reviewed the September 24, 2021, Board meeting evaluation survey results and discussed the following survey comments:
    - Onboarding of new Board members – mentoring opportunities:
        - Pairing of new and experienced Board members
        - Creating WhatsApp groups of three for questions
        - Virtual teambuilding events
    - The Role of the Board Chair as a facilitator and not a commentator;
    - The Board Chair should not be viewed as the gatekeeper of collating Board agenda topics;
        - Lack of response from Board members during call for agenda items
    - Definition of consensus;
        - Opportunity in the future for Bradley Chisholm to facilitate session on Board table discussion
    - Criteria for Consent Agenda items; and
    - Clarification needed on how to read the Risk Register.

2) Public Representation on the Board
    - David presented an environmental scan of the three large Colleges' Board composition and selection processes.

3) Appointment of Board Members to Committees
    - There was a preliminary discussion on the list of Board appointments to Committees for the November Board meeting.
    - The Committee will meet after Board Chair Ishoy speaks to the two new Board members.

4) Board Competency Matrix
    - The Committee came to a consensus that the development of a Board Competency Matrix is a collective Board responsibility. It is recommended to strike a committee to complete the Board Competency Matrix.

vii. Inquiry Committee

The Inquiry Committee met four times via videoconference and seven times via teleconference for the period of August 2021 to September 2021. 31 files were reviewed or disposed of, of which 24 files were new files, 7 were reconsideration files and none were *PODSA* s. 18 report files. 118 calls/tips were received during this reporting period and 25 formal complaints were received. All scheduled "in-person" meetings were held virtually via Microsoft Teams. The number of calls received were lower compared to 2020 but "average" in comparison to previous years.

viii. Jurisprudence Examination Subcommittee

The Jurisprudence Examination (JE) Subcommittee has met once since the last Board meeting. The meeting was held to review the JE statistical data and results from the October sitting.

ix. Legislation Review Committee

The Legislation Review Committee met on October 29, 2021, and discussed the following agenda items:

- Bylaw Amendments to Officially Adopt the NAPRA Standards for Sterile Compounding
- The Policy & Legislation Forecasting Document

x. Pharmacy Advisory Committee

- The Pharmacy Advisory Committee has not met since the last Board meeting.

xi. Practice Review Committee

The Practice Review Committee met on September 28, 2021 and discussed the following agenda items:

- Appointment of Vice-chair
- PRP operational updates including review statistics, risk register, and Insight Articles
- CPBC Orientation.

xii. Quality Assurance Committee

The Quality Assurance Committee met on October 26, 2021 and discussed the following agenda items:

- PDAP operational updates including review statistics
- PDAP Feedback Survey responses
- 2021 CE Audit update
- Exemption Policy review.

xiii. Registrar Evaluation and Succession Planning Committee

The Registrar Search Committee will meet in place of the Registrar Evaluation and Succession Planning Committee until a Registrar and CEO is hired.

xiv. Registrar Search Committee

The Registrar Search Committee (RSC) met on numerous occasions throughout September, October. During these meetings, the following tasks were completed:

- The RSC ranked short list candidates
- The RSC came to consensus on bringing forward 2 candidates to the board for review
- The RSC requested a meeting of the board to assess if more candidates should be brought forward for the board to review
- Two rounds of short list interviews were organized by the Committee and attended by the board
- LeaderFit™ Testing and References were checked for the top two candidates
- The Board deliberated and voted on the final candidates.

xv. Registration Committee

The Registration Committee met twice since the last Board meeting. The committee reviewed three registrant files, in which all three were related to the registrant being unable to check off a point on the statutory declaration.

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

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4b.v Audit and Finance Committee: Finance Report (September 2021 Financials)

INFORMATION ONLY

Purpose

To report on the highlights of the September 2021 financial reports.

Background

The September 2021 financial reports reflect **seven months** of activity. Attached are the Statement of Financial Position, a summary Statement of Revenue and Expenses and more detailed reports on Revenue and on Expenses.

Statement of Financial Position

The College's cash position is well funded to meet payables with a balance of almost $1.923 million. Investments totalled almost $4.9 million. Payables and accruals are just over $733,000. The Working Capital Ratio (Current Assets to Current Liabilities) is 1.08. This is almost the same as a year ago when it was 1.12. It is dropping as the College continues to run deficits, but not too quickly.

Revenue

The total *Licensure revenues* continue to be slightly over budget, by $75,275 or 1%. *Other revenues* (administrative fees, fines, etc.) are also over budget by just over $19,000, mainly due to fine revenues. The combined result is that total revenues are over budget, by almost $93,000 or 2% over budget.

Expenses

Total Year to Date Actual expenses is considerably under budget, by $473,425 or 7%. See the variance analysis which follows for details. Much of the under-budget variances are due to changes in operations due to COVID-19 or timing as the budget includes some increased activities later in the year.

This leaves the combined (revenue and expenses) under budget position at $566,132.

Variance analysis by department:

Department	Budget	Actual	Comment
Board & Registrar's Office	420,891	430,918	Facilitators / consultants are over budget, partially offset by other areas that are under budget. This area will likely remain over budget with the Registrar Search meeting honoraria adding to expenses.
Finance and Administration	1,223,806	1,125,117	Timing re Registrar recruitment invoicing, consulting.
Information Technology	1,464,058	1,360,492	Timing re software licences.
Grant Distribution	6,250	7,000	
Registration & Licensure	626,019	555,394	Timing re committee income replacement (honoraria), legal and consulting.
Quality Assurance	186,129	174,227	Timing re outside services (consultant).
Practice Reviews	916,783	879,498	Gapping in salaries (timing due to accrued throughout the year but hiring will happen in the fall) and Medication Incident Reporting project costs.
Complaints & Investigations	1,222,944	1,118,280	Primarily savings / timing re Discipline – legal and consulting.
Policy & Legislation	327,748	291,488	Gapping in salaries (accrued throughout the year but hiring will happen in the fall) and legal (timing).
Communications & Engagement	250,687	247,903	Timing re consulting.
Projects	12,916	0	Strategic Plan projects will begin in the fall.
Amortization	124,376	118,864	
Total Expenses	**6,872,607**	**6,309,182**	**7% under budget ($473,425)**

Appendix	
1	Statement of Financial Position
2	Statement of Revenue and Expenses
3	Statement of Revenue
4	Statement of Expenses

College of Pharmacists of BC

Statement of Financial Position

As at September 30, 2021

ASSETS	
Cash and Cash Equivalents	1,922,523.96
Investments	4,894,852.29
Receivables	99,693.11
Prepaid Expense and Deposits	322,635.07
Current Assets	7,239,704
Investments in College Place Joint Venture	1,413,683
Development Costs	50,454
Property & Equipment	519,445
Non-current Assets	1,983,582
Total Assets	**9,223,286**

LIABILITIES AND NET ASSETS	
Payables and Accruals	733,291
Capital Lease Obligations (Current)	5,599
Deferred Revenue	5,965,400
Total Current Liabilities	6,704,290
Capital Lease Obligations (non-current)	21,773
Total Liabilities	6,726,063
Total Net Assets	2,497,224
Total Liabilites and Net Assets	**9,223,286**

College of Pharmacists of BC

Statement of Revenue and Expenses

For the 7 months ended September 30, 2021

	Prior Year	Current Year		Current Year	
	Actual	Budget	Actual	Variance ($)	Variance (%)
	YTD 2020/21	YTD 2021/22	YTD 2021/22	(Budget vs. Actual)	(Budget vs. Actual)
Revenue					
Licensure revenue	5,462,712	5,823,883	5,899,158	75,275	1%
Non-licensure revenue	277,293	266,995	284,427	17,432	7%
Transfer from Balance Sheet	-	-	-	-	0%
Total Revenue	**5,740,005**	**6,090,878**	**6,183,586**	**92,707**	2%
Expenses					
Total Expenses Before Amortization	5,662,256	6,658,232	6,190,318	467,913	7%
Amortization	166,258	124,376	118,864	5,512	4%
Total Expenses Including Amortization	**5,828,514**	**6,782,607**	**6,309,182**	**473,425**	7%
Net Surplus/(Deficit) of revenue over expenses after amortization expense	**(88,509)**	**(691,729)**	**(125,597)**	**566,132**	

College of Pharmacists of BC

Statement of Revenue

For the 7 months ended September 30, 2021

	Prior Year	Current Year		Current Year	
	Actual	Budget	Actual	Variance ($)	Variance (%)
	YTD 2020/21	YTD 2021/22	YTD 2021/22	(Budget vs. Actual)	(Budget vs. Actual)
Revenue					
Pharmacy fees	2,094,456	2,194,636	2,227,145	32,509	1%
Pharmacists fees	2,864,906	3,063,008	3,093,829	30,822	1%
Technician fees	503,350	566,239	578,183	11,944	2%
Licensure revenue	5,462,712	5,823,883	5,899,158	75,275	1%
Other revenue (fines/assessments, late fees, certificate of letter of standing)	69,252	67,661	86,860	19,200	28%
Grant Revenue	1,560	1,820	1,560	(260)	(14%)
Investment income	62,717	59,312	57,805	(1,507)	(3%)
College Place joint venture income	143,765	138,202	138,202	(0)	(0%)
Non-licensure revenue	277,293	266,995	284,427	17,432	7%
Transfer from Balance Sheet	-	-	-	-	0%
Total Revenue	**5,740,005**	**6,090,878**	**6,183,586**	**92,707**	2%

College of Pharmacists of BC

Statement of Expenses

For the 7 months ended September 30, 2021

	Prior Year	Current Year		Current Year	
	Actual	Budget	Actual	Variance ($)	Variance (%)
	YTD 2020/21	YTD 2021/22	YTD 2021/22	(Budget vs. Actual)	(Budget vs. Actual)
Expenses					
Board and Registrar's Office	341,287	420,891	430,918	(10,027)	(2%)
Finance and General Administration	1,125,359	1,223,806	1,125,117	98,689	8%
Information Technology	1,275,570	1,464,058	1,360,492	103,565	7%
Grant Distribution	-	6,250	7,000	(750)	(12%)
Registration and Licensure	515,251	626,019	555,394	70,625	11%
Quality Assurance	159,883	186,129	174,227	11,902	6%
Practice Reviews	822,116	916,783	879,498	37,285	4%
Complaints and Investigations	919,838	1,222,944	1,118,280	104,664	9%
Policy and Legislation	268,258	327,748	291,488	36,260	11%
Communications and Engagement	234,695	250,687	247,903	2,783	1%
Projects	-	12,916	-	12,916	100%
Total Expenses Before Amortization	5,662,256	6,658,232	6,190,318	467,913	7%
Amortization	166,258	124,376	118,864	5,512	4%
Total Expenses Including Amortization	**5,828,514**	**6,782,607**	**6,309,182**	**473,425**	7%

College of Pharmacists of British Columbia

BOARD MEETING
November 26, 2021

4b.vi Approval of September 17, 2021 Draft Committee of the Whole Meeting Minutes

DECISION REQUIRED

Recommended Board Motion:

Approve the September 17, 2021 draft Committee of the Whole meeting minutes as circulated.

Appendix	
1	September 17, 2021 Draft Committee of the Whole Meeting Minutes

College of Pharmacists of British Columbia

Committee of the Whole Meeting
September 17, 2021
Via Video Conference

MINUTES

Members Present:
Claire Ishoy, Chair, District 7
Steven Hopp, Vice-Chair, District 4
Alex Dar Santos, Board member, District 1
Christine Antler, Board member, District 2
Andrea Silver, Board member, District 3
Michael Ortynsky, Board member, District 5
Anca Cvaci, Board member, District 6
Bal Dhillon, Board Member, District 8
Tracey Hagkull, Government Appointee
Anne Peterson, Government Appointee
Katie Skelton, Government Appointee
Justin Thind, Government Appointee

Staff:
Bob Nakagawa, Registrar and CEO
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
Matthew Baguley, FOI & Privacy Officer
Tien Huynh, Information Technology Manager
Stephanie Kwok, Executive Assistant and Board Coordinator
Hilary Leung, Policy & Legislation Analyst

Guest Speakers:
Steve Brown, Manager, Cyber Engineering Practice, BDO Canada LLP
Bradley Chisholm, Chief Officer, Strategy and Governance, BC College of Nurses and Midwives
Joe Gallagher, CEO, Qoqoq Consulting LTD
Charles Holmes, CEO, CE Holmes Consulting Inc
Sulksun, Knowledge Keeper, Salish Nation

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1. **WELCOME & CALL TO ORDER**
   Chair Ishoy called the meeting to order at 8:45am on September 17, 2021.

   Chair Ishoy acknowledged the Syilx (pronounced Say-el-ks) Okanagan people on whose unceded traditional territories she chaired the meeting from.

College of Pharmacists of British Columbia

She also recognized that attendees of the videoconference are joining the call from different locations across BC, she acknowledged that the Indigenous Peoples are the traditional stewards of the lands and waters from where we attended the meeting

2. MOVING FORWARD: FROM TRUTH TO RECONCILIATION

Joe Gallagher, CEO, Qoqoq Consulting LTD facilitated a cultural safety and humility session with the Board.

Sulksun opened the session with a chant.

The key topics addressed in module 1: Truth – Review of 21 things you may not know about the Indian Act:

- Why do you think so little is known about the Indian Act?
- How does knowing more about the Indian Act affect your life?
- Which aspects of the Indian Act were most disturbing to you?

The key topics addressed in module 2: Reconciliation – National Day for Truth and Reconciliation:

- What do you think is important to consider on September 30?
- How do you feel about the new Statutory Holiday?
- What will you do on National Day for Truth and Reconciliation?

The key topics addressed in module 3: Reconciliation – Organizing and Strategizing to Act Presentation:

- Explore becoming an anti-racist individually and as an organization
- How will you work to be the best human being you can be?
- How will you embody the values and approaches of the Champions (Dr. Bryce, Dr. Blackstock, MP Qaqqaq)?
- What harmful colonial knots are within your sphere of influence?
- How can you begin to untie them?

Considerations for the Board as a whole:

- What can the Board do to continue to build greater knowledge, understanding and acceptance of issues related to Indigenous peoples?
- What strategic direction will the Board set for the organization related to eradicating Indigenous specific racism and achieving cultural safety and humility?
- How will the Board ensure oversight of process?
- What decisions of the Board are required to enable the work to take place?
- How can the Board contribute to advancing relationships with Indigenous peoples and ensure accountability?

Sulksun closed the session.

College of Pharmacists of British Columbia

3. **CYBERSECURITY SESSION**

Steve Brown, Manager, Cyber Engineering Practice, BDO Canada LLP facilitated a cybersecurity session with the Board.

The key topics addressed includes:

- Cybersecurity facts, figures and statistics;
- Phishing emails;
- Cybersecurity threats and challenges for non-profit organizations;
- Ransomware;
- Cyber incident management; and
- How organizations can protect themselves.

4. **RISK REGISTER DEEP DIVE: IT RISK**

Mary O'Callaghan, Chief Operating Officer and Tien Huynh, Information Technology Manager presented on information technology risks for an organization.

The key topics addressed in the session includes:

- Risk management;
- Recent example of cyber-attacks;
- CPBC Risk Register:
    - High and medium likelihood risks
    - Low likelihood but high impact risks
    - Low likelihood but medium impact risks;
- Challenges for not-for-profit organizations; and
- Suggested additions to the risk register.

COLLEGE RELATIONSHIP SESSION

Bradley Chisholm, CEO, Qoqoq Consulting LTD and Charles Holmes, CEO, CE Holmes Consulting Inc facilitated a Board dialogue on enhancing relations with advocacy groups and government.

The key discussion points include:

- Mandate of external groups and current state of interactions with each;
- Purpose of the College's relationship with these groups;
- How does a relationship with these groups help (or potentially challenge) the College's ability to fulfill our mandate;
- Potential conflict of interest;
- What does relationship mean;
- Terms of engagement; and
- Government relations.

Commitment Statements

Breakout group #1: (Claire, Doreen, Mary, Tracey)

- Be respectful even when there is a divergence of opinions
- Mutual understanding and respect of mandates
- By working together we'll strengthen and resolve our mandates

College of Pharmacists of British Columbia

- Ongoing dialogue – regular and ongoing (respectful and direct)
- Consider other groups? What is our piece in this?
    - Generally centered around College senior leadership staff (thinking of continuity)

Breakout group #2 (Alex, Anne, Ashifa, Gillian, Steven)

- "We commit to being proactive and acting in good faith."
    - Encompasses timely communication
- "We commit to identifying barriers in each other's work."
- "We commit to having respectful communications with each other."

Breakout group #3 (Anca, Bal, Bob, Katie)

- Have clarity and respect for each other
- Work together even when interests are divergent
- Have clearly defined lines of communication
- Committed to make this relationship work and have accountability
- Agreement on transparency of discussion
- Confirm each discussion is clearly within our respective mandates
- Have understanding and respect of each other's views and perspectives

Breakout group #4 (Christine. A, Christine. P, David, Justin, Michael)

- Commitment to an open and honest dialogue
- Commitment to engage in a collaborative and respectful discussions with a healthy debate, especially where mandates differ
- Commitment to acknowledge and respect each other's unique priorities as well as their unique roles
- Commitment to a well-defined relationship – understand our respective mandates and why we're doing what we're doing (our strategic positions)
- Commit to collaboration without collusion
- Commit to regular chats with other organizations about what they're talking to government and other stakeholders about

5. ADJOURNMENT

Chair Ishoy adjourned the meeting at 4:35pm on September 17, 2021.

College of Pharmacists of British Columbia

BOARD MEETING
November 26, 2021

4b.vii. Approval of 2022 Board Meeting Schedule

DECISION REQUIRED

Recommended Board Motion:

Approve the 2022 Board Meeting Schedule as circulated.

The Board Meeting Schedule for 2022 is:

Thursday, February 10, 2022
Friday, February 11, 2022

Friday, April 15, 2022
Friday, April 22, 2022

Thursday, June 9, 2022
Friday, June 10, 2022

Friday, September 16, 2022
Friday, September 23, 2022

Thursday, November 17, 2022
Friday, November 18, 2022

CPBC Annual General Meeting
Thursday, November 17, 2022

*Please note, the Board has the option of meeting in person for the Feb, June and November meetings, depending on the PHO requirements at the time.

College of Pharmacists of British Columbia

BOARD MEETING
November 26, 2021

5. Confirmation of Agenda

DECISION REQUIRED

Recommended Board Motion:

Approve the November 26, 2021 Draft Board Meeting Agenda as circulated, or amended.

Appendix	
1	November 26, 2021 Draft Board Meeting Agenda

College of Pharmacists of British Columbia

Board Meeting
Friday, November 26, 2021

AGENDA

8:45am - 9:15am	30	**1.**	Call to Order *Land Acknowledgement*	Chair Ishoy
		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
9:15am - 9:45am	30	**6.**	Medication Incident Reporting Update	Ashifa Keshavji
9:45am - 10:20am	35	**7.**	Legislation Review Committee: Bylaw Amendments to Officially Adopt the NAPRA Standards for Sterile Compounding **[DECISION]**	Justin Thind
10:20am - 10:30am	10		***BREAK***	
10:30am - 11:15am	45	**8.**	Hospital at Home - How Curiousity and Collaboration are Transforming Acute Care in BC	Winnie Lam Dr. Sean Spina
11:15am - 12:00pm	45	**9.**	Drug Administration Committee: Amendments to Pharmacist Drug Administration Age Limit **[DECISION]**	Alex Dar Santos
12:00pm - 1:00pm	60		***LUNCH***	
1:00pm - 1:20pm	20	**10.**	Governance Committee: a) Appointment of Board Members to Board Committees **[DECISION]** b) Board Meeting Guidelines: Robert Rule's to BCCNM Meeting Guidelines **[DECISION]**	Anne Peterson
1:20pm - 1:50pm	30	**11.**	Registrar and CEO Last Report	Registrar Nakagawa
1:50pm - 1:55pm	5	**12.**	Items Brought Forward from Consent Agenda	Chair

College of Pharmacists of British Columbia

BOARD MEETING
November 26, 2021

6. Medication Incident Reporting Update

INFORMATION ONLY

Purpose

To provide the Board with an update on the College's work towards implementation of mandatory anonymous medication incident reporting in BC.

Background

Medication related issues are among the most common complaints received at the College. Due to its potential impact on patient safety, implementation of mandatory medication incident reporting has been a priority for pharmacy regulatory authorities across Canada. This has prompted the College to examine its existing quality management requirements and explore options for implementation in British Columbia.

At the September 2019 Board meeting, the Board directed the Registrar to require mandatory anonymous medication incident reporting in all pharmacies using any medication incident reporting platform of the pharmacy's choosing that meets the College's criteria. Medication incident reporting is also a key initiative in the College's 2021/22 - 2025/26 Strategic Plan.

Since 2019, the College has participated in the National Association of Pharmacy Regulatory Authority's (NAPRA's) working group to develop national standards of practice for reporting, analyzing, preventing, and learning from medication-related incidents. The College had the opportunity to provide significant feedback during the development and revision of the standards by engaging with members of the Pharmacy Advisory Committee and various staff across departments within the College. The final document entitled the *Model Standards of Practice for Continuous Quality Improvement and Medication Incident Reporting by Pharmacy Professionals* was approved by the NAPRA Board of Directors in May 2021 and published in July 2021 (see Appendix 1). The objective is to promote patient safety in Canada through reporting and learning from medication incidents and near misses, in accordance with federal/provincial/territorial requirements.

Discussion

The NAPRA *Model Standards of Practice for Continuous Quality Improvement and Medication Incident Reporting by Pharmacy Professionals* are based on the principles of a culture of patient safety and a just culture within the pharmacy practice environment, wherein learning is promoted through reporting without fear of punitive action. This provides pharmacy professionals with information and learning opportunities based on meaningful analysis of both pharmacy-level and national/provincial-level data, with the goal of reducing the number of

medication incidents, mitigating risks to patients, and improving the quality and safety of patient care.

It is important to note that the NAPRA standards serve as a model which can be adopted or adapted for implementation by each Pharmacy Regulatory Authority (i.e., the College of Pharmacists of BC). Although the NAPRA standards have distinct sections for continuous quality improvement and medication incident reporting, the College has prioritized implementation of medication incident reporting. Principles of continuous quality improvement permeate through all aspects of practice and the College will examine how these standards fit within our existing quality management requirements.

COVID-19 has impacted the implementation timelines of the Medication Incident Reporting Program by approximately one year due to the delayed launch of the College's 2021/22 - 2025/26 Strategic Plan and the NAPRA Medication Incident Reporting Working Group's temporary pause of work in 2020. Moving forward, the College will continue to engage in opportunities for discussion with other pharmacy regulatory authorities across Canada for the establishment of a national repository of medication incident and near miss reporting data. The first of such meetings occurred on October 26, 2021 through the BC-proposed Continuous Quality Improvement and Medication Incident Reporting Information Sharing Group (National Information Sharing Group) hosted by NAPRA. The College will be using the NAPRA standards and insights gained from the National Information Sharing Group to guide our work in implementing mandatory anonymous medication incident reporting for all pharmacies in British Columbia.

Next Steps

The College will continue to work on implementation of a Medication Incident Reporting Program as included in the College's current Strategic Plan. These next steps include:

- Providing the Board with an update in 2022
- Draft bylaw and policy changes in 2022/23
- Implementation of Medication Incident Reporting Program in 2023/24

Appendix	
1	NAPRA *Model Standards of Practice for Continuous Quality Improvement and Medication Incident Reporting by Pharmacy Professionals*

NAPRA ANORP

National Association of Pharmacy Regulatory Authorities ®
Association nationale des organismes de réglementation de la pharmacie

Model Standards of Practice for Continuous Quality Improvement and Medication Incident Reporting by Pharmacy Professionals

Model Standards of Practice for Continuous Quality Improvement and Medication Incident Reporting by Pharmacy Professionals

Approved by the National Association of Pharmacy Regulatory Authorities' (NAPRA) Board of Directors May 2021, published July 2021.

The National Association of Pharmacy Regulatory Authorities
130 Albert Street, Suite 1800
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Canada

E-mail: info@napra.ca | Telephone: 613-569-9658

Contents

Introduction

Background

Medication incident reporting has long been a recommended part of the practice of pharmacy in Canada to protect patients' health and well-being. In recent years, it has been a priority of provincial/territorial pharmacy regulatory authorities (PRAs) to move towards implementing mandatory reporting programs. These programs improve the ability to analyze and learn from medication incidents and near misses, so that pharmacy professionals may continually improve the quality of pharmacy practice to prevent and mitigate risks to patients.

As part of the National Association of Pharmacy Regulatory Authority's (NAPRA's) 2019–2023 Strategic Plan, the need for the development of national standards of practice for reporting, analyzing, preventing, and learning from medication-related incidents was identified. As many of the stakeholders involved in medication incident reporting are national in scope, it was felt that national standards of practice would help to facilitate continuous quality improvement and medication incident reporting across Canada and would improve the ability to share learnings across the country. Sharing learnings across the country will increase the richness and volume of the data available to improve pharmacy practice in the best interest of the Canadian public.

NAPRA formed a working group consisting of PRA representatives and practising pharmacy professionals with expertise in medication incident reporting in their respective jurisdictions. An environmental scan was conducted, including a review of the literature on medication incident reporting and quality improvement in pharmacy practice and existing national and international standards. A draft document was then developed and revised through a series of consultations with NAPRA's membership, as well as key stakeholders related to medication incident reporting. The final document was approved by the NAPRA Board of Directors in May 2021.

Objective

This document has been developed by NAPRA as a supplement to the model standards of practice for Canadian pharmacists and pharmacy technicians. The objective is to promote patient safety in Canada through reporting and learning from medication incidents and near misses, in accordance with federal/provincial/territorial requirements.

As with all NAPRA documents, these supplemental standards of practice serve as a model, which can be adopted or adapted for implementation as seen fit by the PRA in each province/territory, based on the needs in that jurisdiction. Once these standards are implemented by the PRA in a particular jurisdiction, pharmacy professionals will be expected to follow them in the development of their pharmacy's continuous quality improvement processes and in the event of a medication incident or near miss. These standards represent the minimum expected standards of practice for continuous quality improvement and medication incident reporting. Other practices may be acceptable, but only if the pharmacy manager and/or pharmacy professional is able to demonstrate their equivalency or superiority to the practices outlined herein to the PRA in their jurisdiction.

Introduction

These standards are based on the principles of a culture of patient safety and a just culture within the pharmacy practice environment, wherein learning is promoted through reporting without fear of punitive action. It is important to note that the goal of these standards of practice, and of medication incident reporting in general, is to promote continuous quality improvement processes that contribute to patient safety and enhance patient trust in the safety of pharmacy practice. Continuous quality improvement and mandatory medication incident reporting programs provide pharmacy professionals with information and learning opportunities based on meaningful analysis of both pharmacy-level and national/provincial/territorial-level data, with the goal of reducing the number of medication incidents, mitigating risks to patients, and improving the quality and safety of patient care.

The data gathered from medication incident reporting is not used to trigger disciplinary or punitive action, but rather is used to promote continuous learning and quality improvement that enhance patient safety. The need to share anonymous data with a national and/or provincial database is important, as this will facilitate the sharing of learnings from medication incident reporting across the country. It is important to note that data submitted to a PRA through the medication incident reporting system, in jurisdictions where this is required, will not include any information that could be used to identify the patient, the individual who completed and/or submitted the report, nor any pharmacy personnel involved in the incident or near miss.

The goal of these standards of practice, and of medication incident reporting in general, is to promote continuous quality improvement processes that contribute to patient safety and enhance patient trust in the safety of pharmacy practice.

Glossary

Anonymized reports
Reports that do not include any information that could be used to identify the individual who completed and/or submitted the report, nor any pharmacy personnel involved in the incident or near miss, in accordance with federal and/or provincial/territorial privacy laws.

Contributing factor[1]
A circumstance, action or influence that is thought to have played a part in the origin or development of an incident or near miss, or to increase the risk of an incident or near miss.

Culture of patient safety[2]
A component of organizational culture, which includes the shared beliefs, attitudes, values, norms and behavioural characteristics of employees, and influences staff member attitudes and behaviours in relation to their organization's ongoing patient safety performance. An enabling patient safety culture is characterized by leadership that leads by example, transparent communication, psychological safety facilitating reporting of errors, patient and family engagement, and a commitment to ongoing improvement.

De-identified report
A report that does not include any information that could be used to identify patients, in accordance with federal and/or provincial/territorial privacy laws.

Just culture[3]
The environment of a workplace in which consideration is given to wider systemic issues when things go wrong, enabling professionals and those operating the system to learn without fear of retribution. To encourage reporting of safety issues, inadvertent human error, freely admitted, is generally not subject to sanction. However, people are held to account where there is evidence of unprofessional conduct or deliberate acts.

Medication incident[4]
Any preventable event that may cause or lead to inappropriate medication use or patient harm that has reached the patient. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labelling/packaging/nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

National database
A repository of medication incident and near miss reporting data submitted from across Canada. The data contained in a national database is de-identified and anonymized.

Near miss[5]
An event that could have resulted in unwanted consequences but did not because, either by chance or through timely intervention, the event did not reach the patient.

1 Definition derived from the Canadian Patient Safety Institute's glossary (Canadian Patient Safety Institute n.d.).

2 Definition obtained from Royal College of Physicians and Surgeons of Canada (n.d.).

3 Definition derived from National Health Service (2018).

4 Definition derived from Institute for Safe Medication Practices Canada (n.d.).

5 Definition obtained from Institute for Safe Medication Practices Canada (n.d.).

Glossary

Peer support[6]
Emotional and practical support between two people who share a common experience, such as a mental health challenge or illness.

Pharmacy manager
The pharmacy professional recognized as being in charge of the operations of a specific pharmacy and who is held accountable by the pharmacy regulatory authority for the operations of that pharmacy.

Pharmacy professional
A person authorized to practise as a pharmacist or pharmacy technician by the pharmacy regulatory authority in one of the provinces or territories of Canada. This term includes pharmacy managers. For the purposes of this document, a pharmacy manager would be expected to meet the standards of practice for pharmacy professionals in addition to the standards for pharmacy managers.

Provincial database
A repository of medication incident and near miss reporting data submitted from across a particular province. The data contained in a provincial database is de-identified and anonymized.

Reporting platform
The computer software used by pharmacy professionals for recording medication incidents and near misses at the pharmacy level and reporting them to a national and/or provincial database.

Root cause[7]
The most fundamental reason (or one of several fundamental reasons) a suspected failure, a medication incident, a near miss, or a situation in which performance does not meet expectations has occurred.

Root-cause analysis[8]
An objective analytical process that can be used to perform a comprehensive, system-based review of critical incidents. It includes the identification of the root and contributory factors, determination of risk reduction strategies, and development of action plans along with measurement strategies to evaluate the effectiveness of the plans. (Similar term: incident analysis[9])

Safety self-assessment
A process used by pharmacy professionals to proactively identify potential safety concerns. Regular use of this process may help decrease the number of medication incidents and near misses and identify opportunities for improvement at a pharmacy in order to mitigate risks to patients. The frequency of use may vary depending on province, territory, or organization.

6 Definition obtained from Canadian Mental Health Association (2018).

7 Definition derived from Joint Commission (2015).

8 Definition derived from Institute for Safe Medication Practices Canada (n.d.).

9 The term incident analysis is used in the *Canadian Incident Analysis Framework* (Canadian Patient Safety Institute 2012).

Standards of practice for pharmacy professionals

1. Pharmacy manager standards

The pharmacy manager ensures safe care for their patients through oversight of the continuous quality improvement processes within their pharmacy team and ensuring the competent management of medication incidents and near misses.

1.1 Continuous quality improvement

1.1.1 The pharmacy manager works with owners, employers, and pharmacy personnel to foster a culture of patient safety and a just culture in the workplace environment in order to promote learning and quality improvement that supports patient safety.

1.1.2 The pharmacy manager ensures that pharmacy-specific policies and procedures for continuous quality improvement are developed, documented, and implemented and include the processes for:

1.1.2.1 Identifying root causes and contributing factors for medication incidents and near misses and performing a root-cause analysis as appropriate

1.1.2.2 Reviewing and assessing summary reports and analyses of pharmacy-specific data

1.1.2.3 Reviewing and assessing objective analyses from regional-, provincial/territorial-, and/or national-level data

1.1.2.4 Holding routine[10] team meetings to discuss summary reports and analyses and determine how to address them

1.1.2.5 Completing a safety self-assessment on a routine[10] basis

10 Note: Routine team meetings and safety self-assessments should be held/completed as often as necessary to address issues identified by the pharmacy. The minimum frequency of routine team meetings and safety self-assessments will depend on the requirements set by the PRA in each province and territory.

1.1.3 The pharmacy manager ensures that a continuous quality improvement program for the pharmacy is developed, documented and implemented and includes the processes for:

1.1.3.1 Following up with team members involved in medication incidents and near misses and encouraging them to seek peer support when appropriate

1.1.3.2 Ensuring that pharmacy policies and procedures are reviewed and updated based on the pharmacy's root-cause analyses, safety self-assessments, summary reports and analyses, and objective analyses from regional-, provincial/territorial-, and national-level data

1.1.3.3 Implementing improvements to the pharmacy's procedures in accordance with the pharmacy's continuous quality improvement plan

1.1.3.4 Developing a monitoring process to determine the efficacy of implemented improvements to the pharmacy's procedures

1.1.3.5 Implementing further updates to the pharmacy's procedures if previous improvements are not effective

1.2 Management of medication incidents and near misses

1.2.1 The pharmacy manager ensures that pharmacy-specific policies and procedures are developed, documented, and implemented that clearly outline the steps that pharmacy personnel must take when a medication incident or near miss occurs, including the steps for disclosure.

1.2.2 The pharmacy manager ensures that a pharmacy-specific policy is developed, documented, and implemented that clearly outlines the pharmacy's criteria for determining whether a near miss must be reported to a national/provincial database.[11]

1.2.3 The pharmacy manager works with owners and employers to ensure that appropriate resources are in place to enable pharmacy personnel to devote time to continuous quality improvement and reporting activities.

11 Note: The pharmacy manager should align the pharmacy's criteria with the guidance provided by the PRA in their jurisdiction. In provinces and territories where the PRA defers the decision on when to report near misses to the pharmacy manager, they may refer to Appendix A for sample criteria that can be used to determine whether a near miss should be reported.

1.2.4 The pharmacy manager works with owners and employers to select a reporting platform that:

1.2.4.1 Has processes in place to de-identify patient information and anonymize data, ensuring there are no patient or pharmacy personnel identifiers once data leaves the platform;

1.2.4.2 Is able to integrate with a national/provincial database to share anonymous and de-identified medication incident and near miss reports; and

1.2.4.3 Is able to integrate with the systems in place to share anonymous and de-identified data with the PRA, when required in that jurisdiction.

2. Pharmacy professional standards

Pharmacy professionals ensure safe care for their patients by committing to continuous quality improvement and appropriate handling of medication incidents and near misses.

2.1 Continuous quality improvement

2.1.1 Pharmacy professionals must incorporate continuous quality improvement within their practice, including:

2.1.1.1 Contributing to a culture of patient safety and a just culture in the workplace environment

2.1.1.2 Familiarizing themselves with the pharmacy's policies and procedures for continuous quality improvement

2.1.1.3 Engaging in determining root causes and contributing factors for medication incidents and near misses and in performing a root-cause analysis as appropriate according to the pharmacy's policies and procedures[12]

2.1.1.4 Engaging in team meetings to discuss summary reports and analyses of pharmacy-specific, regional-level, and national-level data

2.1.1.5 Engaging in the pharmacy's safety self-assessment process

2.1.1.6 Engaging in reviewing and updating the pharmacy's policies and procedures in response to the pharmacy's root-cause analyses, safety self-assessments, and summary reports and analyses

2.1.1.7 Implementing procedural improvements established by the pharmacy manager

12 See Appendix B for levels of harm.

2.2 Handling medication incidents and near misses

2.2.1 Pharmacy professionals handle medication incidents openly and transparently according to the established policies and procedures of the pharmacy, including:

2.2.1.1 Disclosing the incident to the patient or patient's agent and other health professionals involved in the patient's circle of care, in accordance with a patient-centred approach and provincial/territorial or national disclosure guidelines

2.2.1.2 Following up with the patient or patient's agent to monitor for effects of the incident on the patient[13]

2.2.1.3 Sharing information about the incident and follow-up plan with other health professionals involved in the patient's circle of care as appropriate

2.2.1.4 Documenting the incident and follow-up plan and submitting a report to a national/provincial database using the pharmacy's reporting platform

2.2.1.5 When appropriate, sharing information with the patient or patient's agent about how the pharmacy will improve and how the pharmacy will share learnings to prevent recurrence

2.2.2 Pharmacy professionals handle near misses according to the established policies and procedures of the pharmacy, including:

2.2.2.1 Documenting the near miss using the pharmacy's reporting platform

2.2.2.2 Determining if the near miss must be reported to a national/provincial database according to the pharmacy's policies and procedures[14]

2.2.2.3 When required, submitting a report of the near miss to a national/provincial database using the pharmacy's reporting platform

13 Note: May be outside of the pharmacy technician scope of practice in some jurisdictions.

14 See 1.2.2.

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Appendix A: Sample criteria for defining a reportable near miss

The following list is a sample of criteria that may be used to determine whether a near miss should be reported to a national/provincial database:

- Were it to reach the patient, the near miss may cause harm.
- The near miss has been a recurrent issue in the pharmacy.
- The near miss provides a learning opportunity for the particular pharmacy or for pharmacy practice in general.
- Reporting the near miss aligns with the guidance set out by the PRA in that province/territory.

Appendix B: Levels of harm

No harm (medication dispensed)
No symptoms detected; no treatment required

Mild harm
Symptoms were mild, temporary, and short term; no treatment or minor treatment was required

Moderate harm
Symptoms required additional treatment or an operation; the incident kept the patient in hospital longer than expected; or caused permanent harm or loss of function

Severe harm
Symptoms required major treatment to save the patient's life; the incident shortened life expectancy; or caused major permanent or long-term harm

Death
There is reason to believe that the incident caused the patient's death or hastened the patient's death

Reference

Boucher AH. (2018). Quality-related events reported by community pharmacies in Nova Scotia over a 7-year period: a descriptive analysis. CMAJ Open. 6(4):E651–E656.

NAPRA ANORP

National Association of Pharmacy Regulatory Authorities ®
Association nationale des organismes de réglementation de la pharmacie

National Association of Pharmacy Regulatory Authorities
130 Albert Street, Suite 1800
Ottawa, Ontario K1P 5G4
Canada

College of Pharmacists of British Columbia

6. Medication Incident Reporting Update

Ashifa Keshavji

Director, Practice Reviews and Quality Assurance

College of Pharmacists of British Columbia

Overview

- Purpose
- Background
- Current State
- NAPRA Working Group
- NAPRA *Model Standards of Practice for Continuous Quality Improvement and Medication Incident Reporting by Pharmacy Professionals*
- National Information Sharing Group
- Next Steps

College of Pharmacists of British Columbia

Purpose

- To provide the Board with an update on the progress of the College's work since the September 2019 Board Meeting when the Board approved the following motion:
  - *Direct the Registrar to require mandatory anonymous medication incident reporting in all pharmacies using any medication incident reporting platform of the pharmacy's choosing that meets the College's criteria*

College of Pharmacists of British Columbia

Background

- Medication Errors:
  - Are a leading cause of preventable injuries
  - Result in significant costs to health systems
  - Have become a focus area for pharmacy regulatory bodies
- In 2019/20 and 2020/21, the most common complaints received by the College were related to medication dispensing errors by pharmacy professionals

College of Pharmacists of British Columbia

Current State: Community Pharmacies

PODSA Bylaws s.24(1)(c): *"A community pharmacy's manager must establish and maintain written quality management policies and procedures that include a process for reporting, documenting and following up on known, alleged and suspected errors, incidents and discrepancies"*

- No central repository to which pharmacy staff can report medication incidents
- Lack of information and no way to quantify the number and types of medication incidents that are occurring within British Columbia pharmacies
- Missed opportunity for pharmacy professionals to learn from errors occurring in other pharmacies

College of Pharmacists of British Columbia

Current State: Hospital Pharmacies

PODSA Bylaws s.29(1)(c): *"A hospital pharmacy's manager must establish and maintain written quality management policies and procedures that include a process for reporting, documenting and following up on known, alleged and suspected errors, incidents and discrepancies"*

- There is a common information system called the BC Patient Safety & Learning System ("BCPSLS"), a "web-based tool used by approximately 100,000 health care providers across BC to report and learn about patient safety events, near misses and hazards"
- Data from the BCPSLS is provided to the Canadian Institute for Health Information ("CIHI") and transmits to Canadian Medication Incident Reporting and Prevention System ("CMIRPS")

College of Pharmacists of British Columbia

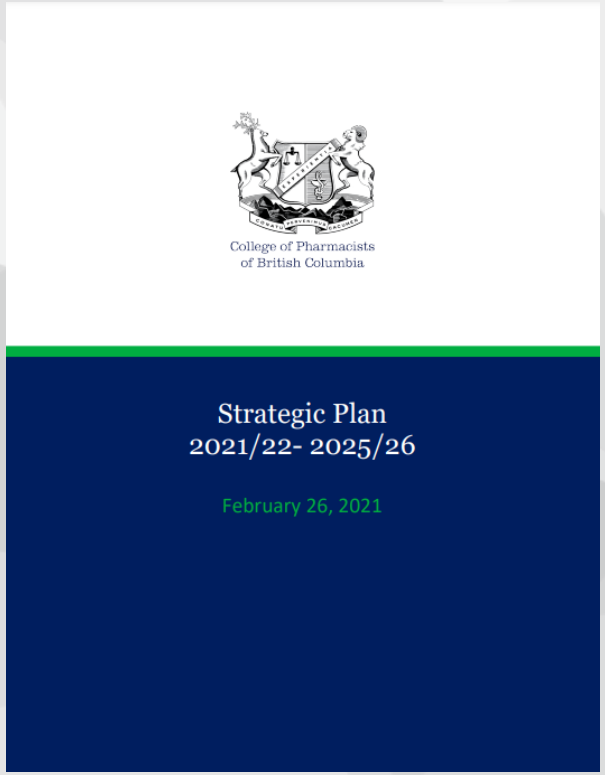
Medication Incident Reporting

- Ability to quantify the number and types of medication incidents that are occurring within BC and Canada
- Anonymized aggregate data analysis for pharmacies and the pharmacy regulatory authority allows for:
  - Shared learning at the pharmacy level
  - Potential identification of systemic public safety risks which gives the regulatory authority data to guide:
    - Communications to registrants and the public
    - Development of programs, policies and legislation for the pharmacy profession

College of Pharmacists of British Columbia

Strategic Plan

- Medication incident reporting is part of the College's 2021/22 - 2025/26 Strategic Plan



College of Pharmacists of British Columbia

NAPRA Working Group

- Working group formed in 2019 consisting of pharmacy regulatory authority representatives and practising pharmacy professionals from across Canada
- Development of national standards of practice for reporting, analyzing, preventing, and learning from medication-related incidents
- National standards of practice would help facilitate continuous quality improvement and medication incident reporting across Canada and improve the ability to share learnings across the country
- Temporary pause of work in 2020 due to prioritizing response to the COVID-19 pandemic

College of Pharmacists of British Columbia

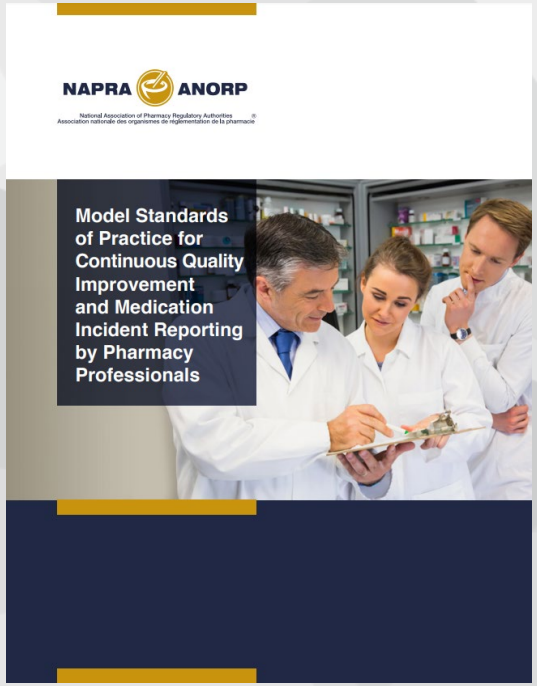
NAPRA Working Group: CPBC Role

- College staff participated in working group meetings and provided detailed feedback throughout development of Standards
  - Our feedback and concerns were considered and incorporated by NAPRA throughout development of all 7 draft versions
- Engagement included:
  - Pharmacy Advisory Committee
  - Management team and department representatives (Practice Reviews and Quality Assurance, Legislation and Policy, Registration and Licensure, Complaints, Communications and Engagement)

College of Pharmacists of British Columbia

NAPRA Standards

- The NAPRA *Model Standards of Practice for Continuous Quality Improvement and Medication Incident Reporting by Pharmacy Professionals* was published in July 2021



College of Pharmacists of British Columbia

NAPRA Standards

- The objective is to promote patient safety in Canada through reporting and learning from medication incidents and near misses, in accordance with federal/provincial/territorial requirements
- Based on principles of a culture of patient safety and a just culture within the pharmacy practice environment, wherein learning is promoted through reporting without fear of punitive action
- Consists of pharmacy manager standards and pharmacy professional standards

College of Pharmacists of British Columbia

NAPRA Standards

- Standards serve as a model which can be adopted or adapted for implementation as appropriate by each province/territory
- Although the NAPRA standards also contain activities surrounding continuous quality improvement, the College has prioritized implementation of medication incident reporting
- College will examine how NAPRA's continuous quality improvement activities fit within our existing quality management requirements

College of Pharmacists of British Columbia

National Information Sharing Group

- Once the NAPRA standards were published, BC initiated a *Continuous Quality Improvement and Medication Incident Reporting Information Sharing Group*
  - Hosted by NAPRA and consists of representatives from other pharmacy regulatory authorities across Canada
  - First meeting held on October 26, 2021
- Work towards establishment of a national repository of medication incident and near miss reporting data
- Discussions also included interprovincial consistency in application and interpretation of standards, challenges and solutions to implementation, engagement, monitoring, and lessons learned

College of Pharmacists of British Columbia

Next Steps

- Provide the Board with an update in 2022
- Draft bylaw and policy changes in 2022/23
- Implementation of Medication Incident Reporting Program in 2023/24

College of Pharmacists of British Columbia

Questions

College of Pharmacists of British Columbia

BOARD MEETING
November 26, 2021

7. Legislation Review Committee: Bylaw Amendments to Officially Adopt the NAPRA Standards for Sterile Compounding

DECISION REQUIRED

Recommended Board 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 approves the proposed draft bylaws of the College of Pharmacists of British Columbia for public posting, which adopt the National Association of Pharmacy Regulatory Authorities' Model Standards for Pharmacy Compounding of Sterile Preparations (non-hazardous and hazardous), as circulated.

Purpose

To propose amendments to the *Pharmacy Operations and Drug Scheduling Act* ("PODSA") Bylaws to adopt the National Association of Pharmacy Regulatory Authorities' ("NAPRA") model standards for sterile compounding, for approval for public posting.

Background

Compounding
As defined under the Pharmacists Regulation, compounding in respect of a drug, is the mixing of one or more other ingredients.

NAPRA Model Standards
NAPRA is an association of the provincial and territorial pharmacy regulatory authorities as well as the Canadian Forces Pharmacy Services. NAPRA provides a platform for its pharmacy regulatory authority members to discuss issues and to take a national approach in addressing common issues in the practice of pharmacy in Canada.
One of NAPRA's roles is creating national model standards and guidelines that its members can in turn adopt or adapt for use in their own jurisdictions. Harmonizing the practice of pharmacy

across jurisdictions, where possible, facilitates the movement of pharmacy professionals across jurisdictions and promotes a consistent level of pharmacy care for patients.

In 2015 and 2016, NAPRA released its *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations* and *Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations,* respectively (collectively referred to as the Model Standards within this briefing note). These Model Standards represent the minimum requirements to be applied in compounding sterile preparations nationally and are expected to be adopted by pharmacy regulatory authorities across Canada.

The aim of the Model Standards is to provide pharmacy professionals who compound sterile preparations with the standards necessary to evaluate their practice, develop service-related procedures and implement appropriate quality controls for both patients and compounding personnel, with a view to guaranteeing the overall quality and safety of sterile preparations. The Model Standards were adapted from standards originally developed by the *Ordre des Pharmaciens du Québec* (the pharmacy regulatory authority of Quebec), which are in turn based on General Chapter of the United States Pharmacopeia (USP) – National Formulary, in effect in the United States.

Patient safety was the driving force behind the development of the Model Standards. The Model Standards were developed in response to devastating consequences resulting from chemotherapy preparation issues in Canada (Marchese Hospital Solutions) and substandard facilities operating in the United States (The New England Compounding Centre). Both incidents are described more below.

Marchese Hospital Solutions

In 2013, Marchese Hospital Solutions supplied nearly 1,200 Canadian cancer patients in hospital in Ontario and New Brunswick with weaker-than-prescribed doses of chemotherapy drugs. As a result, 1,202 patients were affected. The majority of the patients implicated by this error were adults (1,162), and the remainder were pediatric cases (40). A pharmacy technician originally discovered the error, which led to a thorough investigation of the under-dosing of chemotherapy drugs.

The Ontario government established an independent review to determine how the under-dosing and hospital distribution of the chemotherapy drugs occurred, and to recommend ways to prevent future incidents. The independent review and recommendations are summarized in a report titled, *A Review of the Oncology Under-Dosing Incident*. This report included twelve recommendations, one of which was for the Ontario College of Pharmacists (and by extension, NAPRA) to work quickly with Health Canada to define best practices and contemporary objective standards for non-sterile and sterile product preparation within a licensed pharmacy. This incident also resulted in increased regulatory oversight of compounding in Ontario. The Ontario College of Pharmacists was given the authority to inspect premises where a pharmacist or pharmacy technician engages in or supervises drug preparation activities.

Appendix 1 includes media articles related to this incident.

New England Compounding Centre

In 2012, approximately 800 patients across 20 states were diagnosed with a fungal meningitis infection after receiving contaminated injections of methylprednisolone acetate manufactured by the New England Compounding Centre. As a result of this outbreak, more than 100 patients have died.

The outbreak is considered the largest public health crisis ever caused by a contaminated pharmaceutical drug. The former owner of the New England Compounding Centre as well as the supervising pharmacist were sentenced to multiple years in prison.

Appendix 2 includes articles and media publications related to this incident.

Implementation of the Model Standards in B.C.

In 2017, the College Board approved the Model Standards for a phased implementation (see Appendix 3 for the Board briefing note related to this approval). This phased approach was informed by a multi-step engagement process and set the deadline for the official adoption of the Model Standards to May 2021. However, in September 2020, the Board approved a one-time extension due to the onset of the COVID-19 pandemic (see Appendix 4 for the Board briefing note related to this extension). As a result, the deadline was extended from May 2021 to July 2022.

In order for the deadline of July 2022 to be realized, the public posting period should begin in fall 2021 to allow for time to meet the legislative requirements outlined in PODSA (i.e., the 90-day public posting period and 60-day filing period).

Implementation of the Model Standards Across Canada

To date, the Model Standards have been implemented in most provinces across Canada. More specifically, Alberta, Ontario, Manitoba, Saskatchewan, Nova Scotia, New Brunswick and Newfoundland and Labrador have already adopted them. Quebec and Prince Edward Island are the only provinces that have not implemented them[1]. Quebec has not implemented them because, as mentioned above, the Model Standards were adapted from Quebec's standards. Prince Edward Island has not implemented them as, to date, their pharmacies do not compound sterile preparations.

[1] The Model Standards were adopted by these provinces as follows (year(s)): Alberta (2016), Ontario (2016), Manitoba (2017), Saskatchewan (2019), Nova Scotia (2016), New Brunswick (2017) and Newfoundland and Labrador (2016 for non-hazardous Model Standards, 2017 for hazardous Model Standards).

Discussion

Bylaws Adopting the Model Standards
The following bylaw amendments are being proposed to adopt the Model Standards.

Summary of Amendments to the PODSA Bylaws
The Model Standards include standards related to the operation of a pharmacy (e.g., facility and equipment related requirements) which are issues included under PODSA. As such, amendments to the PODSA Bylaws are needed. Bylaw amendments have been included to require pharmacy owners and managers to ensure compliance with the NAPRA standards approved by the Board, applicable to the operation of a pharmacy (please see Appendix 5 for further details).

Summary of Amendments to Standards of Practice under the Health Professions Act ("HPA")
The Model Standards include minimum standards for pharmacists and pharmacy technicians who compound non-hazardous and hazardous sterile preparations. Accordingly, amendments to the College's Community Pharmacy, Hospital Pharmacy and Residential Care Facilities and Homes Standards of Practice documents are required (please see Appendix 6 for further details).

These amendments include a new provision requiring compliance with NAPRA Standards, as approved by the Board, and a new provision which states that only registrants can prepare sterile compounds.

It is important to note that the Board is not being asked to consider approving the draft Standards of Practice amendments at this time. Standards of Practice are not required to be publicly posted. The above-noted amendments are included in this briefing package for informational purposes. The College aims to publicly post them alongside with the draft PODSA Bylaw amendments noted above (if approved by the Board) to provide context for readers. The amended Standards of Practice will be brought forward to the Board for approval at the time of filing of Bylaws, which is expected to take place at their April 2022 meeting.

Summary of Amendments to Professional Practice Policies (PPPs)
College staff expect to amend the following PPPs to align with the adoption of the Model Standards:

- PPP- 64 Guidelines for Pharmacy Compounding: To replace the outdated reference to NAPRA's 2006 Compounding Guidelines.
- PPP- 61 Hospital Pharmacy Published Standards: To be repealed as it references outdated sterile product preparation standards.
- PPP- 57 Standards for Pharmacy Assistant Verification of Sterile Products in Hospital Pharmacy Practice: To be repealed as non-registrants will no longer be permitted to prepare sterile compounds.

It is important to note that, as with the Standards of Practice, the Board is not being asked to consider approving the draft PPP amendments at this time. PPPs are not required to be publicly posted. The above-noted amendments are included in this briefing note for informational purposes. The College aims to publicly post them alongside with the draft PODSA Bylaw amendments noted above (if approved by the Board) to provide context for the public and registrants. Any PPP amendments will be brought forward to the Board for approval at the time of filing of Bylaws, which is expected to take place at their April 2022 meeting.

Policy Decision: Restricting Sterile Compound Preparation to Registrants

The above-noted draft Bylaw amendments clearly limit compounding of sterile products to registrants only. In B.C., as per the Pharmacists Regulation made under the HPA, compounding is listed as a restricted activity that can only be conducted by a registrant while practicing the health profession of the practice of pharmacy.

The Model Standards allow pharmacy assistants "with appropriate training using a formal delegation process that complies with the requirements of the provincial/territorial authority" to prepare sterile compounds. It is our understanding pharmacy assistants were included as "compounding personnel" to accommodate jurisdictions where pharmacy technicians are not regulated. In B.C., pharmacy technicians have been regulated since 2010, and their scope of practice[2] specifically includes compounding prescriptions.

College staff recommend that the preparation of sterile compounds be restricted to registrants (i.e., pharmacists and pharmacy technicians) only. The key reasons supporting this recommendation can be grouped into three themes: public safety, accountability, and education.

Public Safety

Compounding may pose a significant public safety risk if proper procedures and techniques are not followed. These risks were realized with Marchese Hospital Solutions and New England Compounding Centre disasters, noted above.

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[2] HPA Community and Hospital Standards of Practice (section 4 and 10 respectively) define the scope of practice of pharmacy technicians as follows:

Pharmacy technicians in a community/hospital pharmacy may prepare, process and compound prescriptions, including

(a) receiving and transcribing verbal prescriptions from practitioners,
(b) ensuring that a prescription is complete and authentic,
(c) transferring prescriptions to and receiving prescriptions from other pharmacies,
(d) ensuring the accuracy of a prepared prescription,
(e) performing the final check of a prepared prescription, and
(f) ensuring the accuracy of drug and personal health information in the PharmaNet patient record.

More recently, from 2001-2019, a U.S. drug safety project (conducted by the Pew Research Centre) has identified 73 reported compounding errors or potential errors associated with more than 1,562 adverse events, including at least 116 deaths.

Permitting only registrants to compound sterile products aligns with the College's mandate of protecting public health by ensuring that every pharmacist and pharmacy technician in B.C. is fully qualified and able to provide the public with safe and ethical pharmacy care.

Accountability
Pharmacists and pharmacy technicians are regulated registrants with the College. They are held accountable to high professional standards through a number of College regulatory measures, including registration requirements, professional practice requirements, and practice reviews as well as subject to the College complaints process along with inquiry and discipline processes. In the event of a compounding error, registrants may be subject to the College's complaints process and can be held accountable for the error through mechanisms, such as limits and conditions on their practices.

Unregulated pharmacy assistants cannot be held personally accountable to the College. Since they are not regulated, pharmacy assistants cannot go through the College's inquiry and discipline processes. Further, there is no requirement for pharmacy managers to inform the College of the assistants employed in their pharmacy. Currently, the College holds supervising registrants accountable for the work of unregulated staff.

Education/Training
The preparation of sterile compounds requires knowledge, skills and abilities acquired through specific training and education, including aseptic technique and technical competences to ensure quality. Compounding is a foundational part of a pharmacy professional's education. For instance, pharmacy technicians are trained on sterile product handling in their training programs. Additionally, all registrants are also required to meet the College's continuous professional development requirements for their yearly registration renewal.

There is no standardized requirement for sterile compounding education or training for unregulated pharmacy assistants. The level and quality of training will vary across the province.

Potential Impact of Restricting Sterile Compounding to Registrants Only
College staff surveyed health authorities (Fraser Health; Island Health; Northern Health; Provincial Health Services Authority; and, Vancouver Coastal Health) and community pharmacies that have declared that they prepare non-sterile or sterile preparations through the registration renewal process, to better understand who is involved in sterile compounding.

Each pharmacy surveyed was asked to state what percentage of their pharmacy's compounding is prepared by: pharmacists, pharmacy technicians and pharmacy assistants.

Hospital Pharmacy Survey Results Summary
The survey results for hospital sites indicated that only a small number of the sites (5 out of 57) use pharmacy assistants to prepare sterile compounds. In these five sites, pharmacy assistants prepare between 1% to 25% of the total sterile preparations prepared. Based on detailed responses from each site on how many prescriptions of hazardous and non-hazardous sterile compounds each of these sites prepares per month, BC Cancer-Vancouver and Nanaimo Regional Hospital seem to prepare higher number of prescriptions per month with pharmacy assistants preparing approximately 25% of these preparations.

Community Pharmacy Survey Results Summary
Survey results for community pharmacies indicated that only a small number of community pharmacies compound sterile preparations (44 out of the 1,414 pharmacies surveyed, declared that they prepare non-hazardous sterile compounds and only 4 out of the 1,414 declared that they prepare hazardous sterile compounds).

Non-hazardous sterile compounding:
13 pharmacies reported that pharmacy assistants are involved in preparing non-hazardous sterile compounds. Detailed results show that most of these compounds are prepared by pharmacy technicians (approximately 54% pharmacy technician, 33% pharmacy assistant and 14% pharmacist).

Hazardous sterile compounding:
4 pharmacies reported that pharmacy assistants are involved in preparing hazardous sterile compounds. Detailed results show that most of the hazardous compounds at these pharmacies are prepared by either a pharmacist or pharmacy assistant (approximately 43% pharmacist, 46% assistant and 11% pharmacy technician).

The survey results from both hospital and community pharmacies indicate that restricting preparing of sterile compounds to registrants only may have a smaller impact on hospital pharmacies and a moderate impact on community pharmacies.

Legislation Review Committee
At their October 2021 meeting, the Legislation Review Committee discussed the proposed bylaws and the policy decision noted above. The committee is supportive of both.

The committee was interested however in knowing if docking of the proprietary bag and vial systems is compounding, as this work in hospitals has been performed by pharmacy assistants. According to existing compounding standards, in specific the USP 797 Pharmaceutical Compounding – Sterile Preparations standards, docking and activation of proprietary bag and vial systems in accordance with the manufacturer's labeling <u>for immediate administration</u> to an

individual patient is not considered compounding. However, docking of the proprietary bag and vial systems for future activation and administration is considered compounding.

Next Steps

- If approved by the Board, the Bylaw amendments will be publicly posted for 90-days on the College's website.
- Any feedback received will be reviewed, and any additional necessary amendments will be considered.
- After the public posting period ends, the Board's approval will be sought to file the amendments.
- Amendments to the HPA Standards of Practice and any relevant Professional Practice Policies will also be brought forward for the Board's approval.
- Communications on the amendments will be developed and implemented.

Recommendation

The Legislation Review Committee recommends that the Board approve the proposed amendments to the Bylaws to adopt the Model Standards for public posting.

Guiding Questions for the Board

When reviewing the proposed amendments, the Board is asked to consider:

- Do the proposed amendments to the PODSA bylaws clearly adopt the Model Standards in bylaw?
- Is there anything unclear, ambiguous, or unnecessary in the proposed Bylaws?
- Is there anything missing from the proposed Bylaws?

Appendix	
1	Media Articles Related to the Marchese Hospital Solutions Compounding Incident
2	Articles Related to the New England Compounding Centre
3	April 2017 Board Briefing Note
4	September 2020 Board Briefing Note
5	Amendments to the PODSA Bylaws (for Board approval to publicly post)
6	Amendments to Standards of Practice under the HPA (for information)

FOLLOW ON

CANADA

Diluted chemo supplier testifies, says lack of gov't oversight played role

CTVNews.ca Staff Published Monday, April 29, 2013 5:11PM EDT Last Updated Tuesday, April 30, 2013 12:55PM EDT

CTV Toronto: Diluted drug boss in the hot seat

NOW PLAYING

The head of the company that supplied diluted chemo drugs to cancer patients grilled at Queen's Park. Paul Bliss reports.

CTV Kitchener: Marchese head testifies

NOW PLAYING

The president of the company that supplied diluted cancer drugs testified Monday at Queen's Park. Nicole Lampa reports.

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The head of a company at the centre of a chemotherapy drug scandal says a lack of provincial oversight led to the error that saw cancer patients in two provinces receive watered-down medication.

Marchese Hospital Solutions president Marita Zaffiro testified before an Ontario legislative committee Monday, deflecting responsibility from the Hamilton-based company, saying Marchese was not aware of how the hospitals were using their products.

“We did not know that they were using these for multi-patient use,” she said. “It was not specified or discussed at any time during the year-plus of the contract being serviced."

Related Stories

- 11 hospitals buying products from company at centre of cancer drug error
- Feds to propose interim solution to close cancer drugs oversight gap

Related Links

- Marchese Health Care President statement, April 29, 2013.

Zaffiro told the committee she’s “deeply distressed” about the error that saw 1,100 cancer patients in five hospitals in Ontario and New Brunswick receive diluted chemotherapy medication manufactured by Marchese.

“My heart breaks for the patients and families trying to process and understand what they’ve been hearing,” Zaffiro told the committee. “We are deeply distressed to learn that some patients did not receive our preparations in the manner we expected.”

Zaffiro said the drugs supplied by Marchese were prepared under the supervision of a licensed pharmacist and in the manner stipulated under their contract with the hospitals. The contract was arranged through MedBuy, a group purchasing organization.

Marchese mixed the chemo drugs in bags containing saline, which are “overfilled” with more saline to account for evaporation.

Zaffiro said the Marchese-supplied products weren’t “concentration specific.”

Hospitals, however, thought they were receiving bags of a certain concentrate and adjusted the solution accordingly.

It was later discovered that there was too much saline in the bags containing cyclophosphamide and gemcitabine, which diluted the drug concentrations by up to 20 per cent.

Zaffiro also told the committee her company approached federal and provincial regulators to receive regulatory oversight, but was declined.

But she said even with regulatory oversight, the error would still have happened, as her company fell into a grey area that meant neither the federal nor the provincial government was regulating it or inspecting it.

The province and Health Canada have since acknowledged that there was no company oversight for Marchese.

NDP MPP France Gélinas, critic for Health and Long-Term Care, said Monday the provincial ministry’s lack of oversight is hard to forgive.

“Here you have a Ministry of Health that has known for years that we have this grey area. We now know that we have companies operating in that grey area and nothing is done.”

Both levels of government have taken stop-gap measures before a permanent solution is found, including new regulations to ensure that hospitals buy drugs from accredited, licensed or otherwise approved suppliers. Ontario wants to give the college power to inspect facilities where drugs are prepared.

With a report from CTV Toronto’s Queen’s Park Bureau Chief Paul Bliss and with files from The Canadian Press

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INSIGHT

Inside Ontario's chemotherapy scandal

By Diana Zlomislic Investigative Reporter
Tim Alamenciak Staff Reporter
Sun., July 14, 2013 | 18 min. read

Article was updated Jul. 15, 2013

The medication that Diane Marley is about to receive isn't what she thinks it is. It's not what her nurse thinks it is. It's not what her oncologist thinks it is. It's not what the pharmacist who checked the order form and the technicians who triple-checked it after custom-mixing the drug cocktail themselves think it is.

A breakdown of monumental proportions has occurred in the chemotherapy drug-supply chain and Marley is caught in the middle of it.

PHOTO GALLERY: Diane Marley's chemo treatment

It's mid-afternoon on the last Wednesday in March. Marley — mother of Janine, 22, and Emily, 20, wife of Ken, her high-school sweetheart — is sitting in a comfortable recliner at Windsor Regional Hospital's Systemic Therapy Suite crunching on ice cubes to soothe the sores in her mouth and on her lips.

She is at the halfway point in her chemotherapy treatments, a milestone. Simon and Garfunkel are playing in the background.

Eleven weeks earlier, Marley had a lumpectomy on her left breast to remove an apricot-sized tumour from a duct that once carried milk to her nipple — invasive ductile carcinoma, the most prevalent form of breast cancer. The cancer had spread to her lymph nodes, which is why she is undergoing a two-part course of chemotherapy followed by radiation.

Oncology nurse Sarah Irvine snaps on a pair of surgical gloves before wiping an antiseptic swab over a patch of skin below Marley's right collarbone. Using her index and middle fingers, Irvine, who has worked in cancer care for 13 years, feels for the surgically implanted port, a quarter-sized bump on Marley's upper chest just below the skin, the safest entryway to deliver the intravenous drugs — first Doxorubicin, now

a dose of cyclophosphamide — that are so toxic they would eat clean through an ordinary plastic bag. The port is designed to accept a hollow, bevel-edged needle that channels the chemotherapy from the indestructible Braun "crunch" bag that's hanging on a pole to her superior vena cava, the large central vein that feeds blood into the heart.

"One, two, three, take a deep breath," Irvine says as she pushes in the needle.

In the hospital auditorium, two corridors away, David Musyj answers the cellphone in his left jacket pocket. He had just finished a monthly budget meeting with some of the hospital's top administrators.

Claudia den Boer Grima, vice-president of cancer services for the hospital and the region, is on the other end of the line.

"There is a problem with a chemo drug," she says. "It looks like the wrong dose has been given. We don't know how many."

She doesn't go into detail, but Musyj, a lawyer who has spent the last few years promoting, as a billboard announces in the auditorium, "outstanding patient care — no exceptions!" doesn't need to hear much more to know this is a monumental blow to his mission statement.

Den Boer Grima has called him right after hearing the news from Christine Donaldson, regional director of pharmacy services, who in turn heard it from a colleague at London Health Sciences, who heard it from Lakeridge Health in Oshawa, who heard about it from Peterborough Regional Health Centre, where the problem that affected all four hospitals had been discovered exactly seven days earlier.

She also tells him that the pharmacy stopped using cyclophosphamide and gemcitabine immediately after receiving the call from London.

This telephone exchange came right after Marley received her fourth and final dose of cyclophosphamide, one of the oldest types of chemotherapy.

It would be another seven days before she would learn that all her treatments involving this drug had been diluted by as much as 20 per cent.

In the end, 1,202 patients at four hospitals in Ontario and one in New Brunswick learned they received weaker-than-prescribed doses of cyclophosphamide and gemcitabine, beginning in February 2012 and ending in late March this year when a sharp-eyed pharmacy assistant in Peterborough realized something was amiss with the outsourced supply of pre-mixed chemotherapy cocktails from Marchese Hospital Solutions.

One-hundred-and-thirty-seven of these patients have died since starting their treatment. It is unclear what, if any, role the diluted medication played in their deaths.

The most recent stats from Cancer Care Ontario show 333,250 people living in this province have been diagnosed with some form of cancer in the past 10 years. Most have received chemotherapy.

This error — the worst chemotherapy mistake in Ontario's history — has shaken the public's faith in the health-care system and exposed a glaring flaw in Canada's regulatory framework. Yet despite the outrage, the public has had only glimpses behind the scenes of the province's

cancer-care hierarchy — the hospitals, the health-care companies, the governments.

Now, following extensive interviews with health-industry professionals and visits to three of the Ontario hospitals involved, the Star has developed a clearer, more intimate picture of what went wrong.

"When I first heard this I went, 'You've got to be kidding. How did this happen?'" said Dr. Ted Vandenberg, a London oncologist who specializes in breast cancer. Vandenberg, who had 63 patients receive the diluted chemotherapy, believes that in most cases the physical effect is minimal. Of more immediate concern is the psychological impact.

Dr. Jeffrey Rothenstein, an oncologist at Lakeridge Health, tried to assure each of his six affected patients it would have minimal impact on their recovery. Some accept this. Others raised larger concerns about the system.

"There's a huge trust component when a patient is coming for any treatment in the health-care system. Even in those patients that had been treated before and clearly weren't affected by this incident, their trust took a bit of a dent."

Their trust would be further hit. Within two weeks, the Star reported that health-care companies are allowed to mix drugs for hospitals without federal or provincial oversight, prompting top health officials — Ontario health minister Deb Matthews and federal health minister Leona Aglukkaq — to scramble to close that regulatory grey area.

Since the crisis, all the hospitals involved have stopped outsourcing gemcitabine and cyclophosphamide mixtures and brought it in-house, mixing their own medications.

The federal government has new rules defining who can be a drug producer, adding that any facility supervised by a licensed pharmacist can do the job. The province has said that hospitals can only purchase drugs from accredited suppliers.

The Ontario College of Pharmacists has passed legislation that allows it to inspect any premises where a pharmacist works — not just licensed pharmacies.

All of the changes taken together would have seen Marchese Hospital Solutions still able to supply drugs as it did but subject to inspection by the college.

This week Jake Thiessen, the founding director of the University of Waterloo school of pharmacy, submitted a final report of his investigation into the issue. There has been no formal indication when it will be made public. Hospital administrators say they have been told it will be two to three weeks before they or the public see this report.

Joseph Sobel's fingers fly across the keyboard as he flips through patient treatment profiles. As one of the oncology pharmacists at Windsor Regional Hospital, his is a universe of taxanes and nitrogen mustards, a vast constellation of chemotherapy drugs.

Every day he ensures that each patient who comes to the chemotherapy suite gets exactly what the oncologist prescribed — a mammoth task given that many patients are on regimens of five to seven drugs. Beside him, another monitor spits out a wealth of studies regarding chemotherapy outcomes.

German-born chemist Paul Ehrlich is credited with coining the term chemotherapy in the early 1900s, as he tested hundreds of chemicals to see which might hunt down pathogenic organisms and destroy them like "magic bullets."

More than a century later, science is still searching for those magic bullets.

"We're trying to find the right combination of treatments in every single case, as the years go by, to get better outcomes in our patients and prevent the recurrence of breast cancer," says Sobel.

"Everbody's body is different," says Windsor's oncology chief Ken Schneider. "You have to tailor your treatment to the scenario or it's just like cookie-cutter medicine. That would be unsafe."

There is very little clinical evidence to indicate what might happen to a cancer patient who receives an underdose of chemotherapy. There is talk of tracking the Ontario and New Brunswick patients to determine the long-term effects.

Precision in dosing is critical to modern chemotherapy, which grew out of military research to design a chemical weapon using mustard gas during the Second World War. Cyclophosphamide, one of the drugs involved in the dilution scandal, is derived from this family known as "nitrogen mustards." The first trial occurred at Yale University in 1942 when researchers noticed the gas was having an effect on the lymphatic tissues of mice. Since 1959 in Canada cyclophosphamide has been relied on to treat several cancers, including breast cancer and malignant lymphomas.

The future, says Sobel, lies in chemotherapy drugs that are programmed to attack specific cancer cells based on their individual makeup — the "smart bombs" of the chemotherapy world.

"More targeted therapy will look at exact cell-surface markers that are the starting point of replication signals," says Sobel. "So there's a multitude of different ways you can go at and attack a cancer cell. I guess the most beneficial way of doing it is finding a way that just attacks the cancer cell leaving the other cells alone."

At the same time, many of the more recent advances in chemotherapy have been in drugs that alleviate side effects like nausea.

"We were using those same (chemotherapy) drugs 30 years ago, but the supportive-care medications are much better," says Dr. Rothenstein. "The antinausea medications have made the biggest difference."

Almost all anti-cancer drugs wreak havoc on the body. In Marley's case, her skin has darkened and freckles have appeared on her face and the palms of her hands. She has sores in her mouth and suffered crippling fatigue. She has experienced a stabbing pain so extreme it has run the length of her legs to the soles of her feet, making her unable to stand at times.

She was on an aggressive bi-weekly regimen of two drugs in the first phase of her treatment, including Doxorubicin, called the "Red Devil" because of its colour and side effects, and cyclophosphamide. The second phase is even more aggressive — a combination of Taxol and an experimental protocol of carboplatin.

The platinum-based agent carboplatin has been shown to be effective in treating triple-negative breast cancer, a subtype of invasive ductile carcinoma that occurs in 10 to 25 per cent of cases. The triple-negative refers to hormone receptors that, in Marley's case, are missing, which means her specific disease can't be treated with some of the most effective hormone therapies.

Before each treatment, her white blood cell count is measured to make sure her count is high enough to withstand infection. Between treatments, she takes a drug to help elevate her count. She must also fill out a self-reported survey of side effects before each treatment begins so nurses can monitor chemo's cumulative toll on her. During treatments, her temperature, blood pressure and heart rate are recorded regularly.

The upside — if the clinical studies are correct, if her doctor has picked the right protocol and her body responds as studies suggest the might — is that the chemicals will kill off the fast-dividing cancer cells before they destroy major organs. Hair grows back. The body aches ease. The ability to remember why she is at the grocery store returns.

That's the hope anyway.

The bag was cold and that was strange.

In an oncology pharmacy, strange is not good. And on March 20, one week before Marley's last cyclophosphamide treatment, Craig Woudsma, a 28-year-old pharmacy assistant, and a colleague at the Peterborough Regional Health Centre, had a bad feeling.

In this case, it was a shipment of new gemcitabine chemotherapy bags that required refrigeration, according to the label. Previous batches, from a different supplier, had not.

Woudsma noticed more differences. The bags from Marchese only had a total volume and concentration on the label — 4 grams of gemcitabine in 100 mL of saline — instead of the specific concentration, the amount of drug per single mL of saline, as the old bags indicated.

The new bag's label did not contain enough information for him to accurately mix the patient's dose. He needed to know the specific concentration.

"I told the pharmacist in the area. And then it kind of went above me at that point ... They came to me saying, this is kind of a big deal; teleconferencing with the minister of health, that kind of stuff," said recently, sitting on the front steps of his red-brick, semi-detached home in the village of Millbrook, Ont. "It's kind of a foreign concept, to think that what we do, in our corner of the hospital, is going to get that kind of exposure."

Since the matter was made public by Cancer Care Ontario in early April, Woudsma, along with nearly 50 other key players, have been called to testify before the Queen's Park committee investigating the situation.

When preparing the solution, staff at Marchese Hospital Solutions, in Mississauga, Ont., dissolved the medication into a pre-filled 100 mL bag of saline. These bags typically contain between 3 to 20 per cent more solution than 100 mL, referred to in the industry as overfill, included to account for possible evaporation. The company's pharmacy workers did not remove the known overfill when mixing the medication because they thought each bag was going to a single patient.

This means that the bag Woudsma was holding contained 4 grams of gemcitabine in more than 100 mL of solution. The concentration of the medication wasn't what the label would have made him think. It was weaker than advertised.

People have asked Woudsma why he was able to catch a problem that went undetected at other hospitals for more than a year.

Simple, he says. He had something to compare it to.

The hospital had switched that very day to a new supplier — Marchese Hospital Solutions. A bag of the old supply from Baxter CIVA was still on site.

Medbuy, a group purchasing company for hospitals, starting in 2008, had a contract with Baxter Central Intravenous Admixtures to provide drug-mixing services. The two drugs in question, cyclophosphamide and gemcitabine, were outsourced because they come in powder form and are tricky to mix. It takes about four hours to reconstitute them in liquid, and in that time they must be shaken every 20 minutes.

As that contract was about to expire, Medbuy issued a request for proposals for drug-mixing services: Baxter CIVA, which wanted its contract renewed, Quebec-based Gentes & Bolduc and Marchese all stepped forward.

The details of the new arrangement remain known only to Medbuy. It was founded in 1989 to get better deals for hospitals buying products like scalpels, bed pans and even some medications in bulk. The company's 28 member hospital organizations in Ontario, New Brunswick and Prince Edward Island spent a combined $626-million on contract purchases in 2012.

Documents filed by Medbuy with the Queen's Park committee show two sets of labels from Marchese that provide a window on where things may have gone awry.

The first set, submitted with the winning contract bid, carries the name Marchese Health Care, a company accredited with the Ontario College of Pharmacists, and lists a specific concentration of dosages down to the millilitre (in the case of cyclophosphamide, 20 mg/1 mL of liquid).

The second set of labels, plainly different from the first, carries a new company name, Marchese Hospital Solutions, which is accredited by neither Health Canada nor the College of Pharmacists, and has a more general volume indicator — one that displays the total amount of medication in the bag (4 g in 200 mL of liquid).

Marita Zaffiro, president of Marchese, testified at Queen's Park that the Medbuy contract did not indicate the hospitals wanted the labels on these drugs to cite a specific concentration. The reason she included it that way in the RFP was simply to show what could be done.

Company pharmacists, she said, thought each bag was going to one cancer patient.

Sobel ran the calculations in his office. For a single patient to require a 4,000 mg dose of cyclophosphamide, on a common breast cancer treatment regime, that patient would need to be about 7 feet tall and weigh 2,200 lbs.

Higher doses of cyclophosphamide are used in some bone-marrow transplant cases to kill off old tissue, Sobel noted, but in typical breast cancer treatment, it is uncommon.

"The chance of 1,200 patients getting 4,000 mg exactly — it's just impossible."

Four Marchese pharmacists who played a role in the new contract work revealed to the Queen's Park committee in June that they had either limited or no background in oncology.

Zaffiro declined a number of requests by the Star for an interview.

Marchese Hospital Solutions began as Marchese Pharmacy, a Hamilton-area community drugstore that expanded beginning in 1998 when Zaffiro became president. In 1999 the company obtained a contract to supply the Hamilton Niagara Haldimand Brant Community Care Access Centres, business they did until the contract expired in 2011, shortly before it was awarded the Medbuy contract.

It lost the CCAC contract in 2011, shortly before the Medbuy deal, and shed employees. Fifty-seven were either laid off or left the company during this troubled time, according to internal newsletters. But then things started looking up.

Marchese was awarded the contract with Medbuy, worth about $2-million in its first year, in late 2011 and began hiring, this time for what job advertisements described as a "new facility in Mississauga."

Zaffiro attempted to get accreditation for the site, according to her Queen's Park testimony, approaching both the Ontario College of Pharmacists and Health Canada, neither of which took steps to regulate the fledgling business because each thought the other had jurisdiction.

Windsor Regional Hospital was the first to start using Marchese medications on Feb. 24, 2012. London Health Sciences Centre and Saint John Regional Hospital followed soon after.

Medbuy, Marchese and Jake Thiessen have maintained that cost was not a factor in the error. Marchese's bid on the request for proposal came in at about a quarter of the cost of previous supplier Baxter Corporation. Bags from Marchese cost from $5.60 to $6.60; Baxter charged $21 to $34.

When Tory MPP Jane McKenna asked Zaffiro to account for the difference in cost, she said she could only speculate and was not willing to do so. She testified there is "no rational connection between pricing and this incident."

Back in his office, a room he's decorated with TV and movie posters (Sopranos, Spiderman and a life-sized cut-out of his young son swinging a baseball bat), Windsor CEO David Musyj thinks about what went wrong.

The problems, he says, go far beyond Marchese and Medbuy.

"All of us are culpable," he says. "We could have done some things internally that could have prevented this. We could have weighed the bags when they came in."

"Be nice to me," Diane Marley whispers, her head wrapped in a purple turban with metallic thread, resting on a coral pillow she brought from home, as nurse Sarah Irvine accesses her port one last time.

It's Monday, May 27, shortly after 10 a.m.

"We are finally cruising," says Marley's older sister, Deborah Moyes, who is sitting bedside, wiping away tears. A gold crucifix hangs around her neck.

Moyes has accompanied Marley to every appointment at the chemo centre and is always present to hear the doctors describe her sister's treatment plan and prognosis.

It helps that Moyes has a background in health care. She's been a retail pharmacy assistant since she was 17.

Moyes thinks she took the underdosing harder than her sister. "I was just angry," she says. "I know mistakes happen but don't do it to cancer patients. They have enough going on."

The last four treatments have been brutal. Marley is sicker longer. She has battled bladder infections. A persistent pain in her legs makes walking difficult.

Marley tucks her white iPhone into the side of her left bra cup. Her husband Ken, a criminal lawyer, is at trial today.

"When he's not speaking, he's texting me," she says.

Close to five hours later, Irvine squeezes the bottom edges of the IV bag, guiding the last drops of Taxol toward the middle and down the tube.

"Every last drop," Irvine says. "I think I caught the corners."

Moyes recalls their first meeting with the oncologist, how scared her sister was. Marley asked the doctor to reassure her that the side effects would be worth something in the end.

"How do I know that this is going to work?" Marley asked.

The doctor answered with another question.

"Do you believe in God?"

"I do," Marley replied.

"You trust God and you have me."

"Can you imagine a doctor saying something like that?" Moyes said. "We left thinking, OK, that's all we need. We got it, we're good."

Terri Johnston, a nurse with silvery hair pulled back in a purple scrunchy, waltzes to Marley's bedside.

"Happy last che-mo to you, cha-cha-cha, happy last che-mo to you, cha-cha-cha," she sings.

"Every time I saw you, I knew I would get better," Marley says softly, a little groggy from the treatment.

"It's all in the aura, baby," Terri sings back. "Come back when your hair grows in. Soon."

With those last drops, one part of her cancer journey finishes. She still has more tests — endless tests — anxiety, radiation therapy, and surely more tears. But for now she and her sister take some relief in another milestone reached.

Her phone buzzes with a new text. It's her husband Ken. He just heard.

"Hallelujah," he writes.

CANADA

Chemo scandal: Lead investigator Jake Thiessen provides early findings

May. 28, 2013

, looks none too pleased with the outcome of opening day at Rogers Centre between the Jays and the Clevela

ents given defective cher

Ontarians with cancer treatment, agency says

pharmacy technician at a Peterborough hospital late last month. The premixed cocktail of medication, shipped out to at least four hospitals in Ontario and one

"I can't imagine those families have to go thr

ID DIANA ZLOMISLIC

nts in Ontario undergoing chemotherapy
r for diseases that included cancers of the
dadder received watered-down treatment
r dose of medication than was prescribed,
ne agency revealed Tuesday.
ts at Windsor Regional Hospital alone have
their therapy.
travenous treatment was discovered by a

in New Brunswick by a Mississauga
supplier, contained too high a percent-
age of saline solution, diluting the che-
motherapy agent.

The majority of the patients, 665, were
being treated at London Health Sciences
Centre, where the incorrect dosage had
been administered since March 1, 2012.

CANCER continued on A16

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DAVID MUSYJ
PRESIDENT AND CEC
WINDSOR REGIONAL

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Nov. 11, 2016

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May. 11, 2013

More from The Star & Partners

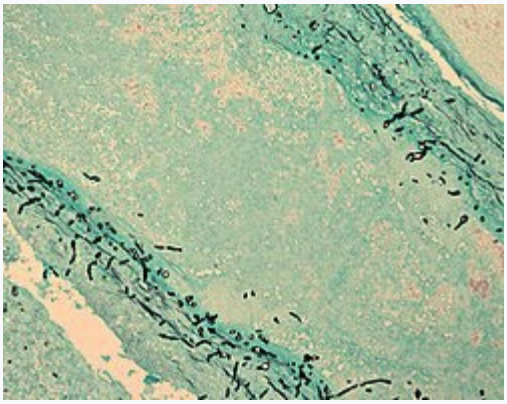
New England Compounding Center meningitis outbreak

From Wikipedia, the free encyclopedia

Coordinates: 42.27320°N 71.42708°W

A **New England Compounding Center meningitis outbreak** that began in September 2012 sickened 798 individuals and resulted in the deaths of more than 100 people.[2][3][4] In September 2012, the Centers for Disease Control and Prevention, in collaboration with state and local health departments and the Food and Drug Administration (FDA), began investigating a multistate outbreak of fungal meningitis and other infections among patients who had received contaminated steroid injections from the New England Compounding Center (NECC) in Framingham, Massachusetts. The NECC was classified as a compounding pharmacy. The traditional role of compounding pharmacies is to make drugs prescribed by doctors for specific patients with needs that can't be met by commercially available drugs.[5]

New England Compounding Center (NECC) meningitis outbreak



Fungal cells (black lines) in infected brain tissue (cyan)

Date	September 21, 2012 (on-going)
Location	United States (23 States)
Cause	Fungal contamination of steroid medication
Deaths	64[1]
Non-fatal injuries	689[1]
Litigation	400+ lawsuits filed against NECC

In October 2012, an investigation of the NECC revealed the company had been in violation of its state license because it had been functioning as a drug manufacturer, producing drugs for broad use rather than filling individual prescriptions. In December 2012, federal prosecutors charged 14 former NECC employees, including president Barry Cadden and pharmacist Glenn Chin, with a host of criminal offenses. It alleged that from 2006 to 2012, NECC knowingly sent out drugs that were mislabeled and unsanitary or contaminated.

In a congressional hearing the FDA Commissioner was asked why regulators at the FDA and the Massachusetts Board of Pharmacy did not take action against the pharmacy years earlier. The legislators were told that the agency was obligated to defer to Massachusetts authorities, who had more direct oversight over pharmacies. The FDA Commissioner also stated, "In light of growing evidence of threats to the public health, the administration urges Congress to strengthen standards for non-traditional compounding." The Drug Quality and Security Act (H.R. 3204), a bill to grant the FDA more authority to regulate and monitor the manufacturing of

compounding drugs, was passed by the Senate on November 27, 2013.

The incident resulted in numerous lawsuits against NECC. In May 2015, a $200 million settlement plan was approved that set aside funds for victims of the outbreak and their families.

Contents []

Outbreak [edit]

In September 2012, an outbreak of fungal meningitis was reported in the United States. The U.S. Centers for Disease Control and Prevention traced the outbreak to fungal contamination in three lots of a medication called methylprednisolone used for epidural steroid injections. The medication was packaged and marketed by the New England Compounding Center (NECC), a compounding pharmacy in Framingham, Massachusetts. Doses from these three lots had been distributed to 75 medical facilities in 23 states, and doses had been administered to about 14,000 patients after May 21 and before September 24, 2012. Patients began reporting symptoms in late August, but, because of the unusual nature of the infection, clinicians did not begin to realize the cases had a common cause until late September. Infections other than meningitis were also associated with this outbreak, which spanned 19 states. As of March 10, 2013, 48 people had died and 720 were being treated for persistent fungal infections.[6][7] In November 2012, some patients recovering from meningitis were reported to be experiencing secondary infections at the injection site.[8] Although no cases of infection were reported to be associated with any other lots of medication, all lots of all medications distributed by NECC were recalled in separate actions by NECC and regulators. Subsequent analysis identified some contamination in other lots.[*citation needed*]

On October 9, 2012, members of the United States Congress asked federal health officials for briefings on the outbreak as a first step toward possible legislative action to strengthen federal drug safety regulations.[9] On November 14, 2012, members of a congressional committee investigating the outbreak accused the Food and Drug Administration (FDA) of failing to prevent

the crisis by moving too slowly against the Massachusetts pharmacy. FDA commissioner Margret Hamburg testified that the agency's efforts to address problems at the compounding center had been hamstrung by Congressional interference, conflicting court rulings regarding FDA jurisdiction, and tenacious litigation by the compounding center itself.[10] At the same hearing, the co-owner of NECC chose to plead the Fifth, refusing to answer all questions.[11] By mid-December, over 400 lawsuits had been filed against NECC.[12]

In October 2012, Massachusetts shut down two more compounding pharmacies over sterility concerns after they conducted a surprise inspection.[13][14] In December, unexpected inspections of three more Massachusetts pharmacies found problems as well.[15]

On December 21, 2012, the New England Compounding Center filed for Chapter 11 bankruptcy protection in the Massachusetts district bankruptcy court.[12]

On September 4, 2014, pharmacist Glenn Adam Chin was arrested at Boston's Logan International Airport before boarding a plane headed to Hong Kong, and was charged with one count of mail fraud. Chin was responsible for supervising the clean rooms at the NECC and was involved in compounding the contaminated methylprednisolone. The FDA affidavit stated that Chin had used improper sterilization and testing techniques, unsafe practices, falsified cleaning logs, and ordered pharmacy technicians to fraudulently mislabel vials. Chin was the first to be charged in the ongoing inquiry.[16][17]

On December 17, 2014, 14 former NECC executives and technicians, including co-founder and president Barry Cadden, were indicted on a host of federal charges related to the outbreak. Most seriously, Cadden and Chin were charged with helping orchestrate a massive racketeering conspiracy that led directly to 25 of the deaths.[18]

Source of infectious agents [edit]

The Centers for Disease Control and Prevention (CDC) traced the outbreak to contaminated methylprednisolone (MPA) used for epidural steroid injections.[19][20] The Food and Drug Administration (FDA) examined foreign materials from unopened vials under microscope and found fungal matter. The fungus was found in the cerebrospinal fluid of several patients, which confirmed fungus caused the meningitis.[21] The medication was packaged and marketed by the New England Compounding Center (NECC) of Framingham, Massachusetts.[20]

According to the CDC, between May 21 and September 24, 2012, patients in 23 U.S. states received injections from three implicated lots of a steroid, preservative-free methylprednisolone acetate, for back pain, and some of these patients developed symptoms consistent with fungal meningitis.[22][23] This form of meningitis can be caused by epidurally administered medications, but is not contagious by person-to-person contact. On October 9, authorities estimated as many as 14,000 patients may have been exposed to the contaminated drug.[24]

The NECC said that immediately after it was notified about the infections it initiated a voluntary recall September 26.[25] Next, on October 4, the Massachusetts Department of Public Health issued a recall of all NECC medications, advising hospitals and clinics to remove and segregate all lots from their stock inventory.[26] NECC also announced on that day they were suspending all of their operations and voluntarily surrendered their licenses to the Massachusetts Department of Health and Human Services, while continuing to cooperate with the ongoing

investigations by the CDC and the FDA.[27]

On October 15, the FDA issued a warning that two more drugs may have been contaminated. Both came from NECC. One was a steroid called triamcinolone acetonide and another was a product used during heart surgery. If injected, the second steroid may cause fungal meningitis, while the heart drug may cause a different fungal infection.[28]

Although no cases of infection were reported to be associated with any other lots of medication, all lots of all medications distributed by NECC were recalled in separate actions by NECC and regulators. Subsequent analysis identified some contamination in other lots.[*citation needed*]

Infectious agents [edit]

Exserohilum rostratum

As of November 15, the CDC reported that 85 patients had laboratory-confirmed fungal infections. A black mold called *Exserohilum rostratum* was found in 84 of the cases and *Aspergillus fumigatus* was found in one case. Other fungi were found in eight cases, but were not known to be significant.[29] According to specialists in fungal diseases, cases of meningitis caused by *Aspergillus* are rare, but cases caused by black mold are even more so, making the discovery of the outbreak and the recommended treatment almost entirely untrodden medical ground.[30]

Aspergillus is a common mold genus that humans and animals are continually breathing, but that rarely causes problems. However, in patients with suppressed immune systems, or if introduced directly into the spinal column, the fungus can be deadly. Despite the availability of antifungal agents, aspergillosis in the central nervous system carries a poor prognosis. Though this case sparked the nationwide investigation, as of November 4, the CDC said *A. fumigatus* had been identified in only one patient. Almost all cases in the outbreak involved a different fungus, *Exserohilum rostratum*, another common mold that rarely causes problems.[31]

Clinical features [edit]

On October 12, 2012, the CDC reported that as of that date, the median age of the patients was 68 years (range: 23–91 years); 48 (69%) were female. At presentation, 57 (81%) had headache, 24 (34%) had fever, 21 (30%) had nausea, and seven (10%) had photophobia (intolerance to bright light). Atypical neurologic symptoms were observed in a minority of patients, subtle gait disturbances were seen in three (4%), and a history of falls was described in eight (11%). Meningeal signs, including nuchal rigidity (the inability to flex the neck forward), Kernig's sign, or Brudzinski's sign, were uncommon, occurring in 10 (14%) patients. Stroke, either as a presenting sign, or as a complication of infection, occurred in 12 (17%).[*citation needed*]

According to the CDC report, for 61 people with symptom onset date available, the earliest date was August 18. For the 48 patients with both injection date and symptom onset date available

for analysis, the median time from last steroid injection to onset of symptoms was 15 days (range: 1–42). A total of 25 of the 48 patients received a single steroid injection; the median time from injection to onset of symptoms for those patients was 16 days (range: 4–42).[32] People who received injections were most vulnerable to stroke and infection within the first 42 days of injection, but three months may be needed for symptoms to appear.[33]

Fungal infections associated with nonepidural injections were also reported. They were related to injections in a peripheral joint space, such as a knee, shoulder, or ankle. People injected in peripheral joints were at risk for joint infections but were not believed to be at risk for meningitis.[34]

On November 4, some people who were treated for meningitis and released returned to the hospital with abscesses, a localized infection of the tissues at the injection site, that could lead to meningitis. The deputy chief of the mycotic diseases branch of the CDC said, "We don't have a good handle on how many people are coming back. We are just learning about this and trying to assess how best to manage these patients. They're very complicated."[35] As of December 7, spinal abscesses had been reported in 23 patients who received injections in Tennessee, and 37 patients in Michigan.[36]

The CDC reported that doctors were also reporting that some people that had been injected with the contaminated drugs had arachnoiditis, a nerve inflammation that can cause intense pain, bladder problems, and numbness.[35]

In 2017, five years after the outbreak, NPR reported that "hundreds of people around the country are still suffering from complications linked to injections of tainted medicine." NPR interviewed patients who had recovered but still experience debilitating aftereffects such as pain, extreme fatigue, mental confusion and inability to concentrate. One woman who had been very active before her illness remains bedridden and on oxygen.[37]

Treatment [edit]

Few clinicians were accustomed to dealing with fungal meningitis due to its rarity. The CDC convened an expert advisory panel to develop recommended treatment guidelines. Many affected patients were elderly and had other existing health problems further making the choice of treatment difficult. On October 23, 2012, the CDC issued an "Official Health Advisory Issuance of Guidance on Management of Asymptomatic Patients Who Received Epidural or Paraspinal Injections with Contaminated Steroid Products".[38] The CDC recommended that health care providers monitor patients who received contaminated injections, but advised against prophylactic treatment with antifungal drugs for patients who did not show signs of infection. They indicated that the greatest risk of developing an infection was within the first six weeks after injection. People diagnosed with meningitis could expect to take antifungal drugs for a minimum of three months, and possibly as long as a year.[30][38]

Cases [edit]

Tennessee was the first state to have a reported case on September 21, 2012. The CDC reported that as of January 14, 2013, 678 people in 19 states had contracted a fungal disease, of whom 44 died.[6] As of March 10, 2013, 48 people had died and 720 were being treated for

persistent fungal infections.[6][7] These cases were associated with three lots of methylprednisolone acetate, portions of which were shipped by NECC to 73 health care facilities in 23 states.[22] The product was also sent to four states where no cases had been reported, and no complaints or cases were found in Massachusetts, the only state where NECC had a license.[39] The final figures, which were disclosed in May 2015 when the litigation came to a close, were over 800 sickened with 64 deaths.[40][41] A later report said that 798 had been affected and "over 100" had died.[42]

Prescribing of steroids for back and joint pain [edit]

The frequency of steroid injections to treat back pain in Medicare patients increased 121% from 1997 to 2006. Some doctors believe the efficacy of steroid injections for back and joint pain has not been demonstrated by scientific evidence, and challenge their use in these cases at all. According to *The New England Journal of Medicine*, "... it's important to note that many patients received these sterile injections for back and joint pain, a procedure that lacks high-quality evidence of efficacy. These problems cannot be laid entirely at the feet of compounders when clinicians persist in clinical practices despite weak evidence of efficacy."[43] Doctors in professional societies are not in agreement about treatment guidelines. Although steroid injection for back pain clearly works in some cases, health researchers are "nearly unanimous" that it is "vastly overused".[44]

A 2009 Cochrane review of injection therapy for subacute and chronic low back pain indicated no strong evidence exists for or against the use of any type of injection therapy.[45] A four-year study released in 2013 suggested epidural steroid injections may actually lead to worse outcomes whether or not the patient later underwent surgery, and no evidence showed receiving steroid injections helped patients to avoid surgery. Also, in patients who had previously been treated with epidural steroids, evidence indicated surgery was more complicated than in patients who had not.[46]

Compounding pharmacies [edit]

See also: Compounding

The NECC was classified as a compounding pharmacy. Such pharmacies are authorized to combine, mix, or alter ingredients to create specific formulations of drugs to meet the specific needs of individual patients, and only in response to individual prescriptions. Since 1938, the FDA had sole authority to regulate drug manufacturing which is subject to strict FDA regulations, but in 1998 Congress exempted compounding pharmacies from FDA oversight despite strong objections of then-FDA Commissioner David Kessler, making oversight the shared responsibility of state and federal agencies. Compounding pharmacies must register with the FDA, but are not registered as drug manufacturers, and the agency does not approve their prescriptions before marketing, nor automatically receive adverse events reports. State law generally controls record keeping, certifications, and licensing for compounding pharmacies.[43] In 2003, an official from the Food and Drug Administration told the Senate Health, Education, Labor and Pensions Committee that in 2001 the agency had done a "limited" survey of drugs from 12 compounding pharmacies, including hormones, antibiotics, steroids, and drugs to treat

glaucoma, asthma, and erectile dysfunction, and 10 of the 29 drugs failed one or more quality tests. However, grassroots mobilization of compounding pharmacists and actions of congressional lobbyists prevented an attempt to establish an FDA oversight committee on pharmacy compounding.[47]

Responding to the NECC meningitis outbreak, health officials and lawmakers said that compounding pharmacies can "fall into a regulatory black hole." Sen. Richard Blumenthal (D-CT), who was on the committee that oversees the FDA, said that compounding pharmacies have "relative immunity from standards of safety and effectiveness." The state, not the FDA, had oversight over NECC, though shipping out of state and manufacturing large batches of pharmaceuticals would have made them a manufacturer, and under FDA control. The compounding pharmacy industry had created safety standards, and in 2004, United States Pharmacopeia, an industry-backed nonprofit, established guidelines, but the industry was required to follow the guidelines in only 17 states. Few compounding pharmacies followed standards for manufacturers because of the cost. Legislation in 1997 would have given the FDA authority to regulate all compounding pharmacies, but that legislation was partially overturned by a 2002 Supreme Court decision.[24][48]

An editorial in *The New England Journal of Medicine* suggested that while NECC appeared to be in clear violation of existing FDA policy[43] the 2002 Supreme Court decision may have weakened federal-state cooperation. The *NEJM* noted:

- First, traditional compounding was limited to a pharmacist or a physician serving a specific patient. Section 503A also permitted compounding of drugs "in limited quantities before the receipt of a valid prescription order . . . based on a history of . . . receiving valid prescription orders." According to the preliminary report from the Commonwealth of Massachusetts, NECC far exceeded these limits in preparing and shipping vials of methylprednisolone acetate. Once disconnected from individual patients, compounding increasingly resembles drug manufacturing.
- Second, compounding is not needed if a drug is commercially available from an FDA-regulated facility. Section 503A prohibited compounding "regularly or in inordinate amounts" any drugs that were "essentially copies of a commercially available drug product." FDA-approved methylprednisolone acetate is sold by Pfizer and two generics companies, but since NECC's version did not contain preservatives, it could sidestep this regulatory process — with tragic results.
- Third, Congress recognized that states could effectively regulate traditional compounding pharmacies, but national-scale businesses required federal coordination. Section 503A provided a test for distinguishing between the two: it limited interstate shipments to no more than 5% of the compounder's business, unless the home state had entered into a "memorandum of understanding" with the FDA, bolstering state and federal cooperation. NECC shipped substantial quantities of drugs to many states. If Section 503A had not been struck down, both the FDA and Massachusetts would have been more directly involved in regulating NECC for more than a decade.[43]

Problems at other compounding pharmacies [edit]

The FDA reported several previous incidents related to tainted drugs packaged at compounding

pharmacies. Fungal contamination in relation to sterile drug recalls represents the second-most common form of microbiological contamination.[49] In August 2011, the FDA reported that repackaged injections of Avastin (bevacizumab) caused serious eye infections in the Miami, Florida, area. A pharmacy had repackaged the Avastin from single-use vials into multiple single-use syringes, distributing them to multiple eye clinics, and infecting at least 12 patients. Some patients lost the remaining vision in the eye being treated.[50]

From November 2011 to April 2012, 33 eye-surgery patients in seven states suffered a rare fungal eye infection tied to injectable drug products made by a compounding pharmacy in Ocala, Florida. Most of those patients suffered partial to severe vision loss.[50]

In October 2012, Massachusetts shut down another compounding pharmacy over sterility concerns after they conducted a surprise inspection. Inspectors went to the Waltham, Massachusetts, location of the Rhode Island-based Infusion Resource company and found, "significant issues with the environment in which drugs were being mixed". The manager of the company was a former employee at Ameridose, which is owned by the same people who ran NECC.[13]

On November 13, manufacturing problems were reported to be found at Ameridose, a Massachusetts company that makes injectable drugs. Ameridose and NECC were founded by brothers-in-law Barry Cadden and Greg Conigliaro.[51] According to an FDA spokesperson, an inspection revealed the firm "fails to test finished product for potency, failed to investigate complaints for ineffective products, failed to investigate violations of their own environmental sampling plan and fails to adequately maintain equipment and facilities used to manufacture sterile drug products". The FDA report also revealed the company had received 33 complaints claiming "lack of effect" and "ineffectiveness" about its drugs. The same problem was found at the plant in 2008, and the FDA spokesperson said the FDA was checking to find what, if any, action was taken in 2008. According to the report, when doctors contacted the firm to say problems with its drugs had been found, the complaints were not classified as adverse events. That included "incidents when women given Ameridose's oxytocin, a drug used to bring on labor, reported fetal distress, severe post birth bleeding and shortness of breath. A blood thinner, heparin, had a complaint that the patient had a life-threatening adverse event [and when] the firm's pain medication fentanyl, given to cancer patients and as an anesthetic, was used, two patients were reported to have gone into respiratory distress."[14]

The New York Times interviewed eight former employees of NECC and Ameridose. Some defended the company, but six said the corporate culture encouraged shortcuts, even when it compromised safety. At Ameridose, a pharmacist complained to management that quality control workers, who were not trained pharmacists, did work they should not have done. She said "near misses" of wrong doses were caught before they were shipped. A quality control technician tried to stop an assembly line and was eventually fired. An industry newsletter said Ameridose was shipping drugs without waiting the 14 days it took for the sterility test results to come back. Compounding pharmacies are only allowed to ship drugs for specific patients; a former NECC salesman said that NECC sold large quantities without the patients' names, and would put the names in the file as the drug was used, a practice that was accepted by some hospitals, but not others.[52]

On December 7, 2012, Massachusetts regulators had taken action against three more compounding pharmacies following unannounced inspections. The Whittier Pharmacist, in Haverhill, was ordered to cease sterile compounding after unspecified violations were found, and OncoMed Pharmaceutical Services was ordered to close its Waltham facility after problems with the storage of chemotherapy drugs were found. Pallimed Solutions, based in Woburn, was told to halt production of sildenafil citrate, which is sold as Viagra, after inspectors found it had been prepared with improper components.[15]

Two compounding pharmacies issued drug recalls in March 2013. Med Prep Consulting Inc and Clinical Specialties Compounding Pharmacy both issued recalls after Med Prep found particles floating in five doses of a compounded solution, and Clinical Specialties heard about five eye infections in patients who had received compounded eye injections.[53]

Investigation [edit]

In October 2012, an investigation of the NECC revealed the company had been in violation of its state license because it had been functioning as a drug manufacturer, producing drugs for broad use, rather than filling individual prescriptions as prescribed by individual doctors within the state. Some doctors and clinics may have turned away from major drug manufacturers and turned to compounding pharmacies as manufacturers because they often charge much lower prices than the major manufacturers.[48] Reuters news service reviewed over a dozen emails to the NECC and found they solicited bulk orders from physicians and failed to require proof of individual patient prescriptions as required under state regulations.[54] In October, Massachusetts officials launched a criminal investigation of the NECC and the Massachusetts Board of Registration in Pharmacy voted to permanently revoke their license to operate in Massachusetts, as well as the licenses of the company's three principal pharmacists to fill prescriptions in Massachusetts.[55]

The preliminary investigation found unsanitary conditions, including fungus in steroid solutions. Massachusetts officials said that the NECC had shipped orders of the contaminated drug without waiting for final results of sterility testing. Records suggested NECC had failed to sterilize products for "even the minimum amount of time necessary to ensure sterility."[56] Mats used to trap dust and dirt outside the rooms were dirty, sterile hoods were not properly cleaned, and a boiler was leaking next to a clean room, according to officials.[56] Investigations also found that medical staff were using fake names such as "Harry Potter," “Baby Jesus," and “Chester Cheeto” to create fraudulent prescriptions for drugs. An email from Cadden read, “All names must resemble ‘real’ names... no obviously false names!”[57]

U.S. and Massachusetts state health regulators were aware in 2002 that steroid treatments from NECC could cause adverse patient reactions.[58] NECC had started to receive complaints in 1999, less than a year after it had been established. Many violations involved filling bulk medication orders without individual prescriptions. In 2004, state health officials charged the pharmacy with failure to comply with accepted standards when mixing methylprednisolone acetate, the same steroid that was the source of the 2012 meningitis outbreak. In 2006, the pharmacy agreed to inspections and improvement measures and an outside investigator was brought in to ensure compliance.[59][60]

House Energy and Commerce Committee hearings [edit]

On November 12, the Oversight and Investigations Subcommittee of the House Energy and Commerce Committee released a detailed report of NECC's regulatory history. The congressional report shows that in 2003, the FDA considered the company a pharmacy, significant because following the meningitis outbreak, public health officials have charged that NECC was operating more as a manufacturer than a pharmacy. Manufacturers are regulated by the FDA and are subject to stricter quality standards than pharmacies. The report also shows that after investigations in 2003, the FDA officials asked that the compounding pharmacy be "prohibited from manufacturing" until it improved its operations, but Massachusetts regulators ultimately reached an agreement with the pharmacy to settle concerns about the quality of its prescription drugs.[61][62]

According to documents summarized by the committee, within less than a year of the pharmacy's opening in 1998, they were cited by the state pharmacy board for providing doctors with blank prescription pads with NECC's information, which are illegal in Massachusetts—the pharmacy's owner and director, Barry Cadden, received an informal reprimand. Cadden continued to receive other complaints involving unprofessional conduct in coming years, and in several instances, Cadden refused to cooperate with investigators and challenged the agency's authority over his business. In 2002, the FDA investigated reports that five patients had become dizzy and short of breath after receiving a steroid used to treat joint pain and arthritis different from the one linked to the current meningitis outbreak. Initially, Cadden cooperated with the investigation, but during a second day of inspections, Cadden told officials that he was no longer willing to provide any additional records, and the FDA did not pursue the investigation. Also in 2002, the FDA received reports that two patients at a Rochester, N.Y., hospital came down with symptoms of bacterial meningitis after receiving injections of methylprednisolone acetate, the same injectable linked to the current outbreak. When officials from the FDA and Massachusetts Board of Pharmacy questioned Cadden, he said vials of the steroid returned by the hospital had tested negative for bacterial contamination. When FDA scientists tested samples of the drug collected in New York, though, they found bacterial contamination in four of 14 vials sampled.[61][62]

Speaking to the committee in a statement, the interim commissioner of the Massachusetts Department of Public Health said, "It is clear that NECC knowingly disregarded sterility tests, prepared medicine in unsanitary conditions, and violated their pharmacy license. Poor judgment, missed opportunities, and a lack of appropriate oversight allowed NECC to continue on this troubling path." He announced that "the board staff who are responsible" had been either fired or replaced.[61]

On November 14, the committee questioned the FDA Commissioner Margaret Hamburg, asking her why regulators at the FDA and the Massachusetts Board of Pharmacy did not take action against the pharmacy years earlier. Hamburg replied that the agency was obligated to defer to Massachusetts authorities, who have more direct oversight over pharmacies and stated, "In light of growing evidence of threats to the public health, the administration urges Congress to strengthen standards for non-traditional compounding." Joyce Lovelace, the widow of 78-year-old Eddie C. Lovelace, who was the first confirmed victim of the outbreak, also spoke at the hearing. Following Lovelace, the committee attempted to question Barry Cadden, the owner and

director of the NECC, but Cadden refused to testify, invoking his Fifth Amendment right to not answer questions to avoid self-incrimination.[63]

During the second day of hearings, senators said that regulators had not only failed to move aggressively against NECC, but also against a sister company, Ameridose LLC, a large-scale drug compounder that supplies drugs to thousands of hospitals nationwide, as well. Although the FDA had repeatedly found reports of adverse events, faulty products, and medication errors in the last decade, no warning letter had ever been issued. In 2002, five patients became ill and two more were hospitalized with meningitis-like symptoms after they were injected with the same steroid implicated in the current outbreak, and yet the state took no action until 2006. Although the FDA has limited authority over compounders such as NECC, Ameridose is licensed by the FDA as a manufacturer and is clearly subject to its regulatory powers.[64]

Litigation and prosecution [edit]

In October 2012, plaintiffs in federally filed fungal meningitis lawsuits petitioned the U.S. Judicial Panel on Multidistrict Litigation (JPML) for establishment of a consolidated litigation in Minnesota federal court. NECC requested that the litigation be transferred to federal court in Massachusetts. In December 2012, the company filed for bankruptcy and U.S. District Judge Dennis Saylor ruled that meningitis lawsuits pending in Massachusetts federal court would be consolidated and allowed to move forward.[36] By mid-December, over 400 lawsuits had been filed against NECC.[12]

In May 2015, federal bankruptcy judge Henry Boroff approved a $200 million settlement plan that would set aside funds for victims of the outbreak and their families.[65] The settlement plan received prior approval from the official committee of unsecured creditors in the bankruptcy case.[66] By 2019, settlement payments had been made to 1963 people with additional claims pending payout.[67]

On December 17, federal prosecutors in Boston unsealed a 131-count federal criminal indictment related to the outbreak. It charged 14 former NECC employees, including president Barry Cadden and pharmacist Glenn Chin, with a host of criminal offenses. It alleged that from 2006 to 2012, NECC knowingly sent out drugs that were mislabeled, unsanitary, or contaminated—forming the basis for a massive RICO indictment against six individuals, including Cadden and Chin. The RICO count alleged 68 overt acts—including 25 counts of second-degree murder in seven states against Cadden and Chin. If convicted, Cadden and Chin faced life in prison.[18]

Cadden was ultimately convicted of racketeering charges but acquitted of second-degree murder charges in March 2017; he was sentenced to 9 years in prison.[68][69] In October 2017, Chin was convicted of racketeering and mail fraud but acquitted of second-degree murder as well; he was sentenced to 8 years in prison.[70][71] On December 20, 2016, director of sales, Robert A. Ronzio, pled guilty to unrelated conspiracy charges of defrauding the FDA, actions that were discovered during the compounding investigation.[72] Carla Conigliaro, majority owner of NECC, and her husband, Douglas Conigliaro, pled guilty to withdrawing cash from their bank accounts in small amounts, after the investigation began, to avoid financial reporting requirements.[73] Carla Conigliaro was sentenced to one year of probation and ordered to pay a

fine of $4,500, and Douglas Conigliaro was sentenced to two years of probation and ordered to pay a fine of $55,000.[74]

In May 2019, two pharmacists were sentenced in connection with the compounding center. Gene Svirskiy was sentenced to 30 months in prison and one year of supervised release; Christopher Leary was sentenced to two years of probation and 100 hours of community service.[75] Michelle Caetano Thomas, an assistant pharmacy professor at the University of Rhode Island, and Kathy Chin were convicted on two felony counts for their role in the scheme for filling obviously phony prescriptions for patients such as Coco Puff, LL Bean, and Mary Lamb.[76]

On July 7th, 2021, Barry Cadden's original 9-year sentence was increased to a 14.5 year sentence by a federal appeals court.[77]

Legislation [edit]

In September 2013, Michigan U.S. Representative Fred Upton introduced the Drug Quality and Security Act (H.R. 3204; 113th Congress) in response to the meningitis outbreak.[78] Rep. Upton's district had three deaths and 19 total deaths occurred in Michigan.[79][80] The bill passed the United States House of Representatives on September 28, 2013 by a voice vote[81] and in November the United States Senate began working on a bill that would modify the Federal Food, Drug, and Cosmetic Act to grant the FDA more authority to regulate and monitor the manufacturing of compounding drugs.[82] The Drug Quality and Security Act (H.R. 3204) was passed by the Senate on November 18, 2013. It was signed into law by President Obama on November 27, 2013.[*citation needed*]

Culture and society [edit]

- In 2019, Cadden and the NECC were criticized by John Oliver in a large segment of his satirical show *Last Week Tonight*.[83]
- "Lethal medicine linked to meningitis outbreak" CBS *60 Minutes* report (March 2013) [84]
- 2020 expose' by American Greed (S13E10) "Painful Greed Turns Deadly"[*citation needed*]

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- Episode of "Something's Killing Me with BD Wong "

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Product safety scandals | Medical scandals in the United States | 2010s disease outbreaks

Department of Justice

U.S. Attorney's Office

District of Massachusetts

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FOR IMMEDIATE RELEASE Wednesday, July 7, 2021

Former Owner of Defunct New England Compounding Center Resentenced to 14 Years in Prison in Connection with 2012 Fungal Meningitis Outbreak

Outbreak was the largest public health crisis ever caused by a contaminated pharmaceutical drug

BOSTON – The former owner of the now-defunct New England Compounding Center (NECC) was resentenced today in federal court in Boston in connection with the 2012 nationwide fungal meningitis outbreak. The defendant was resentenced after the First Circuit Court of Appeals affirmed his criminal convictions but vacated his sentence and forfeiture order.

Barry Cadden, 54, previously of Wrentham, was sentenced by U.S. District Court Judge Richard G. Stearns to 174 months in prison. Cadden was also ordered to pay forfeiture of $1.4 million and restitution of $82 million.

Cadden was originally sentenced in June 2017 by Judge Stearns to nine years in prison, three years of supervised release and forfeiture in the amount of $7.5 million after being convicted by a federal jury in March 2017 of racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead.

Co-defendant Glenn Chin, NECC's former supervisory pharmacist, is scheduled to be resentenced tomorrow by Judge Stearns. Chin was sentenced in January 2018 to eight years in prison, two years of supervised release and ordered to pay forfeiture of $175,000 and restitution in an amount to be determined. In October 2017, Chin was convicted by a federal jury of all 77 counts, including racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead.

In 2017, the government appealed the defendants' sentences. In July 2020, the First Circuit Court of Appeals vacated the defendants' sentences, finding that the Court failed to impose applicable sentencing enhancements and erred in its forfeiture rulings. Significantly, the First Circuit held that the patients who were injected with NECC's contaminated preservative-free methylprednisolone acetate (MPA) may be considered victims of the fraud. According to court documents, more than 100 patients died and approximately 800 patients were sickened as a result of contaminated MPA injections. As a result of the First Circuit's decision, the defendants' convictions were affirmed, and their sentences and forfeiture orders were vacated and remanded to the District Court for resentencing.

In 2012, 753 patients in 20 states were diagnosed with a fungal infection after receiving injections of MPA manufactured by NECC, and more than 100 patients died as a result. The outbreak was the largest public health crisis ever caused by a contaminated pharmaceutical drug.

Cadden was responsible for directing and authorizing shipments of contaminated MPA to NECC customers nationwide. In addition, he authorized the shipping of drugs before test results confirming their sterility were returned, never notified customers of nonsterile results and compounded drugs with expired ingredients. Furthermore, certain batches of drugs were manufactured, in part, by an unlicensed pharmacy technician at NECC. Cadden also repeatedly took steps to shield NECC's operations from regulatory oversight by the FDA by claiming to be a pharmacy dispensing drugs pursuant to valid, patient-specific prescriptions. In fact, NECC routinely dispensed drugs in bulk without valid prescriptions. NECC even used fictional and celebrity names on fake prescriptions to dispense drugs, such as "Michael Jackson," "Freddie Mae" and "Diana Ross."

Acting United States Attorney Nathaniel R. Mendell; Acting FDA Commissioner Janet Woodcock, M.D.; Joseph R. Bonavolonta, Special Agent in Charge of the Federal Bureau of Investigation, Boston Division; Patrick Hegarty, Special Agent in Charge of the Defense Criminal Investigative Service, Northeast Field Office; Christopher Algieri, Special Agent in Charge of the Department of Veterans Affairs, Office of Inspector General, Northeast Field Office; and Joshua McCallister, Acting Inspector in Charge of the U.S. Postal Inspection Service's Boston Division, made the announcement today. Assistant U.S. Attorneys Amanda P.M. Strachan, Chief of Mendell's Health Care Fraud Unit, Christopher R. Looney, David G. Lazarus, Chief of Mendell's Asset Recovery Unit, and Alexandra W. Amrhein prosecuted the case.

Topic(s):
Health Care Fraud

Component(s):
USAO - Massachusetts

Updated July 8, 2021

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FOR IMMEDIATE RELEASE Wednesday, July 21, 2021

Former Supervisory Pharmacist of Defunct New England Compounding Center Resentenced in Connection with 2012 Fungal Meningitis Outbreak

Outbreak was the largest public health crisis ever caused by a contaminated pharmaceutical drug

BOSTON – The former supervisory pharmacist of the now-defunct New England Compounding Center (NECC) was resentenced today in federal court in Boston in connection with the 2012 nationwide fungal meningitis outbreak. The defendant was resentenced after the First Circuit Court of Appeals affirmed his criminal convictions but vacated his sentence and forfeiture order.

Glenn Chin, 53, previously of Canton, was sentenced by U.S. District Court Judge Richard G. Stearns to 126 months in prison and three years of supervised release. Chin was also ordered to pay forfeiture of approximately $473,584 and restitution of $82 million.

Chin was sentenced in January 2018 to eight years in prison, two years of supervised release and ordered to pay forfeiture of $175,000 and restitution in an amount to be determined. In October 2017, Chin was convicted by a federal jury of all 77 counts, including racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead.

On July 7, 2021, co-defendant Barry Cadden, a former owner of NECC, was resentenced by Judge Stearns to 174 months in prison and ordered to pay forfeiture of $1.4 million and restitution of $82 million. Cadden was previously sentenced in June 2017 by Judge Stearns to nine years in prison and three years of supervised release after being convicted by a federal jury in March 2017 of racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead.

In 2017, the government appealed the defendants' sentences. In July 2020, the First Circuit Court of Appeals vacated the defendants' sentences, finding that the Court failed to impose applicable sentencing enhancements and erred in its forfeiture rulings. Significantly, the First Circuit held that the patients who were injected with NECC's contaminated preservative-free methylprednisolone acetate (MPA) may be considered victims of the fraud. According to court documents, more than 100 patients died and approximately 800 patients were sickened as a result of contaminated MPA injections. As a result of the First Circuit's decision, the defendants' convictions were affirmed, and their sentences and forfeiture orders were vacated and remanded to the District Court for re-sentencing.

In 2012, 753 patients in 20 states were diagnosed with a fungal infection after receiving injections of MPA manufactured by NECC, and more than 100 patients died as a result. The outbreak was the largest public health crisis ever caused by a contaminated pharmaceutical drug.

Chin manufactured and oversaw the manufacturing of contaminated MPA. In doing so, Chin ignored pharmacy regulations and NECC's own drug formulation worksheets and standard operating procedures. Specifically, he improperly sterilized the MPA, failed to verify the sterilization process and improperly tested it to ensure sterility. Despite knowing these deficiencies, Chin directed the MPA to be filled into tens of thousands of vials and shipped to NECC customers nationwide. During the fungal meningitis outbreak, the U.S. Centers for Disease Control identified 18 different types of fungi from MPA vials and patient samples.

Chin directed the shipping of drugs prior to receiving test results confirming their sterility, and he directed NECC staff to mislabel drugs to conceal this practice. He also directed the compounding of drugs with expired ingredients, including chemotherapy drugs that had expired several years prior. Chin prioritized drug production over cleaning, directed the forging of cleaning logs and routinely ignored mold and bacteria found inside the clean rooms.

Acting United States Attorney Nathaniel R. Mendell; Acting FDA Commissioner Janet Woodcock, M.D.; Joseph R. Bonavolonta, Special Agent in Charge of the Federal Bureau of Investigation, Boston Division; Patrick Hegarty, Special Agent in Charge of the Defense Criminal Investigative Service, Northeast Field Office; Christopher Algieri, Special Agent in Charge of the Department of Veterans Affairs, Office of Inspector General, Northeast Field Office; and Joshua McCallister, Acting Inspector in Charge of the U.S. Postal Inspection Service's Boston Division, made the announcement today. Assistant U.S. Attorneys Amanda P.M. Strachan, Chief of Mendell's Health Care Fraud Unit, Christopher R. Looney, David G. Lazarus, Chief of Mendell's Asset Recovery Unit, and Alexandra W. Amrhein prosecuted the case.

Topic(s):
Health Care Fraud

Component(s):
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Updated July 21, 2021

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LOCAL

5 Things You Need To Know About The New England Compounding Center Trial

A sketch of federal prosecutor Amanda Strachan during the trial.

Jane Flavell Collins

By **Gabrielle Emanuel**

March 21, 2017

SHARE

The case against former pharmacist Barry Cadden is now in the hands of a federal jury.

Cadden co-owned and ran the New England Compounding Center, the Framingham pharmacy responsible for a nationwide meningitis outbreak in 2012. Contaminated injections produced by the pharmacy killed at least 64 people and sickened more than 700 people.

Jurors are now deliberating on whether Cadden is guilty of the 96 charges—including fraud, racketeering and 25 counts of second-degree murder.

Here's what you need to know about the trial and the 2012 outbreak:

1. What exactly happened in 2012?

In September of 2012, people began to notice a mysterious outbreak of fungal meningitis and other infections in multiple states. This mystified physicians because it's incredibly rare—and incredibly dangerous. Meningitis is when the membrane around the brain and spinal cord is inflamed.

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA)—along with state and local officials—jumped into action. They ultimately traced the deadly outbreak to Cadden's compounding pharmacy named the New England Compounding Center.

His outfit had been shipping out steroid injections that were meant to treat pain. However, they were contaminated with mold. The result was the worst outbreak of meningitis in U.S. history.

An official from the CDC testified during Cadden's trial that this meningitis outbreak was comparable to the Ebola outbreak in West Africa. However, he said, it was worse because it was entirely preventable.

2. What happened at the trial?

This was a long trial (more than nine weeks of testimony) and it's a complicated one (with nearly 100 charges). However, there are two broad issues in the case:

Cleanliness and testing

Federal prosecutors argued that Cadden's compounding pharmacy flouted safety standards to the point of being downright filthy. In the so-called "cleanroom" where sterile drugs were made, the prosecutors said there were flies, oozing oil, and mold.

Under Cadden's direction, prosecutors said, the pharmacy used expired ingredients, fabricated cleaning logs, and improperly tested the drugs. Prosecutors said Cadden knew his injections could harm or kill patients, yet he still shipped them out. They compared it to a game of Russian Roulette and have charged Cadden with 25 counts of second-degree murder.

Cadden's defense attorneys presented a very different picture. They accept that people died from drugs produced at Cadden's pharmacy but, they said, this was not a case of murder.

Defense attorneys argued that Cadden always sought to go above and beyond best practices for the industry, particularly when it came to cleaning. He used an outside lab for testing and, over the years, his pharmacy sent out hundreds of thousands of medications without incident. They say prosecutors cherry-picked the worst lab results, creating a deceptive picture.

But of course, some of the drugs were contaminated with mold. For that, Cadden's lawyers blame contractors and employees at the pharmacy. In particular, they point to Cadden's business partner, Glenn Chin, who was the

Avoiding regulatory oversight

Federal prosecution argued that Cadden went to great lengths to lie to customers and skirt regulations. They showed the jury a training video in which Cadden dismissed the idea that inspectors would catch up with him.

“How can they come in and inspect me?” he asked in the video. “They have no clue what they are looking at. They go around and they’re like: ‘Barry’s place looks great. Yah, I got to go [get a] cup of coffee.’ Really. That is what it is like.”

Prosecutors detailed a complex scheme involving fabricated prescriptions. In an email, Cadden told his employees to make sure bogus patient names did not seem too fake—"No names like Mickey Mouse," he wrote.

In the training video, an employee asked Cadden about patient names and Cadden responded, “That’s actually one of the more difficult things we do. Let’s just talk about the product now, while we are being recorded.”

By appearing to sell custom-made medications for individual patients, Cadden's outfit fell under state regulation as a retail pharmacy. The goal, prosecutors said, was to hide what was really going on: bulk sales that would have subjected Cadden’s pharmacy to federal oversight as a drug manufacturer.

Cadden’s defense attorneys said it was Cadden’s employees and customers who fabricated the prescriptions—not Cadden himself. And, they said, as soon as Cadden knew about problems he acted aggressively and appropriately to fix them. Plus, they pointed to a regulatory landscape that was incredibly murky and showed that lots of compounding pharmacies were struggling to figure out the regulations.

3. Why is Cadden charged with second-degree murder?

Murder is usually decided on the state level, not on the federal level. In this case, the prosecutors listed the second-degree murder counts under their racketeering charges. Federal prosecutors argued that they didn’t need to prove

However, Cadden's defense attorneys want the government to prove intent. During their closing arguments, they told jurors that at the very beginning of the 2012 meningitis outbreak, Cadden spent the night as his pharmacy. He called clinics who had received his drugs and left voicemails warning them to be careful.

In one message he said, "We would like you to quarantine this product at this point and call us as soon as possible to discuss the situation. Again, Barry at New England Compounding. We consider this an emergency."

"Are those the words of a murderer?" asked Cadden's defense attorneys. They argue that Cadden never intended to kill people, and that prosecutors failed to show exactly what Cadden did to cause the deaths.

4. Separate from Cadden's trial, what's been the long-term impact of the outbreak?

First, the victims.

Many of the victims who survived the outbreak still have health problems.

Kristen Townsley of Alabama is one of them. She has juvenile rheumatoid arthritis and, at the time of the outbreak, she was on a carefully calibrated drug regimen. After receiving three of the contaminated injections, she says, she was barely alive. On her 29th birthday, Townsley was not at home in Alabama. Instead, she was in Minnesota getting treatment at the renowned Mayo Clinic.

Now, several years later, she says she's still in and out of the hospital with medical complications resulting from those injections. She has yet to return to her normal medications for juvenile rheumatoid arthritis.

Second, compounding pharmacies.

Congress took steps to improve regulations and increase federal oversight. Since the outbreak, 18 states enacted laws that relate to compounding pharmacies, and other states are in the process. However, there's still a lot of variation state by state.

In Massachusetts, there is more oversight and more resources for inspections. Yet, it's worth noting that there's still not a perfect system. Compounding pharmacies regularly get calls requesting bulk drugs even when they are not supposed to be making medications in bulk, and Massachusetts has been slow to oversee compounded drugs that come from other states but are given to patients here.

One more big impact, insurance.

According to several pharmacists, insurers have used the 2012 outbreak as an opportunity to reduce their coverage of compounded drugs. So many people's custom-made medications are now much more expensive. Insurers says these compounded medications are often used unnecessarily and they're just making sure such medications are only used when absolutely necessary.

5. When the verdict is announced, what happens next?

After the verdict, Cadden awaits his sentencing. His business partner, Glenn Chin, will soon go on trial. He also faces second-degree murder charges.

Chin was the supervisory pharmacist, overseeing the pharmacy's cleanrooms where the drugs were made. Initially, Cadden and Chin were charged together, but because Cadden's lawyers have tried to blame Chin, they ended up getting separate trials.

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STATE HOUSE

September 28, 2021 8:27 AM PDT Last Updated a month ago

United States

U.S. court revives two convictions stemming from 2012 meningitis outbreak

By Nate Raymond

2 minute read

1/3

Gregory Conigliaro, a co-owner of the now-defunct New England Compounding Center, enters the federal court in Boston, Massachusetts, U.S., December 7, 2018. Picture taken on December 7, 2018. REUTERS/Nate Raymond

BOSTON, Sept 27 (Reuters) - A federal appeals court on Monday restored the convictions of a co-owner and former employee of a Massachusetts compounding pharmacy accused of deceiving regulators before its drugs sparked a deadly fungal meningitis outbreak in 2012.

The 1st U.S. Circuit Court of Appeals in Boston **ruled that** a judge wrongly found it was legally impossible for New England Compounding Center co-owner Gregory Conigliaro and ex-employee Sharon Carter to defraud the U.S. Food and Drug Administration.

The ruling could clear the way for them to be sentenced. Defense lawyers did not respond to requests for comment.

Conigliaro and Carter were among 14 people associated with NECC who were indicted after mold-tainted steroids it produced sparked a fungal meningitis outbreak that sickened 793 people nationally, including more than 100 who died.

The defendants included Barry Cadden, NECC's ex-president and co-founder, and Glenn Chin, its former supervisory pharmacist, who were convicted of racketeering and fraud and are serving prison sentences of 14-1/2 and 10-1/2 years, respectively.

Unlike Cadden and Chin, Conigliaro and Carter were not charged with playing a direct role in the outbreak.

A federal jury in 2018 instead found them guilty of misleading the FDA into thinking Framingham, Massachusetts-based NECC was operating like a conventional pharmacy that should be subject to state oversight, rather than a drug manufacturer.

State-regulated compounding pharmacies produce customized drugs pursuant to patient-specific prescriptions. But prosecutors said NECC was actually a drug manufacturer making medications in bulk without valid prescriptions.

U.S. District Judge Richard Stearns said the FDA at the time was unsure it could regulate compounding pharmacies like NECC and was as a result not doing so, making it impossible to impede the agency's functions.

But U.S. Circuit Judge David Barron, writing for Monday's three-judge panel, said Stearns never identified any instance in which the FDA disavowed authority to treat a compounding pharmacy as a manufacturer subject to heightened oversight.

Reporting by Nate Raymond in Boston; Editing by Stephen Coates

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United States

Biden hopeful Democrats can reach spending deal this week

U.S. President Joe Biden on Monday held out hope for an agreement on his major spending plans before attending a climate summit in Scotland, while the White House said Democratic negotiators were closing in on a deal.

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College of Pharmacists of British Columbia

BOARD MEETING
April 21, 2017

4. Legislation Review Committee
b) Compounding – Implementation Plan

DECISION REQUIRED

Recommended Board Motions:

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

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

2. Direct the registrar to draft bylaws to adopt the Model Standards, to be effective for May 2021, which will officially establish minimum requirements to be applied in compounding sterile preparations.

Purpose

To seek approval for the four-year implementation plans to adopt the *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations* and the *Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations,* and to direct the Registrar to draft bylaws to officially adopt them (effective May 2021).

Background

Compounding, in respect to a drug, is defined as mixing together of one or more other ingredients[1]. Evolving practice and increased awareness of the inherent dangers of compounding sterile preparations for the health of both patients and compounding personnel, led the National Association of Pharmacy Regulatory Authorities (NAPRA) to develop a suite of

[1] http://www.bclaws.ca/civix/document/id/lc/statreg/417_2008

new model standards for pharmacy compounding. These model standards will set national standards for pharmacy compounding, and are expected to be adopted by pharmacy regulatory authorities across Canada.

NAPRA recently released two of the three model standards documents for pharmacy compounding. The two released documents are: *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations*[2] and *Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations*[3] (the Model Standards). The final document for non-sterile preparations is expected to be released later in 2017. The release of all three model standards documents will replace NAPRA's Guidelines to Pharmacy Compounding (2006), which was adopted by the Board in 2010.

The Model Standards have been adapted from standards originally developed by the Order of Pharmacists in Quebec, which in turn are based on the General Chapter of the United States Pharmacopeia – National Formulary (USP). The USP standards amongst others (i.e., the Canadian Society of Hospital Pharmacists) are the existing standards of practice for sterile compounding in community and hospital pharmacies in British Columbia. See Appendix 1 for a summary of the existing standards of practice for pharmacy compounding, as referenced in College bylaws and professional practice policies.

The Model Standards will come into effect in each province/territory once they have been adopted by the respective provincial/territorial pharmacy regulatory authorities.

Discussion

The College of Pharmacists of BC has explicit bylaw making authority to establish standards, limits or conditions for the practice of pharmacy.[4] It cannot "simply" adopt the standards established by another organization. Therefore, in order to adopt standards created by another body such as NAPRA, due diligence is required to ensure that the NAPRA Model Standards are appropriate for BC. Accordingly, Dana Lyons, a subject matter expert in compounding, was

[2] http://napra.ca/Content_Files/Files/Mdl_Stnds_Pharmacy_Compounding_NonHazardous_Sterile_Preparations_Nov2016_Revised.pdf

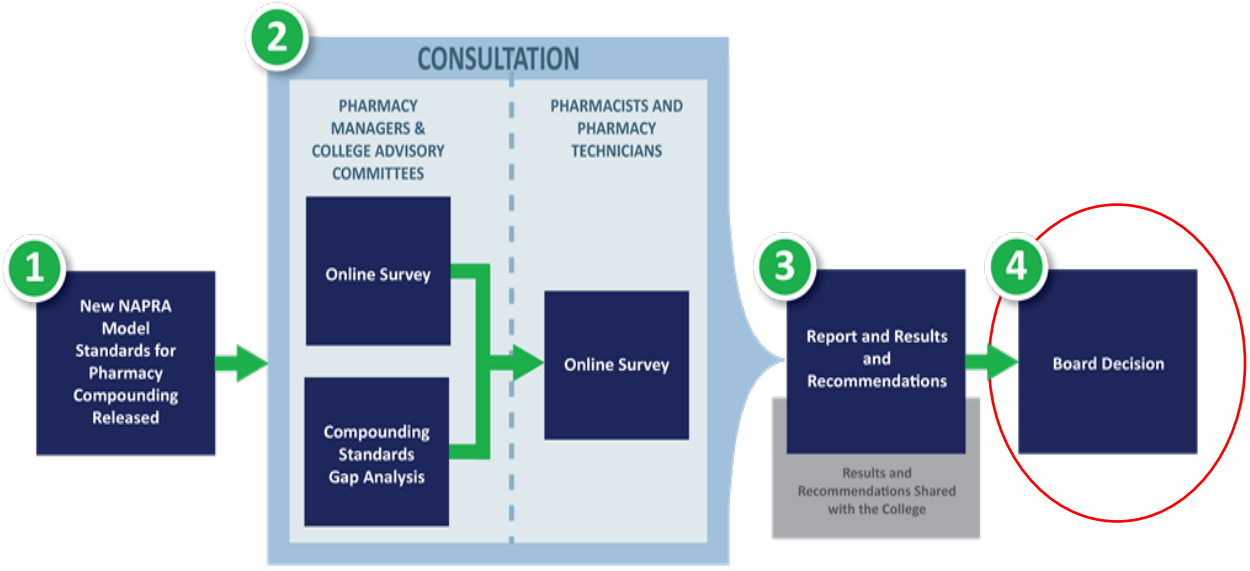
[3] http://napra.ca/Content_Files/Files/Mdl_Stnds_Pharmacy_Compounding_Hazardous_Sterile_Preparations_Nov2016_Revised.pdf

[4] *Health Professions Act*:
19(1) A board may make bylaws, consistent with the duties and objects of a college under section 16, that it considers necessary or advisable, including bylaws to do the following:
(k) establish standards, limits or conditions for the practice of the designated health profession by registrants;

contracted by the College to recommend a plan for adoption and implementation of the two released Model Standards in BC.

Dana Lyons is a registered with the Alberta College of Pharmacists as a Pharmacy Technician, and is a specialist in implementation and management of sterile compounding processes and validation. Ms. Lyons is currently leading the implementation of these standards in pharmacies across Alberta.

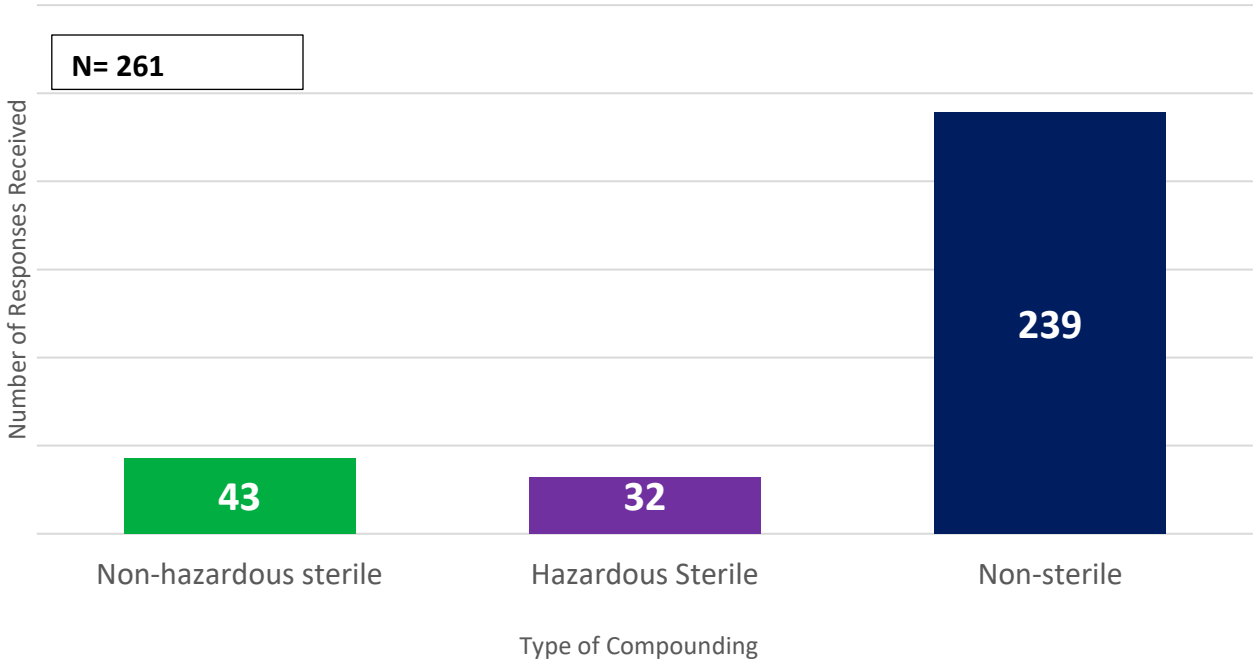
Consultation and Engagement
To inform the adoption and implementation of the two released Model Standards, a multi-step engagement process was developed (see below).



The first step of this process was reaching out to pharmacy managers through an online survey to determine how many pharmacies (community and hospital) are engaged in non-hazardous sterile compounding, hazardous sterile compounding and non-sterile compounding. There was a total of 261 responses received to this survey.

The responses received suggest that most pharmacies compound non-sterile preparations (over 90% of responses received indicated that they compound non-sterile preparations). Also, from the responses received, it can be noted that more non-hazardous sterile compounding takes place than hazardous sterile compounding. Please note that pharmacies can be involved in any combination of the three types of compounding. For example, a pharmacy could be engaged in non-hazardous and non-sterile compounding. Chart 1 below illustrates the results of the survey responses.

Chart 1: Summary of Survey Results for Types of Compounding



Following this survey, a Gap Analysis Survey was developed to determine any gaps in practice in meeting the minimum standards in the Model Standards. The Gap Analysis Survey included a series of questions developed from the required minimum standards described in the Model Standards. The Tool was sent out to pharmacy managers, pharmacists and pharmacy technicians to determine how their current-day practice meets or does not meet the standards indicated in the Model Standards.

Gap Analysis Results

The questions in the Gap Analysis Survey for the Model Standards (non-hazardous sterile compounding) included the standards in the document which used mandatory language (i.e., "must" and "shall"). Based on the responses received, the self-reported compliance with these standards was 48%. This means that the current gap in meeting them is 52%.

The results from the Gap Analysis Survey for the Model Standards (hazardous sterile compounding), indicated that the self-reported compliance with the mandatory standards in the document to be 54%. Therefore, the current gap in meeting them is 46%.

The second step of the consultation process involved an in-person engagement session with those pharmacy managers, pharmacists and pharmacy technicians, who an expressed interest in attending a consultation, during the online survey noted above. This step included a review of the gap survey results and a workshop-style session where each participant was placed in a

small group and worked through a series of questions developed to understand where potential barriers and challenges to meeting the Model Standards may exist.

The third step was to engage more broadly with pharmacy managers, pharmacists and pharmacy technicians who are involved in compounding sterile preparations (non-hazardous and hazardous). To do this, a survey was developed for each of the Model Standards. The survey was designed to understand what knowledge gaps front-line compounders might be facing and also to understand challenges and barriers from their perspective.

Barriers Brought Forward in In-Person Engagement and Surveys

In both the engagement and survey, the top barrier to implementing the Model Standards was the cost of compliance. It was raised that the Model Standards will require some organizations to renovate pharmacies to meet the new minimum standards. The proposed four-year phased implementation plans will allow for at least two budgeting cycles to occur while these standards to be implemented, to address the capital infrastructure cost concerns.

Another identified barrier to implementation is specific to the beyond-use dates (BUD)[5]. The Model Standards require a more stringent way of assigning a BUD. It was raised that this could result in drug wastage and costs to patients, as the BUD setting in the Model Standards may be shorter than how they are currently set. Existing standards referenced in the College's bylaws do permit a less stringent approach; however, the approach included in the Model Standards is consistent with USP standards, which are also referenced in the College's bylaws.

The results of the Gap Analysis Surveys, engagement session and surveys informed the recommendations, timelines and mitigation strategies for successful implementation of the Model Standards, in Ms. Lyons reports which are in Appendix 2 and Appendix 3.

Proposed Implementation Plans

A four-year phased implementation is recommended for both Model Standards. The recommended deadlines for each phase are as follows:

- Phase 1: November 2017
- Phase 2: May 2019
- Phase 3: May 2020
- Phase 4: May 2021

[5] Beyond-use date (BUD): Date and time after which a compounded sterile product cannot be used and must be discarded (because of a risk of loss of sterility); assigned based on risk of contamination.

Each phase includes specific groupings of standards from the Model Standards (see table below and Appendix 2 and 3, for further details).

Phase 1	Phase 2	Phase 3	Phase 4
• Define compounding risk level • Complete gap survey and prioritize a site plan • NAPRA standards: – 6.3 (compounded sterile preparation log) – 6.4 (patient file) – 6.5 (personnel) – 6.6 (aseptic compounding of sterile preparations) – 6.7 (packaging) – 6.8 (storage) – 6.9 (transport and delivery of compounded sterile preparations) – 6.10 (recall of sterile products of final compounded sterile preparations)	• NAPRA standards: – 5.1 (personnel) – 5.2 (policies and procedures) – 5.4 (maintenance log) – 6.2 (compounded sterile preparation protocols)	• NAPRA standards: – 6.1 (beyond-use date) – 6.11 (incident and accident management) – 6.12 (waste management) – 7.1 (program content) – 7.2 (results and action levels) – 7.3 (verification of equipment and facilities) – 7.4 (quality assurance of personnel) – 7.5 (quality assurance of compounded sterile preparation) – 7.6 (documentation of quality control activities)	• NAPRA standard 5.3 (facilities and equipment)

Status of Other Provinces that have Adopted the Model Standards

The two released Model Standards have been adopted by five other provincial pharmacy regulatory authorities (AB, ON, MB, NS, and NL) to date. AB, ON and MB have adopted the Model Standards through multi-year implementation phases. Appendix 4 lists the provinces

that have adopted the Model Standards to date and their implementation deadlines, as applicable.

Bylaws Amendments Needed to Adopt the Model Standards

The College's existing bylaws and policies (Appendix 1) will remain in place until the implementation deadline of May 2021 (i.e., after the four-year implementation period is complete). It should be noted that some of the existing references to compounding standards in the College's Professional Practice Polices are outdated references. However, updating them at this time would lead to further confusion for registrants given that the goal is for them to work towards meeting the Model Standards. Therefore, with approval from the Board, new bylaws to adopt the Model Standards will be drafted to be effective as of May 2021, and all existing references will be repealed at that time.

Next Steps

- Develop bylaws to come into force by May 2021 and repeal existing standards referenced in bylaws and policies, as of that date (will be brought forward to a future Board meeting for approval).
- Develop communications to continually inform and notify registrants of the implementation phases and their respective deadlines.
- Compliance Officers assess the implementation of the Model Standards according to the phases in the implementation plans, through the Practice Review Program. As the bylaws are not to be in effect until 2021, Compliance Officers would only monitor and inform registrants of any instances of non-compliance. The bylaws would not be legally enforceable until 2021.

Recommendation

The Board approve the implementation plans to adopt the Model Standards (non-hazardous and hazardous sterile preparations) and to direct the Registrar to draft bylaws adopting them.

Appendix	
1	Existing College Sterile Compounding Standards
2	Report on Non-hazardous Model Standards Implementation
3	Report on Hazardous Model Standards Implementation
4	Other Jurisdictions that have Adopted the Released NAPRA Model Standards

College of Pharmacists of British Columbia

BOARD MEETING
September 18, 2020

7. Legislation Review Committee
b) Implementation of the National Association of Pharmacy Regulatory Authorities' Model Standards for Pharmacy Compounding

DECISION REQUIRED

Recommended Board Motion:

Due to the COVID-19 State of Emergency, the Board of the College of Pharmacists of BC approves extending the implementation plan to adopt the *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations* and the *Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations* from May 2021 to July 2022.

Purpose

To provide the Board with:

- An update on the progress of the implementation of the *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations* and *Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations*.
- A proposed implementation timeline amendment for officially adopting the above-noted standard.

Background

Compounding

Compounding, in respect to a drug, is defined as mixing together of one or more other ingredients[1]. Healthcare professionals who provide compounding related services and products to patients, must be able to demonstrate that a patient-healthcare professional relationship exists.

Compounding Incidents

Compounding related errors such as the those in the case of both the New England Compounding Centre and Marchese Hospital Solutions[2] incidents have highlighted the patient safety risks involved with improper compounding procedures.

[1] http://www.bclaws.ca/civix/document/id/lc/statreg/417_2008

[2] https://www.fdanews.com/ext/resources/files/archives/10113-01/08-09-13-Canada.pdf

In 2012, over 50 people died and over 800 people were infected from a fungal meningitis outbreak where patients were infected from receiving contaminated steroid injections mixed at the New England Compounding Centre. In 2019, the former supervising pharmacist of the New England Compounding Centre was sentenced in this case. Recently, an appeal in relation to this case was not granted by a United States federal court.

In 2013, Marchese Hospital Solutions supplied nearly 1,200 Canadian cancer patients in Ontario and New Brunswick hospitals with weaker-than-prescribed doses of chemotherapy drugs. As a result, 1,202 patients were affected. Of these, 1,007 were under-dosed with cyclophosphamide, 191 were under-dosed with gemcitabine, and 4 received both oncology medications. The majority of the patients implicated by this error were adults (1,162), and the remainder were pediatric cases (40).

NAPRA Model Standards (sterile and non-sterile preparations)

Evolving practice and increased awareness of the inherent dangers of compounding sterile preparations for the health of both patients and compounding personnel, led the National Association of Pharmacy Regulatory Authorities (NAPRA) to develop a suite of new model standards for pharmacy compounding. These model standards will set national standards for pharmacy compounding and are expected to be adopted by pharmacy regulatory authorities across Canada.

In 2015 and 2016, NAPRA released two of three Model Standards documents for pharmacy compounding. The two released documents were: *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations*[3] and *Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations*[4] (collectively referred to as the "Sterile Model Standards" in this note). The final document, *Model Standards for Pharmacy Compounding of Pharmacy Compounding of Non-Sterile Preparations*[5] (the "Non-Sterile Model Standards") was released in 2018.

The Sterile Model Standards and Non-Sterile Model Standards will come into effect in each province/territory once they have been adopted by the respective provincial/territorial pharmacy regulatory authorities.

CPBC Implementation of NAPRA Model Standards

In April 2017, the Board approved a four-year implementation plan to adopt both the Sterile Model Standards, with the following recommended phases for each document:

- Phase 1 (gap analysis and site plan, personnel conduct): November 2017
- Phase 2 (personnel training, policies and procedures): May 2019

[3] NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations, https://napra.ca/sites/default/files/2017-09/Mdl_Stnds_Pharmacy_Compounding_NonHazardous_Sterile_Preparations_Nov2016_Revised_b.pdf

[4] NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations, https://napra.ca/sites/default/files/2017-09/Mdl_Stnds_Pharmacy_Compounding_Hazardous_Sterile_Preparations_Nov2016_Revised_b.pdf

[5] NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations, https://napra.ca/sites/default/files/documents/Mdl_Stnds_Pharmacy_Compounding_Nonsterile_Preparations_March2018_FINAL.pdf

- Phase 3 (beyond-use dates, verification of facilities): May 2020
- Phase 4 (facility infrastructure): May 2021

The Board also directed the Registrar to draft bylaws to adopt the Sterile Model Standards, to be effective May 2021. This will officially establish minimum requirements to be applied in compounding sterile preparations.

The above-noted implementation plan was informed by a multi-step engagement process (surveys and workshops with pharmacy managers, pharmacists and pharmacy technicians) and the expertise of a subject matter expert in compounding. Please see Appendix 1 for the full April 2017 Board briefing materials for more information on the implementation plan.

Staff are currently reviewing the Non-Sterile Model Standards and are in the process of developing an implementation plan for Board approval.

Discussion

Following April 2017, the College implemented several new processes to inform registrants and to support College staff in monitoring implementation of the Sterile Model Standards. These new processes included:

- Communications to continually inform registrants of the recommended implementation phases and deadlines. This included creating a dedicated webpage and sending Readlinks articles to all registrants at the beginning of each phase of the implementation plan.
- Notifying registrants of the recommended phases and monitoring compliance through the Practice Review Program.
- Updating the annual pharmacy license renewal process to collect information regarding the number of pharmacies that compound sterile and non-sterile preparations.

Furthermore, this initiative was communicated to various stakeholders in presentations through many forums (e.g., presenting at annual pharmacy conferences, etc.).

Recent Consultation on the Model Standards
College staff initially aimed to begin consulting with pharmacies to assess their readiness in implementing the Sterile Model Standards in April 2020. However, on March 11, 2020, the World Health Organization declared the novel coronavirus, COVID-19, a pandemic. In BC, Provincial Health Officer, Dr. Bonnie Henry, declared a public health emergency on March 17, 2020. As a result of the COVID-19 pandemic, planned policy and legislation changes that were not related to COVID-19 were temporarily paused in order to focus on those required to address COVID-19.

In June 2020, College staff surveyed pharmacies to understand the status of their compliance with the Sterile Model Standards. This survey included questions on:

- Compliance with each standard under the four-phases in the implementation plan.
- Barriers being faced with regards to compliance with the Sterile Model Standards.
- If compliance will be fully achieved by May 2021.
- If not expecting to be compliant by May 2021 the date of expected compliance.
- The volume and frequency of compounding non-hazardous and hazardous preparations.
- The percentage of compounding being prepared by a pharmacist, pharmacy technician or non-regulated health professionals (e.g., pharmacy assistant).

The survey (see Appendix 2) was sent out to health authority leaders within each of the following health authorities: Fraser Health; Island Health; Northern Health; Provincial Health Services Authority; and, Vancouver Coastal Health.

The Sterile Model Standards primarily impact hospital pharmacies; however, some community pharmacies also prepare sterile compounds. So, the survey (see Appendix 3) was also sent to pharmacy managers of community pharmacies identified as preparing sterile non-hazardous compounds, hazardous compounds or both.

Below is a summary of key results from the survey.

Survey Results for Both Hospital Sites and Community Pharmacies
The survey was completed by 57 licensed hospital sites and 7 community pharmacies. Regarding community pharmacies, the response rate was low, but this may be because fewer community pharmacy compound sterile preparations[6].

In general, the results from the survey question on compliance with each standard within the four-phases of the implementation plan, indicate that hospital sites and community pharmacies are progressing towards compliance with the Sterile Model Standards. See Appendix 4 for graphs summarizing the average responses for percent compliance with each of the phases in the implementation plan.

Survey Results for Hospital Sites
Overall, the survey results indicate that the majority (84%) of sites will ***not*** be compliant with the Sterile Model Standards by May 2021. Of the 57 responses received:

- Eight sites are expecting to be compliant by May 2021.
- 32 sites are expecting to be compliant by mid-2022, with compliance dates ranging from October 31, 2021 to June 30, 2022.
- Two sites will be sourcing from another pharmacy until their new facilities are ready.
- One site will no longer be compounding and will instead be securing compounded products from a nearby hospital.
- 11 sites will only compound in what is called a segregated compounding area (see below).

[6] Based on data gathered through annual license renewal process and information from pre-reviews under the Practice Review Program, only 15 community pharmacies compound sterile preparations.

- Three sites are planning for new pharmacy sites and are not expecting to be fully compliant until 2024-2025 (see below).

As noted above, 11 sites will compound in what is called a “segregated compounding area”. The Sterile Model Standards allows compounding of sterile preparations in a segregated compounding area, which is a designated space restricted to preparing low-risk sterile preparations (for non-hazardous sterile compounding) and low- and medium-risk preparations (for hazardous sterile compounding).

Also as noted above, three sites are planning for new pharmacy sites. They are not expecting to be fully compliant with the Sterile Model Standards until 2024-2025.

In addition to survey results, four letters were submitted by the following organizations to supplement the explanation of their compliance with the Sterile Model Standards (see Appendix 5): Lower Mainland Pharmacy Services (representing Fraser Health, Vancouver Coastal Health and the Provincial Health Services); Interior Health; Island Health and, Northern Health Authority. These letters highlight the impacts of COVID-19 as a key barrier in compliance with the Sterile Model Standards by May 2021.

Survey Results for Community Pharmacies
Of the seven completed surveys received from community pharmacy managers:

- Four sites are expecting to be compliant with the Sterile Model Standards by May 2021.
- One site is expecting to be compliant by December 2021.
- Two sites will no longer be compounding sterile preparations.

Cross-Jurisdictional Review
To date, the Pharmacy Regulatory Authorities (PRAs) in Ontario, Nova Scotia and Newfoundland and Labrador have already adopted the Sterile Model Standards.

The PRAs in Alberta, Manitoba and Saskatchewan still have active implementation plans, set to end in 2021. It is important to note that Alberta recently extended their implementation timeline by a year for their last phase, due to the COVID-19 epidemic. The extension will end in July 2021 and will allow more time for meeting compliance with standards regarding facilities and equipment. Please see Appendix 6 includes a jurisdiction scan of other pharmacy regulatory authorities and their implementation/adoption of the Sterile Model Standards.

Options

Option One: Extend the May 2021 Deadline to July 1, 2022
In this option, the current deadline of May 1, 2021 to implement the Sterile Model Standards will be extended to July 1, 2022.

Pros:

- Provides hospital and community pharmacies with additional time to implement the Sterile Model Standards, due to the unforeseen onset of the COVID-19 pandemic and focus on urgent issues with the pandemic.
- The majority of hospital sites are expecting to be compliant by this date (96% of the sites for which surveys were completed).
- The moratorium on bylaw amendments[7] may be lifted.

Cons:

- Delays implementation of the national Sterile Model Standards and their enforcement in BC.

Option Two: Continue with the May 2021 Deadline (as was previously approved)
In this option, all pharmacies will be still be required to implement the Sterile Model Standards by the current deadline of May of 2021, and staff will develop bylaw amendments to officially adopt the Model standards by this date.

Pros:

- The national Sterile Model Standards will be adopted and enforced in BC by the original date set.

Cons:

- The majority of hospital sites will not be compliant by this date.
- An extraordinary meeting of the Board will need to be held in October to approve public posting of PODSA bylaw amendments.
- Current moratorium on bylaw amendments may implicate filing of bylaw amendments.
- Does not address the concerns provided by pharmacies regarding COVID-19.

Guiding Question:

A key question for the Board to consider is:

- Does the proposed amendment to the implementation timeline to officially adopt the Sterile Model Standards appropriately balance realistic implementation expectations for hospital pharmacies in light of COVID-19, with the importance of adopting the Sterile Model Standards in the interest of public safety?

[7] On December 2019, the Ministry of Health requested regulatory College's to temporarily pause the submission of any bylaw amendments. On July 13, 2020, Ministry staff notified College staff that this moratorium is still effective until further notice.

Recommendation

The Legislation Review Committee recommends Option 1 (extend the May 2021 deadline to adopt the Sterile Model Standards to July 1, 2022). This option recognizes the compliance date identified by the majority of hospital sites. Importantly, this would be a one-time extension due to the onset of the unforeseen COVID-19 pandemic and its impact on the ability of pharmacies to implement the Sterile Model Standards by the May 2021 deadline. Where possible, earlier compliance is recommended.

Next Steps

If Option 1 is approved, College staff will draft bylaws to adopt the Model Standards, to be effective for July 1, 2022. These bylaws will officially establish minimum requirements to be applied in compounding sterile preparations. The extension will be communicated to registrants, health authorities and the public and the dedicated webpage on the College's website will also be updated accordingly. In addition, the College will continue to work with the remaining three sites that are not expecting to be compliant by July 2022, to further encourage and clarify their level of compliance.

Appendix	
1	April 2017 Board Briefing Materials
2	Survey Questions for Hospital Sites
3	Survey Questions for Community Pharmacies
4	Graphs Summarizing Average Percent Compliance with Sterile Model Standards
5	Letters from Health Authorities
6	Cross-Jurisdictional Scan on the Adoption of the Sterile Model Standards

Pharmacy Operations and Drug Scheduling Act - BYLAWS

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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*;

"BC Annual Report" means an annual report filed with the BC Registry Services;

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

"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 substances" means a drug which includes a substance listed in the Schedules in the regulations made pursuant to the *Controlled Drugs and Substances Act* (Canada), and 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;

"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 section 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" means a person who is authorized to act on a patient's behalf;

"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 licensed to provide pharmacy services;

"*Telepharmacy Standards of Practice*" means the standards, limits and conditions for practice established under section 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 scale, including the measurements and entrances of the pharmacy, demonstrating compliance with the physical requirements in the bylaws and applicable policies;

(d) Form 10A;

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

(f) a copy of the pharmacy's valid business licence issued by the jurisdiction to the direct owner, 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) an email contact of each indirect owner;

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

(c) a copy of the current British Columbia Company Summary; and

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

(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) an email contact of each indirect owner;

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

(c) a copy of the current British Columbia Company Summary; and

(d) 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 valid business licence issued by the jurisdiction to the direct owner, if applicable; and

(d) a copy of the current British Columbia Company Summary or the most recently filed BC Annual Report, 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".

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 valid business licence issued by the jurisdiction to the direct owner, 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.

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 scale, including the measurements and entrances of the pharmacy, demonstrating compliance with the physical requirements in the bylaws and applicable policies.

(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 licensed as a community pharmacy or telepharmacy.

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".

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.

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".

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.

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 1B;

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

(c) a diagram professionally drawn to scale, including the measurements and entrances of the telepharmacy, demonstrating compliance with the physical requirements in the bylaws and applicable policies;

(d) Form 10B;

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

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

Conditions for Telepharmacy Licence

12.1 (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 name on the external signage of the telepharmacy described in section 18(2)(r) 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 Licence Renewal

13 (1) 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 2B;

(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.

(2) An application submitted later than 30 days prior to the expiry of the telepharmacy licence is subject to the fee(s) specified in Schedule “A”.

Telepharmacy Licence Reinstatement

13.1 A direct owner may apply to reinstate a telepharmacy licence that has been expired for 90 days or less by submitting:

(a) an application in Form 3B;

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

(c) if applicable, a copy of the telepharmacy’s valid business licence issued to the direct owner 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.

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 licensed 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 valid business licence issued by the jurisdiction to the new direct owner, 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 by the direct owner:

(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 and telepharmacy licence if applicable, 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), and 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 registrar may amend the pharmacy licence, and telepharmacy licence if applicable, upon receipt of the following from the direct owner:

(a) Form 8D;

(b) the fee(s) specified in Schedule “A”;

(c) a copy of the pharmacy’s valid business licence issued by the jurisdiction to the direct owner with the new corporation name, 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 by the direct owner:

(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 name on the external signage described in section 18(2)(q) or section 18(2)(r), or in the operating name of the pharmacy, the registrar may amend the pharmacy or telepharmacy licence upon receipt of the following from the direct owner:

(a) Form 8E;

(b) the fee(s) specified in Schedule “A”;

(c) for a change of operating name, a copy of the pharmacy’s valid business licence with the new operating name issued by the jurisdiction to the direct owner, if applicable; and

(d) for a change of the name on the external signage, photographs or video demonstrating compliance with section 18(2)(q) or 18(2)(r).

(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”;

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

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

(e) a copy of the pharmacy’s valid business licence with the address of the new location issued by the jurisdiction to the direct owner, if applicable; and

(f) photographs or video demonstrating compliance with section 18(2)(ee)(v).

(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 sections 3(2)(c), (d) and (e) for a community pharmacy;

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

(e) a diagram, photographs or video to demonstrate the changes in layout in accordance with sections 12(c), (d) and (e) for a telepharmacy.

17.1 (1) A direct owner of a pharmacy that is permanently closing must notify the registrar by submitting the following at least 30 days before closure:

(a) an application in Form 4A;

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

(c) documents demonstrating compliance with sections 18(2)(ee)(i), (ii), (iii) and (iv); and

(d) photographs or video demonstrating compliance with section 18(2)(ee)(v).

(2) The manager of the pharmacy receiving drugs, medical devices, and/or patient and prescription records from the closing pharmacy must submit Part 2 of Form 4A within 14 days of receiving date the drugs, medical devices, and/or patient and prescription records.

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) personally manage and be responsible for the daily operation of the pharmacy;

(b) ensure compliance with all legislation, bylaws, policies, procedures applicable to the operation of a pharmacy;

(c) establish policies and procedures

(i) to specify the duties to be performed by registrants and support persons,

(ii) for inventory management, product selection, and proper destruction of non-usable drugs and devices,

(iii) for pharmacy security,

(iv) for emergency preparedness, and

(v) for drug recall of pharmacy inventory;

(d) ensure all policies and procedures are in writing and regularly maintained;

(e) ensure that pharmacy staff are trained in policies and procedures;

(f) ensure that all steps in the drug recall procedure are documented, if the procedure is initiated;

(g) ensure that all individuals working in the pharmacy who present themselves as registrants have been granted and maintain registration with the College, in accordance with the policies approved by the board;

(h) notify the registrar of any appointments, resignations or terminations of registrants employed at the pharmacy as those changes occur;

(i) cooperate with inspectors acting under section 17 of the *Act* or section 28 or 29 of the *Health Professions Act*;

(j) ensure that

(i) registrant and support persons staff levels are commensurate with 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;

(k) ensure that all records related to the purchase and receipt of controlled drug substances are signed by a full pharmacist;

(l) ensure safe and secure storage of all Schedule I, II, and III drugs and controlled drug substances for all aspects of pharmacy practice, in accordance with the policies approved by the board;

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

(n) ensure that each individual working in the pharmacy presents themselves to the public in a manner that clearly identifies their registration class;

(o) ensure that registrants identify themselves in a manner that clearly differentiates them from other individuals working in the pharmacy who are not registrants;

(p) immediately notify the registrar in writing of ceasing to be the pharmacy's manager;

(q) ensure that at a minimum, the name on the external signage of a community pharmacy must be correctly and consistently used on labels and directory listings;

(r) if the pharmacy is a central pharmacy, ensure that at a minimum, the name on the external signage of a telepharmacy must be correctly and consistently used on labels and directory listings;

(s) ensure that narcotic reconciliation is performed in accordance with the policies approved by the board;

(t) notify the registrar of any incident of loss of narcotic and controlled drug substances within 24 hours;

(u) 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;

(v) ensure the pharmacy contains the reference material and equipment in accordance with the policies approved by the board;

(w) 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;

(x) retain the undertakings referred to in subsection (w) in the pharmacy for 3 years after employment or any contract for services has ended;

(y) provide the registrar with access to the pharmacy and premises as defined in section 20(1) in cases where a pharmacy licence has been cancelled or suspended due to loss of eligibility under section 3 of the *Act*;

(z) 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

(i) deliver a prescription to a particular registrant or pharmacy for dispensing of a drug or device specified in the prescription, or

(ii) obtain any other pharmacy service from a particular registrant or pharmacy;

(aa) notify the registrar of persistent non-compliance by a direct owner and indirect owner(s) with their obligations under the bylaws to the *Act*;

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

(cc) in the event of an anticipated temporary closure, which is permitted for no more than 14 consecutive days,

(i) notify patients and the public of the anticipated temporary closure at least 30 days prior to the start of the closure in accordance with the policies approved by the board,

(ii) document steps taken to comply with the bylaws and applicable policies on anticipated temporary closures,

(iii) contact all patients whose prepared prescriptions are ready for pick-up to advise of the closure and provide them with the opportunity to obtain their prepared prescriptions prior to the closure start date,

(iv) make alternate arrangements with local prescribers, as appropriate, and

(v) return any prepared prescriptions in the pharmacy to inventory and reverse those prescriptions in PharmaNet;

(dd) in the event of an unanticipated temporary closure due to unforeseen circumstances, which is permitted for no more than 90 days,

(i) notify the registrar of closures of 15 to 90 days in accordance with the policies approved by the board,

(ii) where possible, contact all patients whose prescriptions are ready for pick-up to advise of the closure and provide them with the opportunity to obtain their prepared prescriptions,

(iii) where possible, notify patients, the public, and local prescribers of the closure and alternate means of obtaining essential pharmacy services during the closure in accordance with the policies approved by the board,

(iv) apply for a new pharmacy licence if the closure will exceed 90 days, and

(v) return any prepared prescriptions in the pharmacy to inventory and reverse those prescriptions in PharmaNet;

(ee) in the event of a permanent pharmacy closure, cancellation, or expiry of the pharmacy licence

(i) provide for the safe and secure 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, in accordance with policies approved by the board,

(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 secure transfer and continuing availability of the prescription records at another pharmacy, or at storage facility that is monitored and secured from unauthorized access, and

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

(3) In the event of a suspension of the pharmacy licence for a period of more than 14 days,

(a) the manager and the direct owner must complete and submit Form 4C, and

(b) the registrar may direct a manager to do any of sections 18(2)(ee)(i), (iii) or (iv).

(4) Subsection (2)(z) 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.

(5) Subsection (2)(z) does not apply in respect of a Schedule III drug or an unscheduled drug, unless the drug has been prescribed by a practitioner.

(6) 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), (b), (c)(ii), (d), (e), (i), (p), (ee)(i) and (ee)(ii).

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

(a) ensure compliance with subsections (2)(c)(i), (c)(iii), (c)(iv), (c)(v), (i), (j), (l), (q), (r), (y) and (z);

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

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

(8) Shareholders must comply with subsections (2)(i) and (7)(c).

(9) A direct owner, manager, directors, and officers must ensure compliance with the National Association of Pharmacy Regulatory Authorities standards as approved by the board from time to time, applicable to the operation of a pharmacy.

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 policies approved by the board,

(c) by return to the manufacturer or wholesaler of the drug, or

(d) by destruction, in accordance with the policies 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.

(6.1) Despite subsection (6), a registrant may dispense drugs included in the controlled prescription program upon receipt of a verbal prescription from a practitioner if doing so is permitted under a section 56 exemption to the *Controlled Drugs and Substances Act.* The pharmacy must receive the original prescription form from the practitioner as soon as reasonably possible.

(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) In this section:

"premises" means:

(a) a hospital as defined in the *Hospital Act*, or
(b) the building or part of the building, within which the pharmacy is located, and includes loading spaces and excludes other businesses in the building.

(2) 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 policies approved by the board.

(3) 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.

(4) All drug shipments must be delivered unopened to

(a) the pharmacy, or

(b) an area of the premises other than the pharmacy if the storage of the drug shipment is temporary, safe and secure.

(5) Non-usable and expired drugs must be stored in the pharmacy in an area separate from other pharmacy stock or drug products until final disposal.

(6) 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,* section 5(2) of the *Hospital Pharmacy Standards of Practice,* or section 5 of the *Dispensing Drugs for the Purpose of Medical Assistance in Dying Standards, Limits and Conditions.*

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 establish and maintain written quality management policies and procedures that

(a) ensure pharmacy staff, equipment, and facilities comply with all legislation, bylaws and policies applicable to the operation of a community pharmacy,

(b) include a process to monitor compliance with the quality management policies and procedures, and

(c) include 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 policies and procedures 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 that is clean and organized,

(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.

Community Pharmacy and Telepharmacy Security

26 (1) A community pharmacy or telepharmacy must:

(a) keep Schedule IA drugs in a locked metal safe inside the dispensary 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 premises in which the pharmacy is located are accessible to non-registrants, the pharmacy must be secured as follows:

(a) if the premises in which the pharmacy is located are closed and accessible to non-registrant staff:

(i) the dispensary area must be secured by a monitored alarm; and

(ii) subject to subsection (2.1), Schedule I and II drugs, controlled drug substances and personal health information, are secured by physical barriers; or

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

(i) the dispensary area must be secured by a monitored alarm;

(ii) subject to subsection (2.1), Schedule I, and II drugs, controlled drug substances and personal health information, are secured by physical barriers; and

(iii) Schedule III drugs are inaccessible to anyone other than full pharmacists, temporary pharmacists and pharmacy technicians.

(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 sections 26(2)(a)(ii) and (b)(ii) 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 or 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).

Permitted Activities of a Community Pharmacy without a Full Pharmacist Present

27 (1) Except as provided in subsection (2), a community pharmacy must not operate

unless a full pharmacist is present.

(2) A community pharmacy may carry on the activities set out in subsection (3) without a full pharmacist present only if:

(a) the registrar is notified of the hours during which a full pharmacist is not present;

(b) the pharmacy is secured in accordance with section 26(2); and

(c) the hours when a full pharmacist is on duty are posted.

(3) Subject to subsection (2) if a full pharmacist is not present, only the following activities may be carried out:

(a) pharmacy technicians may access the dispensary to perform activities outlined in section 4 of the *Community Pharmacy Standards of Practice*, that do not require pharmacist supervision, except if any such activity involves patient interaction; and

(b) receive drug shipments under section 20(4).

(3) Nothing contained in this section relieves a pharmacy manager of their responsibilities under section 18(2)(a).

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 prescriptions 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 establish and maintain written quality management policies and procedures that

(a) ensure pharmacy staff, equipment, and facilities comply with all legislation, bylaws and policies applicable to the operation of a hospital pharmacy,

(b) include a process to monitor compliance with the quality management policies and procedures,

(c) include a process for reporting, documenting and following up on known, alleged and suspected errors, incidents and discrepancies,

(d) document periodic audits of the drug distribution process,

(e) include a process to review patient-oriented recommendations,

(f) include a process that reviews a full pharmacist's documentation notes in the hospital's medical records,

(g) include a process to evaluate drug use, and

(h) regularly update 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 – Telepharmacies

Telepharmacy Operation

31 (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) In accordance with sections 18(2)(c) and (d), a telepharmacy must have policies and procedures on site that outline 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:

"patient record" means the patient record described in section 11(2) of the *Community Pharmacy Standards of Practice* and in the *British Columbia Professional and Software Conformance Standards, Electronic Health Information Exchange* as the "patient record (pharmacy)".

"**PharmaNet**" means "PharmaNet" as defined in section 1 of the *Information Management Regulation*, B.C. Reg. 74/2015;

Operation of PharmaNet

34 A pharmacy must connect to PharmaNet.

Data Collection, Transmission of and Access to PharmaNet Data

35 (1) A registrant must enter the prescription information and record it in PharmaNet at the time of dispensing and keep the patient record current.

(2) A registrant may collect and record patient information in PharmaNet, or access, use and disclose a patient's PharmaNet record only for the purposes of:

(a) dispensing a drug;

(b) providing patient consultation;

(c) evaluating a patient's drug usage;

(d) claims adjudication and payment by an insurer; or

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

(3) A registrant must revise information in PharmaNet 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 120 days of the original entry in PharmaNet.

(4) A registrant must reverse information in PharmaNet, 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.

(5) If a registrant is unable to comply with the deadlines in subsection (3) or (4), he or she must provide the information required to make the correction to the Ministry of Health as soon as possible thereafter.

PART VII – Confidentiality

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 that requires accessing, using or disclosing of patient personal health information.

PART VIII – 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.

Health Professions Act – BYLAWS

SCHEDULE F

PART 1 - Community Pharmacy Standards of Practice

Table of Contents

Application

1. This Part applies to all registrants providing pharmacy services in a community pharmacy.

Definitions

2. In this Part:

"community pharmacy" has the same meaning as in section 1 of the bylaws of the college under the *Pharmacy Operations and Drug Scheduling Act*;

"drug therapy problem" means a potential or actual adverse consequence of drug therapy that interferes with achieving the goals of the drug therapy;

"final check" means ensuring that:

(a) the prescription product and the prescription product label match the prescription information and the information on the manufacturer's label with respect to:

(i) drug,

(ii) dosage form,

(iii) strength,

(iv) quantity, and

(v) drug identification number;

(b) the prescription product label matches the prescription information with respect to the matters set out in section 6(2)(a) to (g);

(c) the drug has not expired and will not expire within the duration of use; and

(d) a pharmacist has completed a clinical assessment of the prescription after reviewing the patient profile.

"**incentive**" means money, gifts, discounts, rebates, refunds, customer loyalty schemes, coupons, goods or rewards;

"patient representative" means a person who is authorized to act on a patient's behalf;

"personal health number" means a unique numerical lifetime identifier used in the specific identification of an individual patient who has any interaction with the BC health system;

"prescription copy" means a copy of a prescription given to a patient by a registrant for information purposes only;

"prescription transfer" means the transfer via direct communication from a registrant to another registrant of all remaining refill authorizations for a particular prescription to a requesting community pharmacy;

"refill" means verbal or written approval from a practitioner authorizing a registrant to dispense additional quantities of drug(s) pursuant to a prescription;

"renewal" means authorization by a full pharmacist to dispense additional quantities of drug(s) pursuant to a previously dispensed prescription, in accordance with section 25.92 of the *Act*;

"*Residential Care Facilities and Homes Standards of Practice*" means the standards, limits and conditions for practice established in Part 3 of this Schedule.

Patient Choice

3. Registrants, owners and directors must not enter into agreements with patients, patient's representatives, practitioners, corporations, partnerships, or any other person or entity, that limit a patient's choice of pharmacy, except as required or permitted under the bylaws.

Community Pharmacy Technicians

4. (1) Pharmacy technicians in a community pharmacy may prepare, process and compound prescriptions, including

(a) receiving and transcribing verbal prescriptions from practitioners,

(b) ensuring that a prescription is complete and authentic,

(c) transferring prescriptions to and receiving prescriptions from other pharmacies,

(d) ensuring the accuracy of a prepared prescription,

(e) performing the final check of a prepared prescription, and

(f) ensuring the accuracy of drug and personal health information in the PharmaNet patient record.

(2) Despite subsection (1), a pharmacy technician in a community pharmacy may dispense a drug but must not

(a) perform the task of ensuring the pharmaceutical and therapeutic suitability of a drug for its intended use, or

(b) do anything described in

(i) sections 6(5), 6(10), 10(2), 11(3), 11(4), 12, 13(2), 13(3) or 13(4) of this Part, or

(ii) Part 4 of this Schedule

(c) dispense a drug pursuant to HPA Bylaws Schedule F, Part 5

(3) A pharmacy technician must identify his or her registrant class in any interaction with a patient or a practitioner.

Pharmacy Assistants

5. A registrant may delegate technical functions relating to the operation of the community pharmacy to a pharmacy assistant if the registrant directly supervises the pharmacy assistant and implements procedures, checks and controls to ensure the accurate and safe delivery of community pharmacy services.

Prescription

6. (1) A registrant must ensure that a prescription is authentic.

(2) A prescription must include the following information:

(a) the date of the prescription;

(b) the name of the patient;

(c) the name of the drug or ingredients and strength if applicable;

(d) the quantity of the drug;

(e) the dosage instructions including the frequency, interval or maximum daily dose;

(f) refill authorization if applicable, including number of refills and interval between refills;

(g) in the case of a written prescription, the name and signature of the practitioner;

(h) in the case of a written record of a verbal prescription,

i. the name of the practitioner and the identification number from the practitioner's regulatory college; and

ii. the name, college identification number and signature or initial of the registrant who received the verbal prescription.

(3) For the purpose of subsection (4), "prescription" includes a new prescription, a refill, a renewal or a balance owing.

(4) 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;

(g) written confirmation of the registrant who

(i) verified the patient identification

(ii) verified the patient allergy information,

(iii) reviewed the personal health information stored in the PharmaNet database in accordance with section 11.4;

(iv) performed the consultation,

(v) performed the final check including when dispensing a balance owing, and

(vi) identified and addressed a drug therapy problem, if any.

(5) A full pharmacist must

(a) review prescriptions for completeness and appropriateness with respect to the drug, dosage, route and frequency of administration,

(b) review patient personal health information for drug therapy problems, therapeutic duplications and any other potential problems,

(c) consult with patients concerning the patient's drug history and other personal health information,

(d) consult with practitioners with respect to a patient's drug therapy unless s.25.92(2) of the *Act* applies, and

(e) take appropriate action respecting a drug therapy problem.

(6) A registrant may receive a verbal prescription directly from a practitioner or from a practitioner's recorded voice message.

(7) A registrant must make a written record of a verbal prescription containing the applicable information in section 6(2).

(8) A registrant must not dispense a prescription issued for more than one patient.

(9) For refill authorizations, a registrant

(a) may accept a refill authorization for Schedule I drugs from a practitioner's agent if confident the agent consulted the practitioner and accurately conveyed the practitioner's direction, and

(b) must

(i) cancel any unused refill authorizations remaining on any previous prescription if a patient presents a new prescription for a previously dispensed drug,

(ii) advise the other pharmacy of the new prescription if unused refills are at another pharmacy, and

(iii) create a new prescription number.

(10) If a full pharmacist authorizes a prescription renewal, he or she must

(a) create a written record,

(b) assign a new prescription number, and

(c) use his or her college identification number in the practitioner field on PharmaNet.

Transmission by Facsimile

7. (1) Prescription authorizations may be received by facsimile from a practitioner to a pharmacy, if

(a) the prescription is sent only to a pharmacy of the patient's choice,

(b) the facsimile equipment is located within a secure area to protect the confidentiality of the prescription information, and

(c) in addition to the requirements of section 6(2), the prescription includes

(i) the practitioner's telephone number, facsimile number and unique identifier if applicable,

(ii) the time and date of transmission, and

(iii) the name and fax number of the pharmacy intended to receive the transmission.

(2) Prescription refill authorization requests may be transmitted by facsimile from a pharmacy to a practitioner, if the pharmacy submits refill requests on a form that includes space for

(a) the information set out in section 6(2),

(b) the name, address and 10 digit telephone number of the pharmacy, and

(c) the practitioner's name, date and time of transmission from the practitioner to the pharmacy.

(3) A registrant must not dispense a prescription authorization received by facsimile transmission for a drug referred to on the Controlled Prescription Drug List, except in a public health emergency declared by the provincial health officer. In a public health emergency, the pharmacy must receive

(a) a completed copy of the Controlled Prescription Program form transmitted by facsimile prior to dispensing the medication; and

(b) the original form by mail as soon as reasonably possible.

(4) Prescription transfers may be completed by facsimile transmission if

(a) the transferring registrant includes his or her name and the address of the pharmacy with the information required in section 8(4), and

(b) the name of the registrant receiving the transfer is known and recorded on the document to be faxed.

Prescription Copy and Transfer

8. (1) If requested to do so, a registrant must provide a copy of the prescription to the patient or the patient's representative, or to another registrant.

(2) A prescription copy must contain

(a) the name and address of the patient,

(b) the name of the practitioner,

(c) the name, strength, quantity and directions for use of the drug,

(d) the dates of the first and last dispensing of the prescription,

(e) the name and address of the community pharmacy,

(f) the number of authorized refills remaining,

(g) the signature of the registrant supplying it, and

(h) an indication that it is a copy.

(3) Upon request, a registrant must transfer to a pharmacy licenced in Canada a prescription for a drug if

(a) the drug does not contain a controlled drug substance, and

(b) the transfer occurs between a registrant and another registrant or an equivalent of a registrant in another Canadian jurisdiction.

(3.1) Despite section 3(a), a registrant may transfer a prescription for a controlled drug substance if the transfer is permitted under a section 56 exemption to the Controlled Drugs and Substances Act.

(4) A registrant who transfers a prescription to another registrant under subsection (3) must

(a) enter on the patient record

(i) the date of the transfer,

(ii) the registrant's identification,

(iii) identification of the community pharmacy to which the prescription was transferred, and

(iv) identification of the person to whom the prescription was transferred, and

(b) transfer all prescription information listed in subsection (2) (a) to (f).

(5) A registrant must make prescriptions available for review and copying by authorized inspectors of Health Canada.

Prescription Label

9. (1) All drugs dispensed pursuant to a prescription or a full pharmacist-initiated adaptation must be labeled.

(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.

(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.

(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.

(5) For a compounded preparation, the label must include all active ingredients.

(6) If a drug container is too small to accommodate a full label in accordance with subsection (2),

(a) a trimmed prescription label must be attached to the small container,

(b) the label must include

(i) the prescription number,

(ii) the dispensing date,

(iii) the full name of the patient, and

(iv) the name of the drug, and

(c) the complete prescription label must be attached to a larger container and the patient must be advised to keep the small container inside the large container.

(7) All required label information must be in English, but may contain directions for use in the patient's language following the English directions.

Preparation of Prescription Product

9.1 (1) A registrant who prepares a prescription product must ensure that:

(a) the prescription product label matches the prescription information and the information on the manufacturer's label with respect to:

(i) drug,
(ii) dosage form,
(iii) strength,
(iv) quantity,
(v) drug identification number;

(b) the prescription product label matches the prescription information with respect to the matters set out in section 6(2)(a) to (g);

(c) the drug is not expired and will not expire within the duration of use; and

(d) his or her identity is documented in writing.

(2) A pharmacy manager must ensure that the record in paragraph (1)(d) is readily available and is retained for at least three years from the date on which the prescription product was last dispensed.

Compounding

9.2 (1) A registrant must comply with the National Association of Pharmacy Regulatory Authorities standards as approved by the board from time to time.

(2) A registrant must not allow a non registrant to prepare sterile compounds.

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Dispensing

10. (1) A registrant may adjust the quantity of drug to be dispensed if

(a) a patient requests a smaller amount,

(b) a manufacturer's unit-of-use standard of package size does not match the prescribed quantity,

(c) the quantity prescribed exceeds the amount covered by the patient's drug plan, or

(d) a trial prescription quantity is authorized by the patient.

(2) A full pharmacist may adjust the quantity of drug to be dispensed, if

(a) he or she consults with a practitioner and documents the result of the consultation, and

(b) if

(i) a poor compliance history is evident on the patient record,

(ii) drug misuse is suspected, or

(iii) the safety of the patient is in question due to the potential for overdose.

(3) If a registrant doubts the authenticity of a prescription, the registrant may refuse to dispense the drug.

(4) All drugs must be dispensed in a container that is certified as child-resistant unless

(a) the practitioner, the patient or the patient's representative directs otherwise,

(b) in the registrant's judgment, it is not advisable to use a child-resistant container,

(c) a child-resistant package is not suitable because of the physical form of the drug or the manufacturer's packaging is designed to improve patient compliance, or

(d) child-resistant packaging is unavailable, or

(e) the drugs are prescribed for medical assistance in dying.

(5) A registrant must not dispense a prescription more than one year from the prescribing date, except for oral contraceptives which may be dispensed for up to two years.

(6) Before dispensing a prescription product, a registrant must perform a final check and record his or her identity in writing.

(7) A pharmacy manager must ensure the record in paragraph (6) is readily available and retained for at least three years after the last date on which that prescription product was last dispensed.

Patient Record

11. (1) A patient record must be established and maintained for each patient for whom a Schedule I drug is dispensed.

(2) For purposes of subsection (1), the patient record must include

(a) the patient's full name,

(b) the patient's personal health number,

(c) the patient's address,

(d) the patient's telephone number if available,

(e) the patient's date of birth,

(f) the patient's gender,

(g) the patient's clinical condition, allergies, adverse drug reactions and intolerances if available including the source and date the information was collected,

(h) the date the drug is dispensed,

(i) the prescription number,

(j) the generic name, strength and dosage form of the drug,

(k) the drug identification number,

(l) the quantity of drug dispensed,

(m) the intended duration of therapy, specified in days,

(n) the date and reason for discontinuation of therapy,

(o) the directions to the patient,

(p) the identification of the prescribing practitioner,

(q) special instructions from the practitioner to the registrant, if appropriate,

(r) past and present prescribed drug therapy including the drug name, strength, dosage, frequency, duration and effectiveness of therapy,

(s) the identification of any drug therapy problem and the description of any action taken,

(t) the description of compliance with the prescribed drug regimen, and

(u) Schedule II and III drug use if appropriate.

(3) If a full pharmacist obtains a drug history from a patient, he or she must request and if appropriate record the following information on the patient record:

(a) medical conditions and physical limitations,

(b) past and current prescribed drug therapy including the drug name, strength, dosage, frequency, duration and effectiveness of therapy,

(c) compliance with the prescribed drug regimen,

(d) Schedule II and III drug use.

(4) A full pharmacist must review the patient's personal health information stored on the PharmaNet database before dispensing a drug and take appropriate action if necessary with respect to any concern regarding the appropriateness of the drug or any drug therapy problem.

Pharmacist/Patient Consultation

12. (1) Subject to subsection (2), a full pharmacist must consult with the patient or patient's representative at the time of dispensing a new or refill prescription in person or, where not practical to do so, by telephone.

(2) Where a patient declines the consultation, the full pharmacist must document that the consultation was offered and declined.

(3) The full pharmacist must conduct the consultation in a manner that respects the patient's right to privacy.

(4) The pharmacist/patient consultation for a new prescription must include:

(a) confirmation of the identity of the patient,

(b) name and strength of drug,

(c) purpose of the drug,

(d) directions for use of the drug including the frequency, duration and route of therapy,

(e) potential drug therapy problems, including any avoidance measures, and action recommended if they occur,

(f) storage requirements,

(g) prescription refill information,

(h) information regarding

(i) how to monitor the response to therapy,

(ii) expected therapeutic outcomes,

(iii) action to be taken in the event of a missed dose, and

(iv) when to seek medical attention.

(i) issues the pharmacist considers relevant to the specific drug or patient.

(5) The pharmacist/patient consultation for a refill prescription must include:

(a) confirmation of the identity of the patient,

(b) name and strength of drug,

(c) purpose of the drug,

(d) directions for use of the drug including frequency and duration,

(e) whether the patient has experienced a drug therapy problem.

(6) If a drug therapy problem is identified during patient consultation for a new or refill prescription, the full pharmacist must take appropriate action to resolve the problem.

(7) If an adverse drug reaction as defined by Health Canada is identified, the full pharmacist must notify the patient's practitioner, make an appropriate entry on

the PharmaNet record and report the reaction to the appropriate department of Health Canada.

Schedule II and III Drugs

13. (1) A registrant must not attribute a new prescription or refill for a Schedule II or Schedule III drug to a practitioner without the authorization of the practitioner.

(2) A pharmacist must offer to consult with the patient or the patient's representative regarding the selection and use of a Schedule II drug at the time of purchase.

(3) The pharmacist/patient consultation for a Schedule II drug must include potential drug therapy problems, including any avoidance measures, and action recommended if they occur.

(4) A pharmacist must be available for consultation with a patient or patient's representative respecting the selection and use of a Schedule III drug.

Sole Pharmacy Services Provider

14. The manager of a pharmacy may enter into an agreement with another person to be the sole provider of pharmacy services in a premise or part of a premise, if

(a) pharmacy services are provided in a manner that is consistent with the *Residential Care Facilities and Homes Standards of Practice,*

(b) patient therapeutic outcomes are monitored to enhance patient safety, and

(c) appropriate provision has been made for safe and effective distribution, administration and control of drugs.

Prohibition on the Provision of Incentives

15. (1) A registrant must not provide or distribute, or be a party to the provision or distribution of, an incentive 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.

(2) Subsection (1) does not prevent a registrant from

(a) providing free or discounted parking to patients or patient's representatives,

(b) providing free or discounted delivery services to patients or patient's representatives, or

(c) accepting payment for a drug or device by a credit or debit card that is linked to an incentive.

(3) Subsection (1) does not apply in respect of a Schedule III drug or an unscheduled drug, unless the drug has been prescribed by a practitioner.

Health Professions Act – **BYLAWS**

SCHEDULE F

PART 2 – Hospital Pharmacy Standards of Practice

Table of Contents

Application

1. This Part applies to all registrants providing pharmacy services in a hospital pharmacy or a hospital pharmacy satellite.

Definitions

2. In this Part:

"bulk/batch drug repacking" means the repackaging in a single process of multiple units, not for immediate use;

"bulk compounding" means the preparation of products which are not commercially available in anticipation of a practitioner's order;

"*Community Pharmacy Standards of Practice*" means the standards, limits and conditions for practice established in Part 1 of this Schedule;

"final check" means ensuring that:

(a) the prescription product and the prescription product label match the product information with respect to:

(i) drug,

(ii) dosage form,

(iii) strength, and

(iv) quantity;

(b) the drug is not expired and will not expire within the duration of use; and

(c) a pharmacist has completed a clinical assessment of the prescription after reviewing the patient profile.

"hazardous drugs" means pharmaceutical preparations in which the concentration, toxicity, environmental persistence, degradation characteristics, flammability, corrosiveness, or reactivity represents a risk to the health of humans or other living organisms;

"hospital pharmacy" has the same meaning as in section 1 of the bylaws of the college under the *Pharmacy Operations and Drug Scheduling Act*;

"hospital pharmacy satellite" has the same meaning as in section 1 of the bylaws of the college under the *Pharmacy Operations and Drug Scheduling Act*;

"individual patient prescription system" means a form of drug distribution in which drugs are dispensed in patient-specific labelled drug containers;

"master formula" means a set of instructions outlining in detail the materials, equipment, and procedures required to produce a specific quantity of a product;

"multiple pouch packaging" means a pouch containing drugs to be administered at a particular time;

"unit dose distribution" means a form of drug distribution in which orders for each patient are dispensed individually and packaged in unit-of-use packages containing one dose;

"ward stock" means drugs that are stocked in a patient care area and are not labelled for a particular patient.

Drug Distribution

3. (1) The pharmacy's manager must establish a drug distribution system that

(a) provides drugs in identified dosage units ready for administration whenever possible and practical,

(b) protects drugs from contamination,

(c) provides a method of recording drugs at the time of administration, and

(d) eliminates or reduces the need to maintain ward stock.

(2) A unit dose, monitored dose, multiple pouch packaging or individual patient prescription drug distribution system must be used for dispensing drugs.

(3) Sterile compounds ~~products~~ must be prepared ~~and distributed~~ in an environment that is in accordance with

~~(a) the Canadian Society of Hospital Pharmacists' Guidelines for Preparation of Sterile Products in Pharmacies,~~

~~(b) the USP Pharmaceutical Compounding – Sterile Products Guidelines, and~~

~~(b)~~ the National Association of Pharmacy Regulatory Authorities~~,~~ standards as approved by the board from time to time

~~(c) such other published standards approved by the board from time to time.~~

(4) A registrant must not allow a non registrant to prepare sterile compounds.

~~(4)~~ (5) Hazardous drugs must be handled and prepared in accordance with the Requirements for the Safe Handling of Antineoplastic Agents in Health Care Facilities published by the Workers Compensation Board of British Columbia and such other published standards approved by the board from time to time.

Preparation of Prescription Product

3.1 (1) A registrant who prepares a prescription product must ensure that:

(a) the prescription product label matches the product information with respect to:

(i) drug,
(ii) dosage form,
(iii) strength,

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(iv) quantity; and

(b) the drug is not expired and will not expire within the duration of use.

Patient Identification

3.2 Unless dispensing to staff, outpatients or the general public under section 4(5), all registrants must use at least two person-specific identifiers to confirm the identity of a patient before providing any pharmacy service to the patient.

Drug Label

4. (1) Drug container labels must include

(a) the generic name of the drug, strength and dosage form, and

(b) hospital approved abbreviations and symbols.

(2) Only hospital pharmacy staff may alter a drug container label.

(3) Inpatient prescription labels must include

(a) a unique patient name and identifier,

(b) the generic name of the drug, strength and dosage form,

(c) parenteral vehicle if applicable, and

(d) hospital approved abbreviations and symbols.

(4) The following information must be included on the inpatient prescription label if not available on the medication administration record:

(a) the frequency of administration;

(b) the route of administration or dosage form;

(c) auxiliary or cautionary statements if applicable;

(d) the date dispensed.

(5) All drugs dispensed to staff, outpatients or the general public from a hospital pharmacy or hospital pharmacy satellite must be labeled and dispensed according to the *Community Pharmacy Standards of Practice.*

(6) Prior to releasing a prescription product, a registrant must perform a final check of the prescription product and record his or her identity in writing as required by section 17.

Returned Drugs

5. (1) Unused dispensed drugs must be returned to the hospital pharmacy.

(2) Previously dispensed drugs must not be re-dispensed unless

(a) they are returned to the hospital pharmacy in a sealed dosage unit or container as originally dispensed,

(b) the labeling is intact and includes a legible drug lot number and expiry date, and

(c) the integrity of the drug can be verified.

Drug Transfer

6. A registrant who supplies a Schedule I drug to another registrant or practitioner must comply with section 8(3) and (4) of the *Community Pharmacy Standards of Practice.*

Inpatient Leave of Absence and Emergency Take-Home Drugs

7. (1) A system must be established to provide drugs to an emergency department short stay patient requiring take-home drugs, who is unable to obtain them from a community pharmacy within a reasonable time frame.

(2) All take-home drugs issued from the emergency department must be documented in the patient's health record.

(3) All inpatient leave of absence drugs must be documented in the patient's health record.

(4) Labels for inpatient pass and emergency department take-home drugs must include

(a) the hospital's name,

(b) the patient's name,

(c) the practitioner's name,

(d) the drug name, strength and directions for use,

(e) identification of the person preparing the drug, and

(f) the date the drug is issued.

(5) Drugs must be dispensed in a container that is certified as child-resistant unless

(a) the practitioner, the patient or the patient's representative directs otherwise,

(b) in the registrant's judgment it is not advisable to use a child-resistant container,

(c) a child-resistant package is not suitable because of the physical form of the drug or the manufacturer's packaging is designed to improve patient compliance, or

(d) child-resistant packaging is unavailable.

Investigational and Special Access Program Drugs

8. Registrants must comply with the policies and directives of Health Canada with respect to storage and dispensing of Special Access Program or investigational drugs.

Bulk/Batch Drug Repackaging and Compounding

9. (1) A registrant must supervise all bulk/batch drug repackaging and bulk drug compounding.

(2) Bulk/batch drug repackaging records must be kept for three years after the repackaging date.

(3) A master formula record must be kept for each bulk compounded drug product.

(4) A separate production record must be kept for each compounded bulk product and must include

(a) the date of compounding,

(b) the lot or batch number assigned to the compounded product,

(c) the manufacturer's name and lot number for each raw material used,

(d) the identification of each registrant and pharmacy assistant involved in each step of the compounding process,

(e) the process including weights and measures performed,

(f) the results of all quality control testing,

(g) a statement of the final yield,

(h) signatures for final verification and authorization for release,

(i) a sample label, and

(j) the expiry date of the product.

(5) A production record must be kept for a period of three years after the expiry date of the compounded batch.

(6) A label must be affixed to the finished bulk/batch repackaged or bulk compounded drug and must contain

(a) generic name(s) of the drug,

(b) strength and quantity of active ingredients,

(c) dosage form,

(d) total amount of final product,

(e) expiry date of the compound,

(f) manufacturer identification and lot number or hospital pharmacy control number,

(g) storage conditions, if applicable,

(h) auxiliary labels, if applicable, and

(i) the name of the hospital.

Hospital Pharmacy Technicians

10. (1) Pharmacy technicians in a hospital pharmacy or hospital pharmacy satellite may prepare, process and compound prescriptions, including

(a) receiving and transcribing verbal prescriptions from practitioners,

(b) ensuring that a prescription is complete and authentic,

(c) transferring prescriptions to and receiving prescriptions from other pharmacies,

(d) ensuring the accuracy of a dispensed prescription,

(e) performing the final check of a dispensed prescription, and

(f) ensuring the accuracy of drug and personal health information in the PharmaNet patient record.

(2) Despite subsection (1), a pharmacy technician in a hospital pharmacy or hospital pharmacy satellite may dispense a drug but must not

(a) perform the task of ensuring the pharmaceutical and therapeutic suitability of a drug for its intended use,

(b) do anything described in

(i) sections 13, 15 or 16 of this Part

(ii) Part 4 of this Schedule, or

(c) dispense a drug pursuant to HPA Bylaws Schedule F, Part 5.

(3) A pharmacy technician must identify his or her registrant class in any interaction with a patient or a practitioner.

Hospital Pharmacy Assistants

11. Specific technical functions may be performed by a pharmacy assistant in a hospital pharmacy or hospital pharmacy satellite after the pharmacy's manager has established written procedures for performing the functions.

Patient Record

12. (1) The registrant must ensure the preparation and maintenance of patient records for each patient for whom drugs are prepared are complete, accurate and current, except patients admitted for less than 24 hours to

(a) surgical day care,

(b) ambulatory care,

(c) emergency short-stay, or

(d) other short-stay diagnostic or treatment units.

(2) The patient record must include

(a) the patient's full name and admission date,

(b) the hospital number and location,

(c) the patient's date of birth and gender,

(d) the attending practitioner's name,

(e) the patient's weight and height if applicable to therapy,

(f) the patient's allergies, adverse drug reactions, intolerances, and diagnoses,

(g) a chronological list of drugs which have been prescribed for the patient since admission to hospital, or, if admission is prolonged, for a minimum period of two years, and

(h) a list of all current drug orders including

(i) the drug name,

(ii) the drug strength,

(iii) the dosage,

(iv) the route,

(v) the dosage form,

(vi) intravenous diluent if applicable,

(vii) the directions for use,

(viii) administration time or frequency,

(ix) the attending practitioner,

(x) the quantity,

(xi) the start and stop date, or length of therapy, and

(xii) the date drug was dispensed, refilled or discontinued.

Patient Oriented Pharmacy Practice

13. (1) During pharmacy hours the full pharmacist must review the drug order before the drug is dispensed.

(2) The full pharmacist must check the drug order for

(a) the patient's name, hospital number and location,

(b) the signature of the practitioner,

(c) the name of the drug,

(d) the dosage form and strength,

(e) the route and frequency of administration,

(f) the duration of treatment if limited,

(g) directions for use,

(h) the date and time the order was written, and,

(i) in the case of verbal and/or telephone orders, the name and signature of the person who received the order.

(3) The full pharmacist must review the pharmacy patient record before dispensing the patient's drug and at appropriate intervals thereafter to assess

(a) appropriateness of therapy,

(b) drug interactions,

(c) allergies, adverse drug reactions and intolerances,

(d) therapeutic duplication,

(e) correct dosage, route, frequency and duration of administration and dosage form,

(f) contraindicated drugs,

(g) intravenous administration problems including potential incompatibilities, drug stability, dilution volume and rate of administration, and

(h) any other drug related problems.

(4) The full pharmacist must notify the patient's nursing staff immediately if a problem with a prescription for a ward stock item is discovered.

(5) The full pharmacist must monitor drug therapy to detect, resolve and prevent drug-related problems at a frequency appropriate for the medical condition being treated.

(6) Monitoring includes but is not limited to

(a) a review of the patient record and/or health record,

(b) discussion with the patient's practitioner and/or other appropriate individual, and

(c) use of physical assessment skills when trained to do so.

(7) The full pharmacist must provide drug information, including patient-specific information to patients and health care personnel.

(8) A full pharmacist, or a limited or student pharmacist under the direct supervision of a full pharmacist, must provide drug consultation to an outpatient or the outpatient's representative, or to an inpatient on request, and must

(a) confirm the identity of the patient,

(b) identify the name and strength of drug,

(c) identify the purpose of the drug,

(d) provide directions for use of the drug including the frequency, duration and route of therapy,

(e) discuss common adverse effects, drug and food interactions and therapeutic contraindications that may be encountered, including their avoidance, and the actions required if they occur,

(f) discuss storage requirements,

(g) provide prescription refill information,

(h) provide information regarding

(i) how to monitor the response to therapy,

(ii) expected therapeutic outcomes,

(iii) action to be taken in the event of a missed dose, and

(iv) when to seek medical attention, and

(i) provide other information unique to the specific drug or patient.

(9) If a full pharmacist requests a history from a patient or a patient's representative, the following information must be obtained:

(a) medical conditions and physical limitations;

(b) allergies, adverse drug reactions, and idiosyncratic responses;

(c) past and current prescribed drug therapy including the drug name, strength, dosage, frequency and duration and effectiveness of therapy;

(d) compliance with the prescribed drug regimen;

(e) Schedule II and III and unscheduled drug use.

(10) A full pharmacist must provide information about the assessment, management and prevention of drug poisoning within the hospital.

Medication Administration

14. (1) The registrant must collaborate with nursing and medical staff to develop written policies and procedures for the safe administration of drugs.

(2) A medication administration record of all prescribed drugs for each patient must be produced from the pharmacy-maintained patient record.

(3) The medication administration record must include

(a) the patient's full name and identification number,

(b) the patient's location in the hospital,

(c) the presence or absence of known allergies, adverse drug reactions, and intolerances,

(d) the date or period for which the drug administration record is to be used,

(e) the name, dosage and form of all drugs currently ordered,

(f) complete directions for use for all drugs,

(g) stop or expiry dates for drug orders for which there is an automatic stop policy (if not reported by another means),

(h) predetermined, standard medication administration times for regularly scheduled drugs, and

(i) changes to drug orders.

Residential Care

15. A full pharmacist providing pharmacy care to residential care patients residing in a facility that is not licensed under the *Community Care and Assisted Living Act* must

(a) use a monitored dosage, multiple pouch packaging or unit dosage system except where the form of the drug does not permit such packaging,

(b) restrict ward stock to drugs that do not have a high potential for toxicity or require a complex dosage titration, and are commonly prescribed on a "when needed" basis,

(c) maintain a current patient record for each patient,

(d) provide administration records of all current drugs for each patient from the pharmacy maintained patient record within seventy-two hours of admission and at least monthly thereafter,

(e) review each patient's drug regimen at least every six months preferably in the setting of multidisciplinary rounds, and

(f) maintain a written record of drug reviews in the patient's permanent health record, including the date of each review, identified concerns and recommendations.

Documentation

16. (1) The full pharmacist must document directly in the patient record all activities and information pertaining to the drug therapy of the patient.

(2) For the purposes of subsection (1), the documentation must include but is not limited to

(a) actual or potential drug-related problems that warrant monitoring,

(b) recommendations for changes in drug selection, dosage, duration of therapy, and route of administration,

(c) recommendations for monitoring the response to drug therapy,

(d) notations of consultations provided to other health care professionals about the patient's drug therapy selection and management,

(e) notations of drug-related patient education and/or consultation provided,

(f) clarification of drug orders and practitioner's telephone orders received directly by the registrant,

(g) allergies, adverse drug reactions and intolerances, and

(h) the full pharmacist's signature.

17. Documentation of the identity of any registrant who prepared a prescription product or performed a final check must be in writing, readily available and retained for at least three years after the date on which the prescription product was last dispensed.

Health Professions Act – **BYLAWS**

SCHEDULE F

PART 3 – Residential Care Facilities and Homes Standards of Practice

Table of Contents

Application

1. This Part applies to registrants providing pharmacy services in or to facilities and homes.

Definitions

2. In this Part:

"administration" means the provision of a drug to a resident as prescribed, or for drugs listed in Schedule II or III of the Drug Schedules Regulation, B.C. Reg. 9/98, or unscheduled drugs initiated by a registered nurse;

"audit" means a periodic review of the pharmacy services provided in accordance with this Part;

"*Community Pharmacy Standards of Practice*" means the standards, limits and conditions for practice established in Part 1 of this Schedule;

"facility" means a community care facility licensed under the *Community Care and Assisted Living Act* to provide care to 7 or more persons;

"final check" means ensuring that:

(a) the prescription product and the prescription product label match the prescription information and the information on the manufacturer's label with respect to:

(i) drug,

(ii) dosage form,

(iii) strength,

(iv) quantity and

(v) drug identification number;

(b) the prescription product label matches the prescription information with respect to the matters set out in section 6(8)(a) to (g);

(c) the drug is not expired and will not expire within the duration of use; and

(d) a pharmacist has completed a clinical assessment of the prescription after reviewing the patient profile.

"home" means a community care facility licensed under the *Community Care and Assisted Living Act* to provide care to 3 to 6 persons;

"licensed practical nurse" means a registrant of the College of Licensed Practical Nurses of British Columbia;

"medication safety and advisory committee" means a committee appointed under section 8.2 of the Adult Care Regulations, B.C. Reg. 536/80;

"monitored dose system" means a system of drug distribution in which drugs are dispensed for an individual resident at scheduled times from packaging which protects a dose or doses from contamination until a designated medication time;

"natural product" has the same meaning as in the *Natural Health Products Regulations* under the *Food and Drug Act* (Canada) as amended from time to time;

"registered nurse" means a registrant of the College of Registered Nurses of British Columbia;

"registered psychiatric nurse" means a registrant of the College of Registered Psychiatric Nurses of British Columbia;

"resident" means a person who lives in and receives care in a facility or home;

"Schedule II and III drugs" mean drugs listed in Schedule II or III of the *Drug Schedules Regulation*.

Supervision of Pharmacy Services in a Facility or Home

3. (1) A registrant must not provide pharmacy services in or to a facility or home unless appointed to do so by the licensee of that facility or home.

(2) A registrant must not allow any person to interfere with the provision of pharmacy services in accordance with the *Act* or the *Pharmacy Operations and Drug Scheduling Act*.

(3) The full pharmacist appointed to provide services to the facility or home must do the following:

(a) visit and audit the medication room at the facility at least every 3 months,

(b) visit and audit the medication room or storage area at the home at least once annually,

(c) make a record of all audits and meetings of the medication safety and advisory committee held in accordance with this bylaw, which must be retained in the pharmacy for at least 3 years, and

(d) arrange a meeting of the medication safety and advisory committee at least once in every 6 month period for a facility and once a year for a home.

(4) The full pharmacist appointed to provide services to a facility or home must be a member of and advise the medication safety and advisory committee about the policies and procedures in place for the

(a) safe and effective distribution, administration and control of drugs,

(b) monitoring of therapeutic outcomes and reporting of adverse drug reactions in respect of residents,

(c) reporting of drug incidents and discrepancies, and

(d) training and orientation programs for staff members who store, handle, or administer drugs to residents.

(5) The policies and procedures referred to in subsection (4) must be included in a manual kept in the facility, home and pharmacy.

(6) Except where a person in care self-administers drugs in accordance with regulations under the *Community Care and Assisted Living Act,* the registrant must ensure that all drugs are stored in a separate and locked area that is not used for any other purpose.

(7) The registrant must ensure that a copy of this Part is available in the facility or home.

Quality Management

4. A pharmacy providing services to a facility or home must have a documented ongoing quality management program that

(a) monitors the pharmacy services provided, and

(b) includes a process for reporting and documenting drug incidents and discrepancies and their follow-up.

Pharmacy Technicians

5. (1) Pharmacy technicians providing pharmacy services to a facility or home may prepare, process and compound prescriptions, including

(a) receiving and transcribing verbal prescriptions from practitioners,

(b) ensuring that a prescription is complete and authentic,

(c) transferring prescriptions to and receiving prescriptions from other pharmacies,

(d) ensuring the accuracy of a dispensed prescription,

(e) performing the final check of a dispensed prescription, and

(f) ensuring the accuracy of drug and personal health information in the PharmaNet patient record.

(2) Despite subsection (1), a pharmacy technician providing pharmacy services to a facility or home may dispense a drug but must not

(a) perform the task of ensuring the pharmaceutical and therapeutic suitability of a drug for its intended use,

(b) do anything described in

(i) sections 3(3), 3(4), 13(4), 15 or 16 of this Part,

(ii) Part 4 of this Schedule, or

(c) dispense a drug pursuant to HPA Bylaws Schedule F, Part 5.

(3) A pharmacy technician must identify his or her registrant class in any interaction with a patient or a practitioner.

Prescription Authorizations

6. (1) A registrant may only dispense a drug to a resident upon receipt of a prescription.

(2) When a resident is readmitted following hospitalization, new prescriptions must be received for that resident before drugs may be dispensed.

(3) A prescription may be transmitted to the pharmacy servicing the facility or home verbally, electronically or in writing.

(4) If a prescription is transmitted to the pharmacy by facsimile, the registrant must comply with section 7 of the *Community Pharmacy Standards of Practice*.

(5) If a prescription is transmitted verbally, the registrant must make a written record of the verbal prescription containing the applicable information in section 6(8).

(6) If a prescription is transmitted electronically, the registrant must use the facsimile or make a written copy as the permanent record for dispensing, numbering, initialling and filing.

(7) A prescription, written and signed by a practitioner on a resident's record, may be electronically transmitted to the pharmacy and the registrant may dispense the drug.

(8) A prescription must include the following information:

(a) the date of the prescription;

(b) the name of the resident;

(c) the name of the drug or ingredients and strength where applicable;

(d) the quantity of the drug;

(e) the dosage instructions including the frequency, interval or maximum daily dose;

(f) refill authorization if applicable, including number of refills and interval between refills;

(g) in the case of a written prescription, the name and signature of the practitioner;

(h) in the case of a written record of a verbal prescription,

i. the name of the practitioner and the identification number from the practitioner's regulatory college; and

ii. the name, college identification number and signature or initial of the registrant who received the verbal prescription.

(9) A registrant may accept a new drug order that is transmitted verbally from a practitioner to a facility's registered nurse, registered psychiatric nurse or licensed practical nurse, if

(a) the drug does not contain a controlled drug substance,

(b) the registered nurse, registered psychiatric nurse or licensed practical nurse writes the verbal order on a practitioner's order form or electronic equivalent, and

(c) transfers the written order to the pharmacy.

Preparation of Prescription Product

6.1 (1) A registrant who prepares a prescription product must ensure that:

(a) the prescription product label matches the prescription information and the information on the manufacturer's label with respect to:

(i) drug,
(ii) dosage form,
(iii) strength,
(iv) quantity; and
(v) drug identification number;

(b) the prescription product label matches the prescription information with respect to the matters set out in section 6(8)(a) to (g);

(c) the drug is not expired and will not expire within the duration of use; and

(d) his or her identity is documented in writing.

(2) A pharmacy manager must ensure the record in paragraph (1)(d) is readily available and is retained for at least three years from the date on which the prescription product was last dispensed.

Patient Identification

6.2 All registrants must use at least two person-specific identifiers to confirm the identity of a resident before providing any pharmacy service to the resident.

Compounding

6.3 (1) A registrant must comply with the National Association of Pharmacy Regulatory Authorities standards as approved by the board from time to time.

(2) A registrant must not allow a non registrant to- prepare sterile compounds.

Dispensing

7. (1) All prescriptions dispensed to residents must be dispensed in a monitored dose system except where the form of the drug does not permit such packaging, and each package must contain not more than a 35 day supply of medication.

(2) Where directions for the use of a drug are changed by the practitioner, the registrant must, following receipt of the required confirmation, initiate and dispense a new prescription.

(3) Before dispensing a prescription product, a registrant must perform a final check and must record his or her identity in writing.

(4) A pharmacy manager must ensure a record in paragraph (3) is readily available and is retained for at least three years from the date on which the prescription product was last dispensed.

Contingency Drugs

8. (1) A registrant may establish a supply of contingency drugs to permit the commencement of therapy upon receipt of a prescription, until the drug supply arrives from the pharmacy.

(2) Contingency drugs must be prepared by the pharmacy and dispensed in a monitored dose system in accordance with section 7(1).

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(3) A list of the contingency drugs must be available in the facility, home and pharmacy.

(4) Records of use of contingency drugs must be kept in the facility or home and must include

(a) the date and time the drug was administered,

(b) the name, strength and quantity of the drug administered,

(c) the name of the resident for whom the drug was prescribed,

(d) the name or initials of the person who administered the drug, and

(e) the name of the practitioner who prescribed the drug.

Nurse Initiated Drugs

9. (1) A registrant may provide Schedule II or III drugs and unscheduled drugs for a resident upon the request of a registered nurse if the medication safety and advisory committee has approved protocols for doing so.

(2) A record of use of all medications must be on the resident's medication administration record.

Standing Orders

10. (1) Standing orders for Schedule II and III drugs and unscheduled drugs that are administered for common self-limiting conditions may be established by the medication safety and advisory committee.

(2) Standing order drugs must be authorized and signed for by a practitioner annually and a record of the signed authorization must be kept in the facility or home.

(3) A record of use of all medications must be on the resident's medication administration record.

Returned Drugs

11. (1) A registrant must provide for the return of all discontinued drugs at the time of the next scheduled delivery.

(2) Policies and procedures must be in place to ensure that upon the hospitalization of a resident, the resident's drugs are returned to the pharmacy.

(3) Previously dispensed drugs must not be re-dispensed unless

(a) they have been returned to the pharmacy in a single-drug, sealed dosage unit or container as originally dispensed,

(b) the labelling is intact and includes a legible drug lot number and expiry date, and

(c) the integrity of the product can be verified.

Drug Containers and Prescription Labels

12. (1) All drugs dispensed pursuant to a prescription must be labeled.

(2) The label for all prescriptions must include

(a) the name, address and 10-digit telephone number of the pharmacy,

(b) the prescription number and dispensing date,

(c) the full name of the resident,

(d) the name of the practitioner or registered nurse,

(e) the strength of the drug,

(f) the dosage instructions including the frequency, interval or maximum daily dose,

(g) the route of administration,

(h) medical indication for use for all “as required” prescription authorizations, and

(i) any other information required by good pharmacy practice.

(3) For single-entity products the label must include

(a) the generic name and at least one of

(i) the brand name,

(ii) the manufacturer’s name, or

(iii) the drug identification number.

(4) For multiple-entity products 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.

(5) For compounded preparations the label must include all active ingredients.

(6) If the pharmacy is unable to supply prescribed Schedule II or III drugs or unscheduled drugs to a resident and the resident has obtained a supply from another source, the drug must be in the original sealed packaging and be sent to the pharmacy for

(a) identification,

(b) repackaging in a monitored dose system if appropriate,

(c) labeling, and

(d) notation on the resident's record and the medication administration record.

(7) If labels are produced to be attached to a resident's medication administration record, the label must state "for MAR".

(8) All drugs must be labelled with the drug expiry date and manufacturer's lot number, except multi-drug sealed dosage units.

(9) A registrant must not delegate the labelling of drugs in a monitored dose system to an employee of a facility or home.

Resident Records

13. (1) A registrant must maintain a record for each resident.

(2) The record must include

(a) the resident's full name, personal health number, birth date, gender, practitioner name, name of the facility or home, and if possible, the resident's location within the facility or home,

(b) diagnoses,

(c) the presence or absence of known allergies, adverse drug reactions or intolerances relevant to drugs,

(d) the prescription number, names and drug identification numbers or natural product numbers for all drugs dispensed,

(e) the medical indication for use for all "as required" prescription authorizations and drugs dispensed,

(f) directions for use, dosage form, strength, quantity, route of administration, dosage times, dates dispensed, and

(g) the dates and reasons for early discontinuation of drug therapy if applicable.

(3) When a drug is to be administered on a "when necessary" basis, the record and prescription label must clearly indicate

(a) the specific indication for which the drug is to be given,

(b) the minimum interval of time between doses, and

(c) the maximum number of daily doses to be administered.

(4) A full pharmacist must review the resident record before dispensing a drug and take appropriate action when necessary with respect to

(a) the appropriateness of drug therapy,

(b) drug interactions,

(c) allergies, adverse drug reactions, and intolerances,

(d) therapeutic duplication,

(e) contraindicated drugs,

(f) the degree of compliance,

(g) the correct dosage, route, frequency and duration of administration and dosage form, and

(h) any other potential drug-related problems.

Resident Medication Administration Records

14. (1) The registrant must provide a medication administration record for each resident.

(2) The medication administration record must be current for each resident based on the information on the resident's record and must be sent to the facility or home each month.

(3) A resident's medication administration record must include

(a) the resident's full name,

(b) the resident's location within the facility or home, where possible,

(c) the name of the practitioner,

(d) allergies,

(e) diagnoses,

(f) the month for which the record is to be used,

(g) the name and strength of all drugs currently being administered, including those to be administered on a "when necessary" basis, and

(h) full directions for use.

Resident Medication Review

15. (1) The full pharmacist responsible for a facility must

(a) review each resident's drug regimen on site or by videoconference at least once every 6 months with a practitioner if available, or a registered nurse and a facility staff member approved by the medication safety and advisory committee, and

(b) review the resident's personal health information stored on the PharmaNet database before releasing any drug to the facility.

(2) A full pharmacist must maintain a record of the reviews referred to in subsection (1) in the resident's record and in the record at the pharmacy, and the record of review must include information about

(a) the people in attendance,

(b) the date of the review, and

(c) recommendations, if any.

(3) At a facility or home, if a resident's practitioner does not attend the review, the full pharmacist must advise the practitioner of any recommendations arising from the review.

(4) The full pharmacist responsible for a home must

(a) review each resident's drug regimen and document the result of the review at least once every 6 months, and

(b) conduct the review on site at least once in every 12 month period.

(5) To continue dispensing drugs for a resident in a facility or home, prescriptions must be received from the resident's practitioner every six 6 months, either by written, verbal or electronic communication.

Resident Oriented Pharmacy Practice

16. (1) When a resident is first admitted to a facility or home, the full pharmacist must obtain a history for the resident, and the following information must be obtained if available:

(a) allergies, adverse drug reactions, and intolerances,

(b) past and present prescribed drug therapy including the drug name, strength, dosage, frequency and duration of therapy,

(c) compliance with prescribed drug regimen,

(d) Schedule II, III and unscheduled drug use, and

(e) laboratory results.

(2) The full pharmacist must routinely provide written or verbal drug information relevant to a resident's drugs to the medical, nursing or other appropriate facility or home staff.

(3) If an adverse drug reaction as defined by Health Canada is identified, a full pharmacist must

(a) notify the resident's practitioner,

(b) make an appropriate entry on the resident's record, and

(c) report the reaction to the Canada Vigilance Program Regional Office.

(4) Where a self-medication program is deemed suitable for a resident, the full pharmacist must comply with all applicable regulations under the *Community Care and Assisted Living Act* and must

(a) participate in the development of policies and procedures for the program, including appropriate storage and security requirements,

(b) ensure a drug consultation with the resident occurs,

(c) ensure authorization from the resident's practitioner and the medication safety and advisory committee is obtained,

(d) include any drugs in the self-medication program in the drug regimen review referred to in section 13(4), and

(e) document the consultation referred to in paragraph (b) in the resident's record.

(5) The drug consultation referred to in subsection (4)(b), should occur in person with the resident or resident's representative and must

(a) confirm the identity of the resident,

(b) identify the name and strength of drug being dispensed,

(c) identify the purpose of the drug,

(d) provide directions for use of the drug including the frequency, duration and route of therapy,

(e) discuss common adverse effects, drug and food interactions, and therapeutic contraindications that may be encountered, including their avoidance, and the actions required if they occur,

(f) discuss storage requirements,

(g) provide information regarding

(i) how to monitor response to therapy,

(ii) expected therapeutic outcomes,

(iii) action to be taken in the event of a missed dose, and

(iv) when to seek medical attention, and

(h) provide other information unique to the specific drug or resident.

Respite Care

17. (1) When a resident is admitted for short-stay respite care, the registrant must confirm all prescription authorizations with the resident's practitioner.

(2) The registrant must dispense drugs using a monitored dose system and provide medication administration records.

(3) Emergency stay respite care residents who arrive without notice may be administered drugs from their own supply if it is reasonable and safe to do so only until a supply is obtained from the pharmacy.

Leave of Absence Drugs

18. (1) The registrant must establish a system to ensure that leave-of-absence drugs are prepared correctly.

(2) The label on a leave of absence medication must include

(a) the facility or home name,

(b) the resident's name,

(c) the practitioner's name,

(d) the drug name, strength, quantity and complete directions for use,

(e) the initials of the person preparing the drug, and

(f) the date of issue.

(3) All leave of absence drugs must be documented on the resident's medication administration record.

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7. Legislation Review Committee

Justin Thind

Chair, Legislation Review Committee

College of Pharmacists of British Columbia

7 a) Bylaw Amendments to Officially Adopt the NAPRA Standards for Sterile Compounding

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Defining Compounding

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What is Compounding?

- Compounding is defined under the *Pharmacists* Regulation, as the mixing of one or more other ingredients.
- Healthcare professionals who provide compounding related services and products to patients/clients must be able to demonstrate that a **patient-healthcare professional relationship** exists.

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What is Sterile Compounding?

- Includes any manipulation of a sterile or nonsterile product intended to produce a final preparation that is sterile.
- Compounded sterile preparations can be administered directly (intravenously (into vein), intramuscularly (into muscle), subcutaneously (under skin), intrathecally (into spine), vs. oral administration where the digestive system has an opportunity to remove contaminants.
- Critical that every step during preparation ensures the product does not become contaminated.

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NAPRA National Compounding Standards

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National Association of Pharmacy Regulatory Authorities (NAPRA)

- NAPRA is an association of the provincial and territorial pharmacy regulatory authorities as well as the Canadian Forces Pharmacy Services.
- One of NAPRA's roles is creating national model standards and guidelines that its members can in turn adopt or adapt for use in their own jurisdictions.

NAPRA ANORP

National Association of Pharmacy Regulatory Authorities ®
Association nationale des organismes de réglementation de la pharmacie

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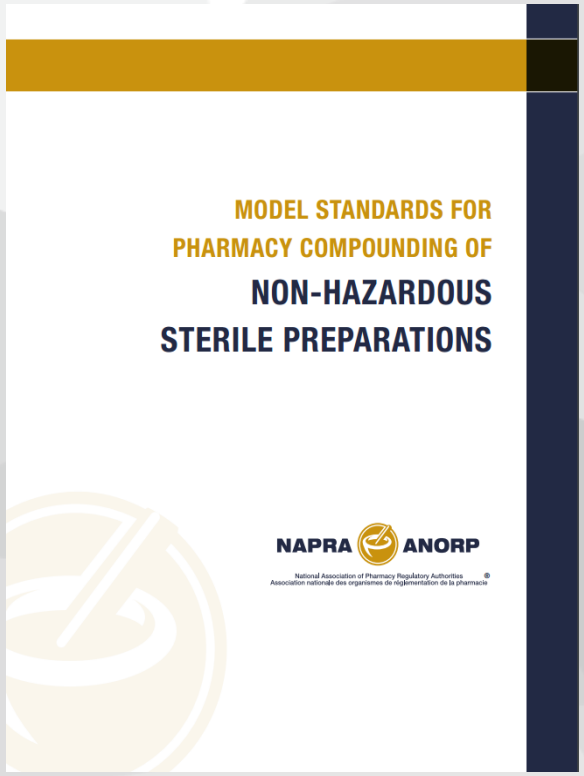
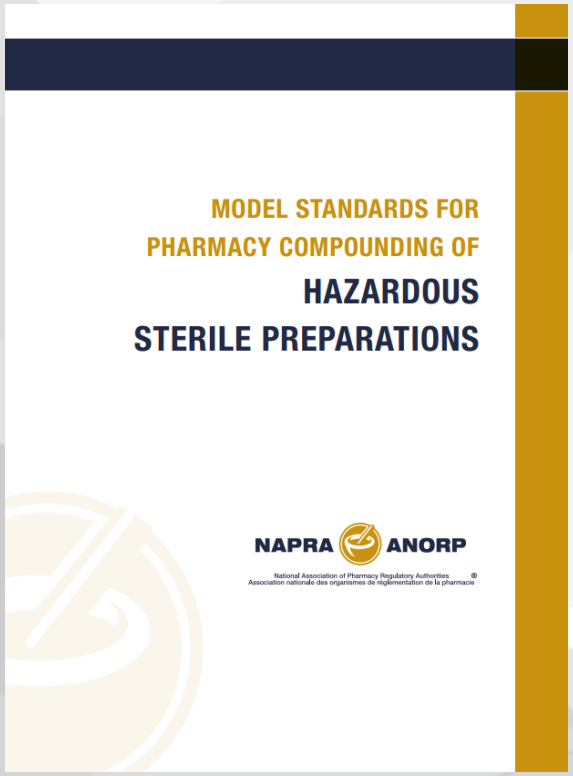
NAPRA Sterile Compounding Standards: Background and Overview





Compounding, https://www.bcpharmacists.org/compounding

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Compounding Related Incidents

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Compounding Incidents – Marchese Hospital Solutions

Marchese Hospital Solutions

- In 2013 Marchese Hospital Solutions supplied nearly 1,202 Canadian cancer patients in hospital in Ontario and New Brunswick with weaker-than-prescribed doses of chemotherapy drugs.
- Hospitals have said the saline bags that the chemotherapy drugs came in were overfilled, diluting the concentration of the cancer-fighting drugs by as much as 20%.
- This incident resulted in an independent review and increased regulatory oversight of compounding in Ontario.

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Compounding Incidents - NECC

New England Compounding Centre (NECC)

- In 2012, over 100 patients died and over 800 people were infected from a fungal meningitis outbreak when patients were infected from contaminated steroid injections.
- This outbreak is considered the largest public health crisis ever caused by a contaminated pharmaceutical drug.
- The former owner of the New England Compounding Centre as well as the supervising pharmacist were sentenced to multiple years in prison.

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NECC: Fungal Meningitis Outbreak

Samples of Cladosporium species (L), and Aspergillus fumigatus, two of the fungi diagnosed in the fungal meningitis outbreak . (Harrison McClary/Reuters)

https://www.washingtonpost.com/national/health-science/the-drug-in-fungal-meningitis-cases-is-hard-to-make-and-unusually-dangerous-when-contaminated/2013/02/08/1fb0176e-5a9e-11e2-88d0-c4cf65c3ad15_story.html

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PEW Charitable Trusts

- 2001 to 2019: 73 *reported* compounding errors, 1562 adverse events and 116 deaths.
- Because many events go unreported, these numbers could be an underestimation of the number of compounding errors in the US since 2001.
- Contamination was the most common error.

THE PEW CHARITABLE TRUSTS

https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2020/us-illnesses-and-deaths-associated-with-compounded-or-repackaged-medications-2001-19

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BC's Implementation of the Model Standards

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Compounding Implementation Timeline

Phase	Deadline	Details
1	November 2017	• Gap analysis and site plan • Personnel conduct
2	May 2019	• Personnel training • Policies & procedures
3	May 2020	• Beyond use dates • Verification of facilities
4	May 2021	• Facility infrastructure
	July 2022	• Extended Full Compliance Deadline

Board Highlights June 2020, https://www.bcpharmacists.org/board-highlights-june-12-2020

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Adoption of NAPRA Model Standards Across Canada

- To date, seven other provincial pharmacy regulatory authorities have adopted/ adapted the two Model Standards:
  - Alberta (2016)
  - Ontario (2016)
  - Nova Scotia (2016)
  - Manitoba (2017)
  - New Brunswick (2017)
  - Saskatchewan (2019)
  - Newfoundland and Labrador (2016 and 2017)
- Many of these jurisdictions also took a phased approach to implementing them.
- Quebec and Prince Edward Island are the only provinces that have not adopted/adapted the Model Standards.

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Proposed Bylaws Adopting the Model Standards

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Proposed PODSA Bylaws

- The Model Standards include standards related to the operation of a pharmacy (e.g., facility and equipment related requirements) which are issues included under PODSA. As such, amendments to the PODSA Bylaws are needed.
- Bylaw amendments have been included to require pharmacy owners and managers to ensure compliance with the NAPRA standards approved by the Board, applicable to the operation of a pharmacy.

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Planned Amendments to HPA Standards of Practice

- The Model Standards include minimum standards for pharmacists and pharmacy technicians who compound sterile preparations. Accordingly, amendments to the College's Standards of Practice documents are required.
- These amendments include a new provision requiring compliance with NAPRA Standards, as approved by the Board, and a new provision which states that only registrants can prepare sterile compounds.

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Planned Policy Amendments to Existing PPPs

- The following PPPs will require amendments to align with the adoption of the Model Standards:
  - PPP- 64 Guidelines for Pharmacy Compounding: To replace the outdated reference to NAPRA's 2006 Compounding Guidelines.
  - PPP- 61 Hospital Pharmacy Published Standards: To be repealed as it references outdated sterile product preparation standards.
  - PPP- 57 Standards for Pharmacy Assistant Verification of Sterile Products in Hospital Pharmacy Practice: To be repealed as non-registrants will no longer be permitted to prepare sterile compounds.

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Restricting Sterile Compounding to Registrants

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Policy Decision: Restrict Sterile Compounding to Registrants

- Compounding is listed as a restricted activity that **can only be conducted by a registrant** while practicing pharmacy, under the *Pharmacists Regulation*.
- The Model Standards allow pharmacy assistants "with appropriate training using a formal delegation process that complies with the requirements of the provincial/territorial authority" to prepare sterile compounds.
  - It is our understanding pharmacy assistants were included as "compounding personnel" to accommodate jurisdictions where pharmacy technicians are not regulated.
- It is recommended that the preparation of sterile compounds be restricted to registrants (i.e., pharmacists and pharmacy technicians) only.

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Reasons Support the Policy Decision

Theme	Rationale
1. Public Safety	Compounding may pose a significant public safety risk if proper procedures and techniques are not followed.
2. Accountability	Pharmacists and Pharmacy Technicians are regulated, and are held accountable by the College when practicing pharmacy.
3. Education/Training	Preparing sterile compounds requires certain knowledge, skills and abilities acquired through specific training and education, including aseptic technique and technical competencies to ensure quality. Compounding is a foundational part of a pharmacy professional's education.

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Potential Impacts of Restricting Sterile Compounding to Registrants

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Hospital and Community Pharmacy Surveys

- To understand the possible impacts of restricting sterile compounding to registrants only, College staff surveyed health authorities and community pharmacies.
- Each pharmacy surveyed was asked to state what percentage of their pharmacy's compounding is prepared by: pharmacists, pharmacy technicians and pharmacy assistants.
- The survey results indicate that restricting preparing of sterile compounds to registrants only may have a smaller impact on hospital pharmacies and a moderate impact on community pharmacies.

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Hospital Pharmacy Survey Results - Summary

- The survey results for hospital sites indicated that a small number of the sites (5 out of 57) use pharmacy assistants to prepare sterile compounds.

- In these sites, pharmacy assistants prepare between 1% to 25% of the total sterile compounds.

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Community Pharmacy Survey Results - Summary

- Survey results for community pharmacies indicated that a small number of community pharmacies compound sterile preparations.

Non-hazardous sterile compounding:

- Detailed results show that just over half (54%) of those compounds are prepared by pharmacy technicians.

Hazardous sterile compounding:

- Detailed results show that about half of those compounds are prepared by a pharmacist (43%) and another half by pharmacy assistants (46%).

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Next Steps

- If approved by the Board:
  - The Bylaw amendments will be publicly posted for 90-days.
  - Any feedback received will be reviewed, and any additional necessary amendments will be considered.
- After the public posting period ends:
  - The Board's approval will be sought to file the amendments.
  - Amendments to the HPA Standards of Practice and any relevant Professional Practice Policies will also be brought forward for the Board's approval.
  - Communications on the amendments will be developed and implemented.

College of Pharmacists of British Columbia

7 a) Bylaw Amendments to Officially Adopt the NAPRA Standards for Sterile Compounding

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 approves the proposed draft bylaws of the College of Pharmacists of British Columbia for public posting, which adopt the National Association of Pharmacy Regulatory Authorities' Model Standards for Pharmacy Compounding of Sterile Preparations (non-hazardous and hazardous), as circulated.*

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Questions

College of Pharmacists of British Columbia

7 b) Temporary and Limited Training Requirement Suspension in Professional Practice Policy 66

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Professional Practice Policy-66, Opioid Agonist Treatment

- PPP-66 provides guidance to registrants employed in community pharmacies that provide opioid agonist treatment (“OAT”) services.
- It requires that registrants employed in a community pharmacy that provides OAT services to compete certain OAT training: OAT-CAMPP.

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Review of PPP in Relation to BC's COVID-19 Vaccine Roll-out and Immunizations

- The College was recently contacted by officials responsible for Province's COVID-19 vaccine roll-out and immunization efforts.
- It was requested that the College review PPP-66's training requirements to determine if they pose a barrier to accessing COVID vaccinations, and particularly boosters.

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Proposed Temporary Amendment to PPP-66

- It is recommended that PPP-66 be amended to temporarily suspend the OAT-CAMPP requirement in an aim to help effectively address the COVID-19 public health emergency, as follows:
  - A limited suspension for pharmacists who are **only** providing COVID-19 immunizations, including boosters, and/or flu immunizations.
  - The suspension be lifted once the COVID-19 public health emergency ends.

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Next Steps

- If approved by the Board:
  - The amendment would take effect immediately.
  - The existing PPP would be replaced with the amended version.
  - Communications on the amendments would take place.

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7 b) Temporary and Limited Requirement Suspension in Professional Practice Policy 66

MOTION:

Amend Professional Practice Policy – 66 Opioid Agonist Treatment to temporarily suspend the OAT-Compliance and Management Program for Pharmacy training requirement for pharmacists who are only providing the COVID-19 and/or flu immunizations, including boosters, during the COVID-19 public health emergency.

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Questions

College of Pharmacists of British Columbia

BOARD MEETING
November 26, 2021

8. Hospital at Home – How Curiosity and Collaboration are Transforming Acute Care in BC

INFORMATION ONLY

Presentation Synopsis

On November 9, 2020, Island Health launched a prototype of the Hospital at Home (HaH) program out of Victoria General Hospital with a subsequent expansion in March 2021 to Royal Jubilee Hospital. This initiative includes a collaborative research and evaluation component to understand the impact of implementing HaH from a variety of perspectives.
HaH allows for a subset of acutely ill, clinically stable patients to choose a safe and effective alternative to traditional facility based in-patient treatment. HaH patients have 24/7 access to treatment, diagnostics, and hospital-level expertise from the comfort of their own home. Since the launch of the program, the HaH team has established clinical workflows and implemented new technologies to support this transformative care delivery model. Currently there are 18 inpatient beds with half being based out of Victoria General Hospital and half out of Royal Jubilee Hospital.

This presentation will discuss the background to the HaH initiative, the use of Patient Oriented Research methods to inform its design and evaluation, and outline the integral role of pharmacy within this program.

Presenters' Biographies

Winnie Lam

Winnie Lam graduated from the University of British Columbia, Faculty of Pharmaceutical Sciences with her BSc in Pharmacy in 1990. She completed her Hospital Pharmacy Residency at BC Children's Hospital in 1991 and her Masters of Business Administration from the University of Victoria in 2002. Winnie has worked in all aspects of pharmacy practice, ranging from pediatrics/neonatal clinical pharmacy at Royal Columbia Hospital to managing a retail pharmacy in Victoria. Winnie also worked at PharmaCare as a Pharmacist Consultant and assisted with the Special Authority Program and pharmacy audits. Currently, Winnie is the Regional Pharmacy Manager of Operations for Island Health and has been with the Health Authority for over 20 years. Her area of specialty is sterile products and is leading the pharmacy department towards NAPRA and Hazardous drugs compliance.

Dr. Sean Spina

Dr. Sean Spina graduated from the University of British Columbia Faculty Of Pharmaceutical Sciences with his BSc in Pharmacy in 2000 and his Doctor of Pharmacy in 2007. He is currently the Director of Special Projects at Royal Jubilee Hospital in Victoria, BC, Canada. He is also a Clinical Associate Professor with the University of British Columbia, Faculty of Pharmaceutical Sciences and an Adjunct Assistant Professor with the University of Victoria Health Information Sciences Faculty. Sean is the Principal Investigator of Alternatives to Traditional Hospital Care Offered in Monitored Environments (AT-HOME). Since the beginning of his career, Dr. Spina has been interested in incorporating technology into clinical practice, and is committed to engaging patients, families, clinicians, and decision makers in the research process. He has authored several published articles on these topics and has received numerous local, provincial, and national awards for his work in formally evaluating the impact technology has on clinical practice and patient care. The Health Employers Association of British Columbia recognized Dr. Spina and his team for their work in 2017 by awarding them the Top Provincial Innovation Award in the “Excellence in BC Health Care” category. Website: http://profiles.islandhealth.ca/sean-spina

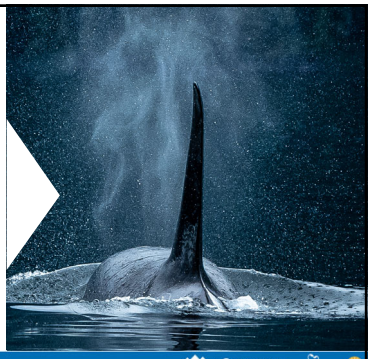
Hospital at Home
How Curiosity and Collaboration are Transforming Acute Care in BC

Winnie Lam
Regional Pharmacy Manager
Island Health

Dr. Sean Spina
Director,
Special Projects

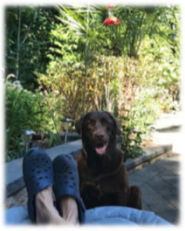
November 26, 2021

Land Acknowledgement



Outline

- Background
  - The Journey
  - Partnership
- Pharmacy practice reinvented
  - Creativity
  - Collaboration
- Patients as partners
- Questions



The Journey

HaH…The Journey

- Video

Patient Oriented Research

Traditionally, patients have mostly been the subjects of health research, or "study participants" but …

…POR is done differently!

- ☑ is done in partnership with patients (as part of the research team!);
- ☑ answers research questions that matter to patients;
- ☑ measures outcomes that matter most to patients (like quality of life)

Why Engage Patients?

PATIENT-ORIENTED RESEARCH:

- ☐ Engages PATIENTS AS PARTNERS
- ☐ Focuses on PATIENT-IDENTIFIED PRIORITIES to improve PATIENT-CENTRED OUTCOMES
- ☐ Is conducted by multidisciplinary teams in partnership with RELEVANT STAKEHOLDERS
- ☐ Aims to apply KNOWLEDGE GENERATED to improve healthcare systems & practice

Government Partnership

Collaboration

- Access & Flow
- Acciona
- ATHOME Investigators
- BCAS
- BioMed
- Communications
- CHS
- Decision Support
- EHR-HIM
- Emergency Medicine
- Executive Sponsors
- Finance
- FMO
- Hospitalist Working Group
- HR
- IMIT / EHR
- International consultation
- IPC
- Lab/POCT
- Lab informatics
- Legal and Risk
- LP&S

- LTC
- Medical Affairs
- Medical Imaging
- MOH
- OH&S
- Patient Partners
- PDO
- Performance monitoring
- Pharmacy
- Pharmacy Informatics
- Privacy/Security
- Professional Practice
- Research and Capacity building
- SIHI
- Site leadership
- Staffing
- Transportation
- Victoria Hospitals Foundation
- Virtual Care

Learning Health System

"...organizations or networks that continuously **self-study and adapt** using data and analytics to generate knowledge, engage stakeholders and implement behavior change to transform practice."

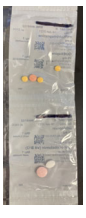
Engaging Patients and Families as Partners: A Canadian Approach to Developing, Implementing, and Evaluating Hospital at Home

Dr. Sean Spina
Principal Investigator: ATHOME
Director, Special Projects (HaH/MHSU)

Alternatives to Traditional Hospital Care Offered in Monitored Environments (AT-HOME) - Investigators

Medication Distributions Dilemma

Community or hospital dispensing format?
Labelling? Storage/narcotics safety?



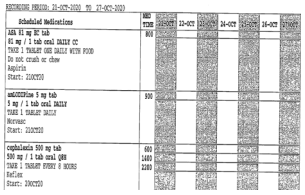
Medication Documentation Dilemma

Hospital Medication Administration Records (MARs)

Daily MARs

Scheduled Medications (Sorted by Start Date)	Time	Initials
tiotropium 18 mcg inhale DAILY Spiriva Inhale contents of ONE capsule ONCE daily using Handihaler Device. Start:02-JUL-2020	0900	____
diltiazem CD 180 mg oral DAILY Cardizem CD hold if SBP less than 100mmHg Do not crush or chew Start:02-JUL-2020	0900	____
levothyroxine 125 mcg oral DAILY Synthroid (125 mcg= 0.125 mg) Start:02-JUL-2020	0900	____
budesonide–formoterol 200 mcg–6 mcg 1 puff inhale BID Symbicort 200 Turbuhaler Inhale ONE puff TWICE daily *RINSE MOUTH AFTER USE* Start:02-JUL-2020	0900 2100	____ ____

Weekly MARs



Medication Systems - Collaborations

Working groups

- Nurses
- Medication safety
- Pharmacists
- Pharmacy Technicians
- Patient Care Partner
- Professional Practice
- Technologies
- Risk management
- Physicians

Medication Distribution - Collaboration

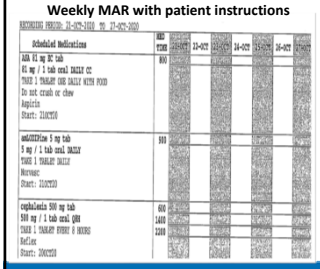
Key decisions

- Dispensing – child resistant vials* with labels in lay language
- Storage – provide lockable tote with key
- Nurses – carry own supply for emergencies (Epi-pen, gravol, etc)

*Ongoing process improvement

Medication Administration - Creativity

Weekly MAR with patient instructions



Patient Friendly MAR

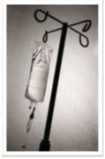
Scheduled Medications	Time	Initials
cholecalciferol 1,000 IntUnit tab (vit D3) Take ONE tablet (1000 IntUnit) orally daily Start: 04-FEB-2021	9:00 AM	____
ferrous fumarate 300 mg tab Take ONE tablet (300 mg) orally at bedtime Start: 04-FEB-2021	9:00 AM	____
furosemide 20 mg tab Take ONE tablet (20 mg) orally daily Start: 05-FEB-2021	8:00 AM	____
metoprolol 25 mg tab Take ONE tablet (25 mg) orally TWICE daily Start: 04-FEB-2021	9:00 AM 9:00 PM	____ ____
pantoprazole magnesium EC 40 mg tab Take ONE tablet (40 mg) orally TWICE daily Start: 04-FEB-2021	9:00 AM 9:00 PM	____ ____
rosuvastatin 20 mg tab Take ONE tablet (20 mg) orally daily Start: 04-FEB-2021	9:00 PM	____
warfarin 2 mg tab Take ONE tablet (2 mg) orally daily	5:00 PM	____

Medication Systems - Creativity

Intravenous medication deliveries

Traditional IV bags

- Gravity (pole)
- Cumbersome
- Nursing administer



Elastomeric balls

- Pressure delivery
- Portable
- Patient administer

Role of Clinical Pharmacists

AT ADMISSION

- Support med rec
- Assess patient for medication-related reasons for admission
- Ensure current medications are optimized for safety and efficacy
- Collaborate with patient to confirm desired outcomes
- Educate patient and caregivers

DURING ADMISSION

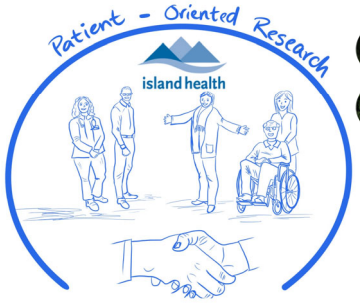
- Identify and resolve medication related issues (allergies, drug interactions, dosing in specialized populations)
- Virtual visits to address medication-related questions
- Educate patient and caregivers

AT DISCHARGE

- Support med rec
- Liaise with community pharmacy to ensure safe and efficient transfer of pharmacy care
- Assist with discharge planning (e.g., PharmaCare Special Authority approvals)
- Educate patients and caregivers

A new model of acute-care delivery

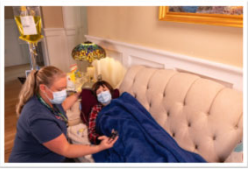
"….HaH was safe for all involved, more patient-centered and probably at less cost than at a hospital.
We are eternally grateful for [my father's] speedy recovery due to the exemplary care and attention to detail by the HaH team."
- NAME, wife, caregiver, taxpayer"



Patients as Partners: the Story of Island Health HaH

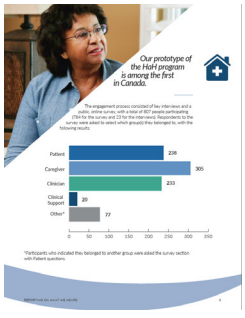
Dr. Sean Spina BSc(Pharm) ACPR PharmD FCSHP
Principal Investigator, ATHOME;
Co-Lead, Hospital at Home Evaluation;
Clinical Coordinator, Department of Pharmacy, Island Health

Beth Bourke RN
Patient Partner, Hospital at Home



Drawing credit: Rounak Haddadi

Public / Stakeholder Engagement on HaH



What we heard

Evaluation / Research

- Patient Health Outcomes
- Process and Policy

Program

- Communication
- Support
- Safety

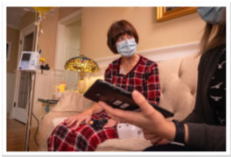
Implementation Evaluation

DIMENSIONS
- ACCEPTABILITY
- ADOPTION
- APPROPRIATENESS
- FEASIBILITY
- FIDELITY
- COST
- REACH
- SUSTAINABILITY

Impact

Patient and Family Caregiver engagement resulted in:

- The development and implementation of a **virtual call bell**
- Integration of a comprehensive **communication platform**
  - (voice and text messaging)
- A HaH **evaluation framework** grounded in PFC priorities



AT-HOME POR Program of Research

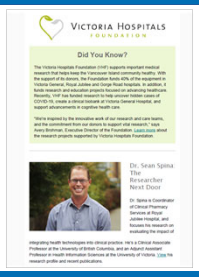
What	Experience (AT-HOME/ Decision Support)	**IN**vestigation of the impact of a **P**harmacist in a **H**ospital **A**t Home **C**are **T**eam (IN PHACT) (AT-HOME)	Technology (AT-HOME)
	Clinical Outcomes Evaluation (Decision Support)	Human Health Resourcing (Finance)	Synergy of DS/Research
Who	Pharmacists / Physicians	Patients	Contractors / Students
	Island Health Operations / Decision Support	Research Department / BC SUPPORT Unit	UVic / UBC

Impact

Patient and Family Caregiver engagement resulted in:

- Patient Friendly MAR
- Caregiver waiver trial
- Patient education binder
- Streamlined access for diagnostics testing

Impact



Questions

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College of Pharmacists of British Columbia

BOARD MEETING
November 26, 2021

9. Drug Administration Committee - Amendments to the *Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions*

DECISION REQUIRED

Recommended Board Motion:

Approve the following resolution to amend the *Health Professions Act* Bylaws Schedule F Part 4 – Certified Practice – Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions to lower the patient age limit for drug administration by injection to 4 years of age, and to include other minor updates as previously approved by the Board, but not remove the limit that restricts pharmacists to administering immunizations only, as circulated.

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

Purpose

To propose amendments to the Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions (Standards, Limits and Conditions) to lower the age limit for drug administration by injection to 4 years of age.

Background

Age Limitation

Concerns have been raised that some children in British Columbia (BC) have not been able to receive routine vaccines as easily during the COVID-19 public health emergency, as many public health resources have been prioritized for COVID-19 vaccination clinics. Public health nurses have been reassigned to carry out essential duties related to COVID-19 since at least November 2020, including contact tracing and providing COVID-19 vaccinations.[1]

[1] Baker, R., "Some early childhood vaccinations in B.C. delayed by pandemic response" Canadian Broadcasting Corporation, Nov. 21, 2020. Available from: https://www.cbc.ca/news/canada/british-columbia/immunization-delays-due-to-covid-19-contact-tracing-1.5811170 [Accessed Nov. 2, 2021]

In particular, the concern is that some children may not have received the recommended school entry vaccines for children aged 4-6. In BC, there are two vaccines recommended for children aged 4-6 prior to entering school, the tetanus and diphtheria toxoids, acellular pertussis and inactivated polio vaccine (Tdap-IPV), and the measles, mumps, rubella and varicella vaccine (MMRV).[2,3] In addition, this year the influenza vaccine is recommended for everyone 6 months of age and over, with rare exceptions.[4]

The Ministry of Health has indicated that children can receive necessary publicly funded vaccines from other sources, including community health centres, community pharmacies, and family doctors.[5] As per the College's Standards, Limits and Conditions, pharmacists are only permitted to administer vaccines by injection to children aged 5 and older.[6] While school entry vaccines are recommended for children between the ages of 4 and 6, pharmacists are unable to provide school entry vaccines to children who are 4 years of age. Pharmacists are also unable to provide annual influenza vaccinations to children under 5 years of age.

On June 11, 2021, the Drug Administration Committee (DAC) met, and directed the College to look further into this issue.

Approved In-Principle Standards, Limits and Conditions
At the November 2020 Board meeting, the Board approved amendments to the Standards, Limits and Conditions in-principle, but did not file them with the Ministry of Health. This was due to the bylaw moratorium and ongoing work with the Ministry in moving the amendments forward (Appendices 1 & 2).

The approved in-principle Standards, Limits and Conditions included general updates to strengthen requirements and improve clarity, as well as removal of the limit that restricts pharmacists to administering drugs only for the purpose of immunization.

Discussion

Inter-Jurisdictional Scan
The current age limit for drug administration by injection in the Standards, Limits and Conditions aligns with most other Canadian jurisdictions; however, in the past few years, a few provinces have permitted pharmacists and pharmacy technicians to administer injections to

[2] As per the BCCDC Immunization Manual, separate MMR and varicella vaccine may be recommended for select special populations.
[3] BCCDC Immunization Manual Chapter 2: Immunization, Part 1 – Immunization Schedules (page 5). [Accessed Nov. 2, 2021]
[4] Influenza: ImmunizeBC, available from: https://immunizebc.ca/influenza. [Accessed Nov. 2, 2021]
[5] Bains, M., "New Westminster school trustee urges restart of school-based vaccination program," Canadian Broadcasting Corporation, May 19, 2021. Available from: https://www.cbc.ca/news/canada/british-columbia/new-westminster-school-trustee-urges-restart-of-school-based-vaccination-program-1.6030430 [Accessed Nov. 2, 2021]
[6] Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions, College of Pharmacists of BC. Available from: https://library.bcpharmacists.org/6_Resources/6-1_Provincial_Legislation/5099-HPA_Bylaws_Drug_Administration_Injection_Intranasal.pdf [Accessed Nov. 2, 2021]

patients as young as 2 years of age (Appendix 3, Table 1). In 2020, the United States federal government granted authority to pharmacists in all states to administer vaccinations to children as young as 3 years old during the COVID-19 pandemic.[7] The rationale for this was to increase access to childhood vaccinations in response to declining rates of vaccination, as access to health care services had likely been impacted by COVID-19.

Safety

There have been no significant safety concerns demonstrated in the literature or reported by other Canadian jurisdictions regarding pharmacist administration of injections to young children. The literature describes instances where pharmacy professionals (including pharmacy technicians) in North America were appropriately trained and successfully administered vaccinations to children as young as 2 months of age (Appendix 4).

Training & Competency

The Canadian Council on Continuing Education in Pharmacy (CCCEP) accredited injection training programs must include learning objectives on demonstrating the age-appropriate injection sites and proper client positioning used for immunization, and on choosing the correct needle length and gauge for the age and size of the client. It is up to accredited programs to deliver content that meets the required learning objectives. Because of BC's current age limit, accredited programs in BC do not provide specific training for injecting patients under the age of 5, but students are provided with resources and information on where to find relevant information should it be required. However, in general, techniques for administering subcutaneous and intramuscular immunizations are not significantly different for patients 4 years of age compared to those who are 5.[8]

There are CCCEP accredited training programs available in Canada for pharmacists to enhance their knowledge about pediatric injections in children under the age of 5 that include learning objectives on selecting appropriate needle and syringe sizes, positioning techniques, and pain management strategies, should a pharmacist determine they need additional training to administer injections to children (Appendix 5).

Need for Policy Change

Access to health care services, including vaccine access, is the responsibility of the Ministry of Health, and is not within the College's jurisdiction. The College has not received a request from the Ministry of Health to amend the Standards, Limits and Conditions to improve vaccine access for children under 5 years of age. However, a change to the College's requirements could have a beneficial impact on public health and safety.

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[7] Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19, March 17, 2020, Department of Health and Human Services, USA. Available from: https://www.hhs.gov/sites/default/files/third-amendment-declaration.pdf [Accessed Nov. 2, 2021]

[8] BCCDC Communicable Disease Control Manual, Chapter 2: Immunization, Appendix B: Administration of Biological Products (p. 16, 23). [Accessed October 19, 2021]

Pharmacists in BC have been involved in administering publicly funded vaccines to patients 5 years and up for many years. Pharmacists in Vancouver Coastal Health are involved in an immunization "catch-up" program for older school age children who have missed routine vaccinations.[9] Additionally, Fraser Health recommends children may receive school entry vaccines from a pharmacist, for children 5 years of age and older.[10] Reducing the age limit to capture 4-year-old children could have a beneficial impact for children accessing school-entry vaccines through pharmacies.

COVID-19 Vaccine for Children 5-11 Years of Age
COVID-19 vaccines in BC have been offered to the public based on year of birth and not actual age.[11] If COVID-19 vaccines are approved in Canada for the 5-11 age group, it is likely that some 4-year-old patients would be eligible for vaccination based on their year of birth (e.g., children aged 4 but turning 5 that calendar year may be eligible to receive the COVID-19 vaccine, depending on final public health recommendations). It is expected that some pharmacies will provide COVID-19 vaccines to the 5-11 age group.[12] Under the current College limitation, pharmacists would only be permitted to vaccinate children who have already turned 5 years old. Depending on the availability of other COVID-19 vaccine centres in the area, this may create a barrier for some children aged 4 to receive a COVID-19 vaccine.

Meeting of the DAC
The DAC met on November 1, 2021, to consider the College's findings (Appendix 6). The DAC recommended that the Standards, Limits and Conditions be amended to reduce the patient age limit for drug administration by injection to 4 years of age.

Additional Considerations

The Ministry of Health announced a partial lifting of the bylaw moratorium in the summer of 2021; however, the Ministry will still prioritize bylaw changes based on a number of factors, including alignment with Government priorities, and those that address BC's public health emergencies.

Because a change in age limit may impact the province's COVID-19 vaccine roll-out to 5–11-year-olds, it may be prioritized by the Ministry of Health. However, it is unclear if the other general updates to the Standards, Limits and Conditions to strengthen provisions and provide improved clarity would be prioritized based on the current prioritization framework. The

[9] School age immunization campaign, Vancouver Coastal Health. Available from: http://www.vch.ca/public-health/communicable-diseases-immunizations/immunizations/school-age-immunization-campaign [Accessed Nov. 2, 2021]
[10] Children and youth immunizations, Fraser Health. Available from: https://www.fraserhealth.ca/health-topics-a-to-z/immunizations/children-and-youth-immunization#.YRbrkYhKiUk [Accessed Nov. 2, 2021]
[11] "Which age group do I fit in?...", ImmunizeBC. Available from: https://immunizebc.ca/ask-us/questions/covid-19/which-age-group-do-i-fit-my-birthday-year-puts-me-different-group-depending-on-time [Accessed Nov. 2, 2021]
[12] Sajan, B., "Pharmacies doling out Moderna and Pfizer in pilot project just before younger kids expected to be OKed for vaccine" CTV News, October 14, 2021. Available from: https://bc.ctvnews.ca/pharmacies-doling-out-moderna-and-pfizer-in-pilot-project-just-before-younger-kids-expected-to-be-oked-for-vaccine-1.5623691 [Accessed Nov. 2, 2021]

College has reached out to the Professional Regulation and Oversight Branch, Ministry of Health to discuss further.

Work with the Ministry of Health regarding the removal of the limit that restricts pharmacists to administering immunizations only is ongoing, and accordingly, it is recommended that this part of the approved in-principle standards not be moved forward at this time.

Recommendation

It is recommended that the Board approve the proposed amendments to the Standards, Limits and Conditions to lower the patient age limit for drug administration by injection to 4 years of age, and to include other minor updates as previously approved by the Board, but not to remove the limit that restricts pharmacists to administering immunizations only, as circulated (Appendix 7).

Next Steps

If approved by the Board, the amendments to the Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions will be submitted to the Ministry of Health for filing, for a period of 60 days.

Guiding Questions

When reviewing the proposed amendments, the Board is asked to consider:

- Do the proposed amendments address the concerns raised?
- Are the proposed amendments in the interest of the public?
- Is there anything missing, unclear, ambiguous, or unnecessary in the draft proposed amendments?

Appendix	
1	November 2020 Board Briefing Note (without appendices)
2	September 2020 Board Briefing Note (without appendices)
3	Inter-jurisdictional Scans – Patient Age Restrictions and Education Requirements
4	Summary of Literature Search
5	Injection Training Programs
6	November 2021 Drug Administration Committee Briefing Note (without appendices)
7	Proposed Amendments to the *Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions* (clean and track changes)

Appendix 1

College of Pharmacists of British Columbia

BOARD MEETING
November 20, 2020

7. Drug Administration Committee – Amendments to the *Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions*

DECISION REQUIRED

Recommended Board Motion:

Accept the amendments to the *Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions,* as circulated.

Background

The Board was presented with the proposed amendments to the *Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions (Standards, Limits and Conditions)* at the September 2020 Board meeting (see Appendix A)[1]. The Board decided to table the in-principle acceptance of the proposed amendments until the November 2020 Board meeting; however, the Board did direct the Registrar to engage with the Ministry of Health on moving the proposed amendments forward.

Discussion

Since the September Board meeting, the National Advisory Committee on Immunization (NACI) released updated recommendations for post-vaccination observation periods for influenza vaccinations during the COVID-19 pandemic.[2] Their recommendations were also incorporated into the BC Centre for Disease Control "Guidance for Influenza Vaccine Delivery in the Presence of COVID-19 (October, 2020)" document.[3]

[1] Note: An updated version of the proposed *Standards, Limits and Conditions* has been included with the September 2020 briefing materials in Appendix A, which includes minor referencing changes within the application section as recommended by legal counsel, and minor updates recommended by the Drug Administration Committee.

[2] An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI): Recommendations on the Duration of the Post-vaccination Observation Period for Influenza Vaccination during the COVID-19 Pandemic (Accessed October 15, 2020)

[3] See page 6 of the BCCDC's "Guidance for Influenza Vaccine Delivery in the Presence of COVID-19 (October, 2020)" (Accessed November 5, 2020)

The College considered moving forward with the proposed amendments to the *Standards, Limits and Conditions* (not including the removal of the restriction that limits pharmacists to administering immunizations only) in response to the updated recommendations from NACI, as they already include a more principle-based post-vaccination wait-period requirement. The Drug Administration Committee (DAC) met on October 30, 2020 to discuss the proposed amendments to the *Standards, Limits and Conditions* in the context of the NACI recommendation. At that time, the DAC suggested and approved additional minor changes to the *Standards, Limits and Conditions* which include a clarified requirement for ensuring the frequency of drug administration is appropriate, and taking appropriate steps to ensure the right drug is administered to the right patient. These changes are included in the draft amendments in Appendix A.

The College discussed moving the proposed amendments forward (not including the removal of the restriction that limits pharmacists to administering immunizations only) with the Ministry of Health, however the Ministry was not supportive of any changes to the *Standards, Limits and Conditions* in response to the NACI recommendation at this time.

The Registrar continues to engage with the Ministry of Health, as directed by the Board at the September meeting, on the removal of restrictions. A letter was sent to Mark Armitage, the Assistant Deputy Minister, Ministry of Health, on October 16, 2020 in response to the letter dated August 20, 2020 (see Appendix B). As outlined in the letter, the Registrar met with executives from the Ministry of Health on November 16, 2020. The College committed to providing a written response to questions raised at the meeting.

Recommendation

It is recommended that the Board approves, in-principle, the proposed amendments to the *Standards, Limits and Conditions*, as circulated.

Next Steps

The Registrar will continue to engage with the Ministry of Health on moving the proposed amendments to the *Standards, Limits and Conditions* forward.

Appendix	
A	Drug Administration Committee September 2020 Board Briefing Materials (note: contains an updated version of the proposed amendments to the *Standards, Limits and Conditions* as described in footnote 1)
B	Letter from Christine Antler to Mark Armitage, October 16, 2020

Appendix 2

College of Pharmacists of British Columbia

BOARD MEETING
September 18, 2020

3. Drug Administration Committee - Amendments to the *Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions*

DECISION REQUIRED

Recommended Board Motions:

1. Accept the amendments to the *Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions*, as circulated.

2. Direct the Registrar to engage with the Ministry of Health to move the amendments to the *Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions* forward.

Purpose

- To propose amendments to the *Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions.*
- To provide the Board with a recommendation for moving forward with the removal of certain restrictions on pharmacist drug administration authority.

Background

The *Pharmacists Regulation* enables pharmacists to administer any drug specified in Schedule I, IA or II of the *Drug Schedules Regulation* or a substance through intradermal, intramuscular or subcutaneous injection or the intranasal route. It also requires a committee (i.e., the Drug Administration Committee ("DAC")) to be established to develop, review and recommend the standards, limits and conditions under which a registrant may administer a drug or substance to patients and the successful completion of a certification program.

Currently, the College of Pharmacists of British Columbia ("the College") *Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions* ("*Standards, Limits and Conditions*") only permits a pharmacist to administer a drug for the purpose of immunization. At its February 2019 meeting, based on the recommendations of the DAC, the Board directed the Registrar to remove certain restrictions on pharmacist injection and intranasal administration of medications.

In April 2019, the College received a letter from the Assistant Deputy Minister, Ministry of Health, inviting the College to work with the Professional Regulation and Oversight Branch to establish a working group to determine the impacts of removing the restrictions on pharmacist drug administration. The first meeting of the Safe Drug Administration by Pharmacists Working Group ("Working Group") was held on October 28, 2019. A second meeting of the Working Group was scheduled to take place on February 12, 2020, but was cancelled after staff from the Ministry of Health indicated they were unable to participate. Additionally, in December 2019 the Ministry of Health announced a temporary moratorium on bylaws submitted by health professional regulatory Colleges.

The DAC next met on May 25, 2020. At that meeting, an overview of the events following February 2019 was presented. Additionally, the DAC was presented with two options to move forward with their February 2019 recommendation to remove certain restrictions on pharmacist drug administration. In considering the two options, the DAC was informed of a meeting between the Ministry of Health and the College held on May 22, 2020. The DAC was made aware that the Ministry of Health advised that a response would be provided to the College on a collaborative path forward within one week. As a result, the DAC decided to postpone their decision and wait for the response from the Ministry of Health.

Following the College's meeting with the Ministry of Health in May 2020, the College provided briefing materials to the Assistant Deputy Minister, which contained the findings gathered for the second Working Group Meeting. The briefing note and findings are available in Appendix 1.

At their June 2020 meeting, the Board was given an update on these events (see Appendix 2). The DAC was also to reconvene in June to discuss the response from the Ministry of Health once it was received.

Discussion

The College did not receive a response from the Ministry of Health on a timeline or collaborative path forward in June, as anticipated. In light of this, the College continued working on the *Standards, Limits and Conditions,* and the DAC reconvened on August 14, 2020 to review the proposed amendments and options.

Proposed Amendments to the *Standards, Limits and Conditions*
On August 14, 2020 the DAC was presented with proposed amendments to the *Standards, Limits and Conditions*, to align with the DAC's previous recommendation to the Board. Amendments were made to the limits to allow administration of Schedule I and II drugs by injection and the intranasal route with the exception of Schedule IA, and to prohibit the injection of cosmetic drugs and substances. As recommended, the existing age limits were maintained.

In addition to the amendments directed by the Board, the College reviewed the *Standards, Limits and Conditions* and compared them to drug administration standards for pharmacists in Canadian jurisdictions where pharmacists are not limited to administering vaccines only. Overall, the *Standards, Limits and Conditions* align well with the drug administration standards of pharmacy regulatory authorities in other Canadian jurisdictions (see Appendix 3). Despite this, some areas were identified where the *Standards, Limits and Conditions* may benefit from additional provisions or clarification. These additional amendments are summarized in Appendix 4.

The proposed amendments are presented in Appendix 5. The DAC recommends that the Board move forward with the proposed amendments to the *Standards, Limits and Conditions*, as circulated.

Options Presented to the DAC for Moving Forward

The first option presented to the DAC was to proceed with the original DAC recommendations as approved by the Board in February 2019. The Working Group would be provided a summary of the information gathered for the second Working Group meeting, and would be informed of the decision to proceed with the original DAC recommendations.

The second option was to reschedule the second Working Group meeting when the Ministry of Health staff are available and the moratorium has been lifted. The Working Group would then present findings to the DAC, and the DAC would review and present the findings to the Board, if changes to the original recommendation result from the findings.

The new, third option presented to the DAC was to recommend that the Board direct the Registrar to post the proposed amendments to the *Standards, Limits and Conditions* for public comment. It is important to note that the *Health Professions Act* ("HPA") does *not* require the public posting of amendments to standards, limits and conditions. However, this option was recommended to the DAC to better ensure transparency and provide an opportunity for all stakeholders, including the public, to provide meaningful feedback, and to allow more time to engage with the Ministry of Health.

The DAC discussed the three options for moving forward. However, since posting the amendments for public comment is not required under the HPA and may be considered a strategic decision, the DAC determined that the Board should decide how to proceed.

Engagement with the Ministry of Health

A letter was received from Mark Armitage, Assistant Deputy Minister, Ministry of Health, two weeks after the DAC meeting on August 28, 2020 (see Appendix 6). In the letter, the Ministry requested that the College not proceed forward with the *Standards, Limits and Conditions* to allow more time for the Working Group to complete its work. Specifically, the letter requested that the *Standards, Limits and Conditions* not be posted for public comment. A timeline on a path forward was not presented.

The Ministry of Health also advised that the temporary bylaw moratorium is still in effect, and that they would inform of the Colleges when they are in a position to return to regular operations. At this time, the Ministry of Health is only advancing bylaw changes that align with their current priorities: the COVID-19 response, the opioid overdose emergency response, restarting health services to address the needs of the broader population, and modernization of the regulation of health professionals.

Recommendation

It is recommended that the Board accept the amendments to the *Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions* as recommended by the DAC, and direct the Registrar to engage with the Ministry of Health to move the amendments forward.

Guiding Questions:

When reviewing the proposed amendments to the *Standards, Limits and Conditions*, the Board is asked to consider:

- Do the proposed amendments to the *Standards, Limits and Conditions* align with the Board's previous direction to the Registrar to remove certain restrictions on pharmacist drug administration authority?

Appendix	
1	Briefing materials provided to the Ministry of Health, May 26, 2020 (with selected appendices)
2	June 2020 Board Briefing Note (without appendices)
3	Drug Administration by Pharmacists – Jurisdictional Scan Summary
4	Summary of Additional Amendments to the *Standards, Limits and Conditions*
5	Proposed amendments to the *Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions* (clean and track changes)
6	August 28, 2020 Letter to CPBC from Mark Armitage, Assistant Deputy Minister

Appendix 3: Inter-Jurisdictional Scans

Table 1. Jurisdictional Scan – Patient age restrictions for pharmacist injection administration

	BC	AB	SK	MB	ON	NB	NL	NS	PEI	YT
Age limit for injection of any drug (not including vaccines)	N/A	5+	5+	5+	N/A	2+	5+	2+	Any age in accordance with a prescription	5+
Age limit for injection of vaccine	5+	5+	9+, or 5+ for flu vaccine	7+	5+, or 2+ for flu vaccine	2+	5+	2+	18+, or 5+ for flu/rabies vaccines. Or, any age in accordance with a prescription	5+

Table 2. Jurisdictional Scan – Educational requirements for pharmacist drug administration to young children

	BC	ON	NB	NS	PEI
Age limit for injection of any drug (not including vaccines)	N/A	N/A	2+	2+	Any age in accordance with a prescription
Age limit for injection of vaccine	5+	5+, or 2+ for flu vaccine	2+	2+	18+, or 5+ for flu/rabies vaccines. Or, any age in accordance with a prescription
Education program must be CCCEP accredited (Stage II) or part of CCAP accredited pharmacy curriculum	✓	✓	✓	✓	✓
Continuing competency declaration – injection administration renewal requirement	At least one vaccine administered every 3 years	Up to pharmacist to determine if competent, no annual declaration	At least one injection administered every 3 years	Declaration that a "sufficient number" of injections have been performed in past 2 years	Declaration that a "sufficient number" of injections have been performed in past 1 year
Additional training for pediatric injections required by PRAs that allow injection of kids <5 years?	N/A	Not required, but available (3 courses listed on website)	Required, but specific courses not specified	Not required but under development	Not required, but pharmacists should seek out opportunities as needed

Appendix 4: Literature Search Results

Table 1. Literature Search Summary – Pharmacy Professional Drug Administration for Pediatrics

Reference	Summary
Vaccinating pediatric patients requires preparation, planning – American Pharmacy Association – Pharmacy Today January 2021	• The U.S. Department of Health and Human Services (HHS) expanded pharmacists' authority to immunize children ages 3-18 years during the COVID-19 pandemic • "Overall, for children ages 3 years and up through adolescence, the technique for vaccine administration is the same as for adults. Foster says needle size is important to remember…. Pharmacists need to be fast when giving a vaccine to a child, and a parent or caregiver can provide support by holding the child still". • The article includes a number of vaccination tips for pediatric vaccination
Hofstetter, A.M., and Schaffer, S. Childhood and Adolescent Vaccination in Alternative Settings. Communities, Public Health and Health Policy Vol 21, 2021.	• Delayed and under vaccination exist in certain patient populations and communities in the United States. • A strategy to address this major public health problem is to offer vaccinations in nonprimary care settings, such as schools, emergency rooms, hospitals, and pharmacies. • This will increase the proportion of children and adolescents receiving on-time vaccines • These settings should not replace the medical home, but rather serve as a critical safety net for high-risk individuals and communities in situations where access to traditional locations may be limited such as during the COVID-19 pandemic

Omecene, N.E., et al. Implementation of pharmacist-administered pediatric vaccines in the United States: major barriers and potential solutions for the outpatient setting. Pharmacy Practice, 2019; 17(2).	• Pharmacists working in outpatient settings are in a prime position to improve pediatric vaccination rates by recommending, administering, or educating families and patients about vaccines
	• Pediatric vaccination rates are less than optimal in the US
	• More than 90% of the US population lives within 2 miles of a community pharmacy, and these present accessible options to improve vaccination rates and capacity
	• Studies have consistently demonstrated improved adult vaccination rates with community pharmacy involvement, though literature in the pediatric population is lacking, but one could expect similar success
	• *Potential barriers to pharmacist-administered vaccines in outpatient settings and potential solutions*
	  ○ Regulatory barriers, however states continue to pass legislation to expand pharmacist authority to administer pediatric vaccines; training should be provided to pharmacy students
	  ○ Attitudinal barriers – physician and parental, specifically. For physicians, pharmacists can consider collaborating with them to gain comfort, and implementation of a immunization delivery program for pharmacists. For parental barriers, evidence suggests increasing parental familiarity and experience with pharmacist-administered vaccination through advocacy may improve buy-in
	  ○ Logistical barriers – missed opportunities for vaccination are a relevant risk factor for pediatric patients in the US; injections for patients under 2 require specific positioning for injections into anterolateral thigh muscle – if sole pharmacist, may be difficult. Additionally, anecdotally, pharmacists are less willing to provide injections to kids under 2.
	Continued on next page

Reference	Summary
McKeirnan, K., and Sarchet, G. Implementing Immunizing Pharmacy Technicians in a Federal Healthcare Facility. Pharmacy, 2019; 152(7).	• Pharmacy technicians are legally allowed to administer immunizations in specific US states, provided they meet certain criteria, including the completion of an accredited immunization training course • This research sought to gather information about implementing immunizing pharmacy technicians in a federal facility serving a large rural and medically underserved population • From July 2018 to June 2019, seven immunization-trained pharmacy technicians administered over 4,000 injections • Injections were administered to patients ranging from 2 months old to 85 years old • Pharmacy technicians trained and certified to administer immunizations increase access to vaccination care and have the potential to drastically increase the number of immunizations given and reduce the number of deaths from vaccine preventable diseases
Terriff, C.M, and McKiernan, K. Training student pharmacists to administer emergency pediatric influenza vaccine: a comparison of traditional vs. just-in-time training. Currents in Pharmacy Teaching and Learning, 2017 (9).	• In this study, traditional training (TT) and just-in-time training (JITT) of third year pharmacy students was compared for injection training, including injection of pediatrics/infants. Evaluation included a simulated emergency infant vaccination • The American Pharmacist Association (APhA) Pharmacy-Based Immunization Delivery Program includes pediatric content, but the assessment and final certification are only for adolescent and adult immunization administration • JITT for student pharmacists to learn skills required to immunize infants elicits similar outcomes (interest, confidence, comfort and administration competency) as TT for emergency pediatric influenza vaccination
Taddio, Anna. New clinical practice guideline for pain management during routine childhood vaccination – What pharmacist need to know. Canadian Pharmacists Journal, May/June 2011; 144(3).	• This summary article was published in 2011 to inform pharmacists of updated pain management for young children during routine vaccinations (note, this article was published in 2011 and there may be new guidance now) • The guidance includes recommendations for infants and young children

Appendix 5: Injection Training Programs

Table 1. Summary of Pediatric Injection Educational Programs Available for Pharmacists in Canada

Course Name	Course Type	Province	Topics/Learning Objectives
Administering Injections to Young Children (Online Modules) (2020 - 2021), Pear HealthCare Solutions	Online, CCCEP Accredited (note there is an associated in-person workshop that seems to be optional, but is only available in Ontario)	Ontario	• Accurately identify the appropriate injection site for both intramuscular (IM) and subcutaneous (SC) injections for children between the ages of two and five through landmarking • Select the appropriate needle and syringe size for administration of vaccines to toddlers and young children • Demonstrate how to position a young child to prepare for an IM or SC injection • Identify strategies to deal with challenging situations, including highly active children and those who fear needles, and offer approaches to increase comfort and reduce pain in children • Engage the parent/caregiver prior to and during the injection process and discuss vaccination with children and their parent/caregiver • Document injection administration for young children • Discuss how and what to communicate with the interprofessional team within the child's circle of care regarding injection administration • Review what to expect after administering a vaccine to a young child and how to discuss this with the child and parent/caregiver

Injections and Immunizations for Children, PharmAchieve	Online, CCCEP Accredited	Ontario (Available in BC)	1. Demonstrate proper procedures for administering vaccines to children under five years of age
			2. Become familiar with routine immunizations for children and possible precautions or contraindications associated with each vaccine:
			  ○ Choose appropriate distractions for children to redirect focus away from the site of injection
			  ○ Employ additional measures such as use of a sucrose solution, a pain-relieving ointment, or a cooling spray
			  ○ Be knowledgeable of which psychological intervention techniques are effective
			3. Understand and apply techniques to reduce pain and anxiety during vaccination events
			4. Demonstrate a good understanding of vaccine side effects and reactions
			5. Prepare to monitor and follow up with patients after immunization

Mastering Injections in Pediatrics, Ontario Pharmacists Association	Online, CCCEP Accredited	Ontario	• Describe the administration technique for children under five, including the selection of the appropriate supplies, land marking and injection techniques. • Identify the appropriate type and dose of vaccine based on the child's age and previous immunization history. • Demonstrate awareness of the different pain management and comfort techniques that can be used specifically for children. • Recognize potential adverse reactions and understand the appropriate treatment, monitoring and follow-up considerations. • Identify the appropriate documentation and communication procedures necessary for the parent/caregiver and other relevant healthcare professionals. *Continued on next page*

Course Name	Course Type	Province	Topics/Learning Objectives
Administering Injections to Young Children, Pear Healthcare Solutions	Online and Live Workshop, CCCEP Accredited	New Brunswick	Learning Objectives 1: Accurately identify the appropriate injection site for both intramuscular (IM) and subcutaneous (SC) injections for children between the ages of two and five through landmarking Learning Objectives 2: Engage the parent/caregiver prior to and during the injection process and discuss vaccination with children and their parent/caregiver Learning Objectives 3: Demonstrate how to position a young child for an IM and SC injection
Pediatric Injection Techniques, Dalhousie Continuing Education	Online Webinar, Accredited	New Brunswick	This webinar will review intramuscular and subcutaneous injection techniques in pediatric patients, including site selection, needle length, the maximum volume to be administered, and administration process. It will also review common methods of holding pediatric patients during injections.

Appendix 6

College of Pharmacists of British Columbia

DRUG ADMINISTRATION COMMITTEE
November 1, 2021

Amendments to Pharmacist Drug Administration Age Limit

DECISION REQUIRED

Recommended Drug Administration Committee Motion:

The Drug Administration Committee (DAC) recommends that the *Health Professions Act* Bylaws Schedule F Part 4 – Certified Practice – Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions, be amended to lower the patient age limit for drug administration by injection to 4 years of age, as circulated.

Purpose

To provide a recommendation for amendments to the Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions (Standards, Limits and Conditions) to lower the age limit for drug administration by injection to 4 years of age.

Background

Concerns have been raised that some children in British Columbia (BC) may not be able to receive routine vaccines as easily during the COVID-19 public health emergency, as many public health resources have been prioritized for COVID-19 vaccination clinics. The particular concern is that some children may not be able to receive the recommended school entry vaccines for children aged 4-6.

In BC, there are two vaccines recommended for children aged 4-6 prior to entering school: tetanus and diphtheria toxoids, acellular pertussis and inactivated polio vaccine (Tdap-IPV), and measles, mumps, rubella and varicella vaccine (MMRV).[1,2] In addition, an annual influenza vaccine is recommended for children between 6 months and 4 years of age.[3]

[1] As per the BCCDC Immunization Manual, separate MMR and varicella vaccine may be recommended for select special populations

[2] BCCDC Immunization Manual Chapter 2: Immunization, Part 1 – Immunization Schedules

[3] https://www.healthlinkbc.ca/healthlinkbc-files/inactivated-influenza-vaccine

Public health nurses have been reassigned to carry out essential duties related to COVID-19 since at least November 2020, including contact tracing and providing COVID-19 vaccinations.[4] The Ministry of Health has indicated that children can receive necessary publicly funded vaccines from other sources, including community health centres, community pharmacies, and family doctors.[5] Pharmacists are currently permitted to administer publicly funded vaccines by injection to children age 5 and older.[6] While school entry vaccines are recommended for children between the ages of 4 and 6, pharmacists are unable to provide school entry vaccines to children who are 4 years of age. Pharmacists are also unable to provide annual influenza vaccinations to children under 5 years of age.

On June 11, 2021, the Drug Administration Committee (DAC) directed the College to conduct a literature review on decreasing the age restrictions for both immunizations and injections overall and the findings brought back to DAC for further consideration (Appendix 1). The DAC asked the College to consider both the need for the policy change, and to consider what age would be safe and appropriate for the age limit to be lowered to.

Discussion

The current age limit for drug administration by injection in the Standards, Limits and Conditions is in alignment with most other Canadian jurisdictions; however, in the past few years, a few provinces have permitted pharmacists and pharmacy technicians to administer injections to patients as young as 2 years of age (Appendix 2, Table 1). Additionally, in 2020, the United States federal government granted authority to pharmacists in all states to administer vaccinations to children as young as 3 years old during the COVID-19 pandemic.[7] The rationale for this was to increase access to childhood vaccinations in response to declining rates of vaccination, as access to health care services had likely been impacted by COVID-19.

Safety

There have been no significant safety concerns demonstrated in the literature or reported by other Canadian jurisdictions regarding pharmacist administration of injections to young children. The literature describes instances where pharmacy professionals (including pharmacy

[4] https://www.cbc.ca/news/canada/british-columbia/immunization-delays-due-to-covid-19-contact-tracing-1.5811170
[5] https://www.cbc.ca/news/canada/british-columbia/new-westminster-school-trustee-urges-restart-of-school-based-vaccination-program-1.6030430
[6] https://library.bcpharmacists.org/6_Resources/6-1_Provincial_Legislation/5099-HPA_Bylaws_Drug_Administration_Injection_Intranasal.pdf
[7] https://www.hhs.gov/sites/default/files/third-amendment-declaration.pdf

technicians) in North America were appropriately trained and successfully administered vaccinations to children as young as 2 months of age (Appendix 3, Table 1).

Nova Scotia and New Brunswick both allow pharmacists and pharmacy technicians to administer injections to children as young as 2, including vaccines and other drugs. To date, neither regulatory body has received any complaints due to this activity, suggesting it is safe and not a public safety risk. Additionally, there have been no complaints received in Ontario, where pharmacists may administer the flu vaccine to children as young as 2.

Training

Pharmacist injection training programs that are accredited by the Canadian Council on Continuing Education in Pharmacy (CCCEP) must include learning objectives on demonstrating the age-appropriate injection sites and proper client positioning used for immunization, and on choosing the correct needle length and gauge for the age and size of the client. It is up to accredited programs to deliver content that meets the required learning objectives. Because of BC's current age limit, there is no specific training for injecting patients under the age of 5, however students are provided with resources and information on where to find relevant information should it be required.

The literature suggests pharmacists should be aware of several considerations when vaccinating children as young as two, particularly administration sites, needle size, positioning and pain management strategies (Appendix 3, Table 1). Pharmacists may require additional training to ensure they are competent in these areas when administering vaccines to young children. However, in general, techniques for administering subcutaneous and intramuscular injections are not significantly different for patients 4 years of age compared to those who are 5.[8]

There are CCCEP accredited training programs available in Canada for pharmacists to learn about pediatric injections in children under the age of 5 that include learning objectives on selecting appropriate needle and syringe sizes, positioning techniques, and pain management strategies (Appendix 4). Most programs are only available in certain provinces, and only one program appears to be available to pharmacists across Canada (the PharmAchieve program). Most focus on vaccination of pediatric patients, but don't appear to be limited to training on vaccines only.

[8] BCCDC Communicable Disease Control Manual, Chapter 2: Immunization, Appendix B: Administration of Biological Products (p. 16, 23). Accessed October 19, 2021.

Of the jurisdictions that permit pharmacists to administer vaccines to children as young as 2 years of age, only one (New Brunswick) requires pharmacists undertake additional training (Appendix 2, Table 2).

Need for Policy Change

Access to health care services, including vaccine access, is the responsibility of the Ministry of Health, and is not within the College's jurisdiction. The College has not received a request from the Ministry of Health to amend the *Standards, Limits and Conditions* to improve vaccine access for children under 5 years of age. However, a change to the College's requirements could have a beneficial impact on public health and safety.

Pharmacists in BC have been involved in administering publicly funded vaccines to patients 5 years and up for many years. Pharmacists in Vancouver Coastal Health are involved in an immunization "catch-up" program for older school age children who have missed routine vaccinations.[9] Additionally, Fraser Health recommends children may receive school entry vaccines from a pharmacist, for children 5 years of age and older.[10]

In general, the literature suggests there are many demonstrated public benefits to pharmacists administering vaccines to adults, including increased vaccination coverage of high-risk populations, improvement in the patient experience of care, and benefits to the health system (Appendix 3, Tables 2 and 3). Increased vaccination rates are due to the availability of pharmacists, the convenience of receiving a vaccine at a local pharmacy, and health promotion activities conducted by pharmacists. These benefits reported for adult patients are expected to extend to the pediatric population as well. Pharmacies have been recommended as alternative vaccination sites to improve vaccination uptake for children and adolescents where access may be an issue.

To further explore this issue, the College had a discussion on September 29, 2021 with the BC Immunization Committee (BCIC), a group tasked with overseeing the implementation of the ImmunizeBC Framework, about the potential benefits or consequences of pharmacists administering vaccines to children as young as 2.[11,12] Several issues were discussed:

- The general public health benefits to increasing the "pool of immunizers".

[9] http://www.vch.ca/public-health/communicable-diseases-immunizations/immunizations/school-age-immunization-campaign
[10] https://www.fraserhealth.ca/health-topics-a-to-z/immunizations/children-and-youth-immunization#.YRbrkYhKiUk
[11] https://www.health.gov.bc.ca/library/publications/year/2007/immunizebc.pdf
[12] https://www2.gov.bc.ca/assets/gov/health/health-drug-coverage/pharmacare/vaccine-guide.pdf

- Questions about pharmacists' training regarding pediatric care in general and competency to administer injections to very young kids, and about how those competencies would be maintained.
- Questions about why age "2" was chosen, vs. age "4" which would capture the children eligible for school-entry vaccines. It was noted that there is added complexity when it comes to immunization "catch-up" for children who missed their 18-month vaccines, and may be needing them at 2 years of age.
- Existing operational concerns with pharmacists administering publicly funded vaccines, including documentation, recordkeeping, and communication with health authorities.

The Pharmacists and Immunization Working Group, a working group of the BCIC, published a guidance document for pharmacists in early 2021 that addresses some of the existing operational concerns identified by the BCIC.[13] Pharmacists would continue to be expected to offer publicly funded vaccines by working with their local public health units and in accordance with the recommendations of the BC Centre for Disease Control. Many operational issues identified exist today and are managed at the program level, as they are not in the jurisdiction of the College. The BCIC indicated they are interested in hearing about how the College expects to proceed with any changes to the age limits for immunization.

Regarding continuing competency, it would be up to each pharmacist to ensure they maintain the competencies required to administer an injection to a young child. BC's drug administration re-certification process requires a pharmacist administer at least one injection every 3 years to maintain competency; this is in general alignment with other Canadian jurisdictions that permit pharmacists to administer injections to young children (Appendix 2, Table 2).

COVID-19 Vaccination for Children Age 5-11

COVID-19 vaccines in BC have been offered to the public based on year of birth and not actual age.[14] If COVID-19 vaccines are approved in Canada for the 5-11 age group, it is likely that some 4-year-old patients would be eligible for vaccination based on their year of birth (e.g., children aged 4 but turning 5 that calendar year may be eligible to receive the COVID-19 vaccine, depending on final public health recommendations). It is expected that some pharmacies will provide COVID-19 vaccines to the 5-11 age group.[15] Under the current College limitation,

[13] Pharmacists and Publicly Funded Vaccines in B.C. General Information. Available from: https://www2.gov.bc.ca/assets/gov/health/health-drug-coverage/pharmacare/vaccine-guide.pdf
[14] https://immunizebc.ca/ask-us/questions/covid-19/which-age-group-do-i-fit-my-birthday-year-puts-me-different-group-depending-on-time
[15] https://bc.ctvnews.ca/pharmacies-doling-out-moderna-and-pfizer-in-pilot-project-just-before-younger-kids-expected-to-be-oked-for-vaccine-1.5623691

pharmacists would only be permitted to vaccinate children who have already turned 5 years old. Depending on the availability of other COVID-19 vaccine centres in the area, this may create a barrier for some children aged 4 to receive a COVID-19 vaccine.

Recommendation

That the DAC recommend the Standards, Limits and Conditions be amended to lower the age limit for drug administration by injection to 4 years of age, as circulated (Appendix 5).

This recommendation is supported by the absence of any known public safety concerns, and by similar policy changes in Canada and the United States. Injection techniques do not differ significantly between children aged 4 and 5.

Implementing this change addresses the key issues discussed by the DAC by allowing pharmacists already involved in health authority-based immunization "catch-up" programs to administer school entry vaccines to children who are 4 years of age, and, in the future, allow pharmacists to provide COVID-19 vaccines to eligible children who are turning 5.

Next Steps

If approved, the recommendation from the DAC will be presented to the Board for further approval and filing with the Ministry of Health.

Appendix	
1	June 2021 Drug Administration Committee Briefing Note (without appendices)
2	Inter-jurisdictional Scans – Patient Age Restrictions and Education Requirements
3	Summary of Literature Search
4	Injection Training Programs
5	Proposed Amendments to the *Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions* (clean and track changes)

HPA BYLAWS SCHEDULE F
Part 4 – CERTIFIED PRACTICE – DRUG ADMINISTRATION BY INJECTION AND INTRANASAL ROUTE
STANDARDS, LIMITS AND CONDITIONS

APPLICATION

This Part applies to all practising pharmacists, and should be read in conjunction with sections 4 (c.1) and 4.1(1) of the *Pharmacists Regulation,* B.C. Reg. 417/2008 under the *Health Professions Act,* R.S.B.C. 1996 c. 183, and in conjunction with sections 43, 43.1 and 46(5.1) of the College bylaws made under the *Health Professions Act.*

STANDARDS

1. A pharmacist who administers a drug acts in the best interest of the patient and takes all appropriate steps to ensure that the drug is administered safely.

2. A pharmacist who administers a drug does so within the scope of their education, training and competence.

3. A pharmacist must assess the appropriateness of the drug for a patient, including:
    (a) Appropriate indication for the patient
    (b) Appropriate dose and route of administration
    (c) Appropriate time and frequency for administration
    (d) Allergy status
    (e) Risk factors, including immunosuppression and pregnancy
    (f) Contraindications and precautions including anaphylaxis and fainting
    (g) Prior immunization history, if applicable

4. Obtain informed consent from the patient or patient's representative with regards to:
    (a) Drug to be administered
    (b) Purpose of the drug
    (c) Benefits and risks of the drug
    (d) Expected reaction
    (e) Remaining for an appropriate wait period following administration of the drug

5. If administering a drug by injection, prepare and provide care of the injection site including:
    (a) Assessing the injection site
    (b) Selecting and landmarking the injection site
    (c) Determining the requirement for dressings

6. Prepare for drug administration including:
    (a) Taking appropriate steps to ensure the right drug is administered to the right patient
    (b) Ensuring the drug is stable, and has been stored and labelled appropriately prior to administration
    (c) Using aseptic technique and universal precautions for infection control in preparation, administration, and disposal of the drug

7. Following drug administration, a pharmacist must
   (a) Ensure devices, supplies and any remaining drug are disposed of safely and appropriately
   (b) Ensure the patient is appropriately monitored
   (c) Notify and provide relevant information to other health professionals, as appropriate
   (d) Report adverse events or reactions to the applicable government agency, as required

8. A pharmacist must document for each drug given:
   (a) Informed consent
   (b) Assessment of the appropriateness of the drug for the patient
   (c) Drug and dose administered
   (d) Lot number and expiry date of the drug
   (e) Route of administration
   (f) Site of administration
   (g) Date and time of administration
   (h) The identification of the pharmacist who administered the drug
   (i) Patient response
   (j) Any adverse reaction experienced due to the drug administered and management provided
   (k) Patient or patient's representative contact information
   (l) Providing patient or patient's representative with the administering pharmacist's contact information
   (m) Patient teaching done, including adverse reactions and management and plans for follow-up

9. Ensure there is ready access to drugs, devices and other necessary equipment and supplies used to treat reactions to administered drugs.

10. Respond appropriately to complications and emergencies if they arise.

11. Develop, maintain and review, at least annually, a policy and procedure manual including:
   (a) Emergency procedure and treatment protocol
   (b) Precautions required for patients with latex allergies

12. Maintain a setting within which the drug is to be administered that is clean, safe, comfortable and appropriately private and furnished for the patient.

LIMITS

1. A practising pharmacist must not administer a drug by injection or intranasal route unless it is for the purpose of immunization.
2. A practising pharmacist must not administer an injection to a child under 4 years old.
3. A practising pharmacist must not administer a drug by intranasal route to a child under 2 years old.

CONDITIONS

1. A practising pharmacist must apply to the College of Pharmacists of B.C. for certification to administer immunizations within 1 year of successful completion of the required certification program.

2. A practising pharmacist must not provide immunization services in B.C. prior to receiving notification from the College of Pharmacists of B.C. of their certification to administer immunizations.

HPA BYLAWS SCHEDULE F
Part 4 – CERTIFIED PRACTICE – DRUG ADMINISTRATION BY INJECTION AND INTRANASAL ROUTE
STANDARDS, LIMITS AND CONDITIONS

APPLICATION

This Part applies to all practising pharmacists, and should be read in conjunction with sections 4 (c.1) and 4.1(1) of the *Pharmacists Regulation,* B.C. Reg. 417/2008 under the *Health Professions Act,* R.S.B.C. 1996 c. 183, and in conjunction with sections 43, 43.1 and 46(5.1) of the College bylaws made under the *Health Professions Act.*

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2. A pharmacist who administers a drug does so within the scope of their education, training and competence.

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    (a) Appropriate indication for the patient
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    (c) Appropriate time and frequency for administration
    (d) Allergy status
    (e) Risk factors, including immunosuppression and pregnancy
    (f) Contraindications and precautions including anaphylaxis and fainting
    (g) Prior immunization history, if applicable

4. Obtain informed consent from the patient or patient's representative with regards to:
    (a) Drug to be administered
    (b) Purpose of the drug
    (c) Benefits and risks of the drug
    (d) Expected reaction
    (e) Remaining for an appropriate wait period following administration of the drug

5. If administering a drug by injection, prepare and provide care of the injection site including:
    (a) Assessing the injection site
    (b) Selecting and landmarking the injection site
    (c) Determining the requirement for dressings

6. Prepare for drug administration including:
    (a) Taking appropriate steps to ensure the right drug is administered to the right patient
    (b) Ensuring the drug is stable, and has been stored and labelled appropriately prior to administration
    (c) Using aseptic technique and universal precautions for infection control in preparation, administration, and disposal of the drug

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10. xAppendix 7 - Proposed Amendments to the Drug Administration Standards (Track Changes)~~5. xAppendix 5 - Proposed Amendments to the Drug Administration Standards (Track Changes)~~HPA_Bylaws_Drug_Administration_Injection_Intranasal v2019.1 (Track Changes) Posted 2016-06-06

7. Following drug administration, a pharmacist must
   (a) Ensure devices, supplies and any remaining drug are disposed of safely and appropriately
   (b) Ensure the patient is appropriately monitored
   (c) Notify and provide relevant information to other health professionals, as appropriate
   (d) Report adverse events or reactions to the applicable government agency, as required

8. A pharmacist must document for each drug given:
   (a) Informed consent
   (b) Assessment of the appropriateness of the drug for the patient
   (c) Drug and dose administered
   (d) Lot number and expiry date of the drug
   (e) Route of administration
   (f) Site of administration
   (g) Date and time of administration
   (h) The identification of the pharmacist who administered the drug
   (i) Patient response
   (j) Any adverse reaction experienced due to the drug administered and management provided
   (k) Patient or patient's representative contact information
   (l) Providing patient or patient's representative with the administering pharmacist's contact information
   (m) Patient teaching done, including adverse reactions and management and plans for follow-up

9. Ensure there is ready access to drugs, devices and other necessary equipment and supplies used to treat reactions to administered drugs.

10. Respond appropriately to complications and emergencies if they arise.

11. Develop, maintain and review, at least annually, a policy and procedure manual including:
   (a) Emergency procedure and treatment protocol
   (b) Precautions required for patients with latex allergies

12. Maintain a setting within which the drug is to be administered that is clean, safe, comfortable and appropriately private and furnished for the patient.

LIMITS

1. A practising pharmacist must not administer a drug by injection or intranasal route unless it is for the purpose of immunization.
~~1. A practising pharmacist must not administer any Schedule IA drug by injection or intranasal route.~~
~~2. A practising pharmacist must not administer drugs and substances for cosmetic purposes by injection.~~
~~3.~~2. A practising pharmacist must not administer an injection to a child under ~~5~~ 4 years old.

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~~4.~~3. A practising pharmacist must not administer a drug by intranasal route to a child under 2 years old.

CONDITIONS

1. A practising pharmacist must apply to the College of Pharmacists of B.C. for certification to administer ~~Schedule I and II drugs by injection or intranasal route~~immunizations within 1 year of successful completion of the required certification program.

2. A practising pharmacist must not ~~administer a drug or substance by injection or intranasal route~~provide immunization services in B.C. prior to receiving notification from the College of Pharmacists of B.C. of their certification to administer ~~drugs and substances by injection or intranasal route~~immunizations.

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10. xAppendix 7 - Proposed Amendments to the Drug Administration Standards (Track Changes)~~5. xAppendix 5 - Proposed Amendments to the Drug Administration Standards (Track Changes)~~HPA_Bylaws_Drug_Administration_Injection_Intranasal v2019.1 (Track Changes) Posted 2016-06-06

College of Pharmacists of British Columbia

9. Drug Administration Committee: Amendments to the HPA Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions

Alex Dar Santos

Member, Drug Administration Committee

College of Pharmacists of British Columbia

Purpose of Presentation

- To provide a recommendation for an amendment to the Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions (Standards, Limits and Conditions) to lower the patient age limit for drug administration by injection to 4 years of age.

College of Pharmacists of British Columbia

Background

- Concerns have been raised that some children in BC have not been able to receive routine vaccinations as easily during the COVID-19 public health emergency.
- Many public health resources have been prioritized for COVID-19.
- Main concern: some children aged 4 may not be able to receive recommended school- entry vaccines.

College of Pharmacists of British Columbia

School-Entry Vaccinations

- School-entry vaccines are recommended for children aged 4-6 prior to entering kindergarten.
- In British Columbia, there are two vaccines recommended for children aged 4-6 prior to entering school.
- As per ImmunizeBC, immunizations are not mandatory for school-entry in BC, but are recommended for children as soon as they are eligible.

College of Pharmacists of British Columbia

School-Entry Vaccinations

- Concern has been raised that some children, particularly those age 4, are not able to receive the recommended school-entry vaccines from a pharmacist, since pharmacists may not inject a patient under 5 years of age

LIMITS

1. A practising pharmacist must not administer a drug by injection or intranasal route unless it is for the purpose of immunization.
2. A practising pharmacist must not administer an injection to a child under 5 years old.
3. A practising pharmacist must not administer a drug by intranasal route to a child under 2 years old.

College of Pharmacists of British Columbia

June 11, 2021 Meeting of the DAC

- On June 11, 2021, the Drug Administration Committee (DAC) met.
- The DAC directed the College to further look into this issue.

College of Pharmacists of British Columbia

Inter-Jurisdictional Scan

- An interjurisdictional scan was conducted.
- The College's current age limit for drug administration by injection aligns with most other Canadian jurisdictions.
- However, a few provinces have recently allowed pharmacists to administer injections to patients as young as 2 years of age.
- In 2020, the United States federal government granted authority to pharmacists in all states to administer vaccinations to children as young as 3 years of age during the COVID-19 pandemic.

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Safety

- No significant safety concerns identified where pharmacy professionals administer drugs by injection to children under the age of 5.
  - Pharmacy professionals have been trained and successfully vaccinated many individuals as young as 2 months of age.
  - No reported safety concerns from other pharmacy regulatory authorities in Canada that allow pharmacy professionals to administer injections to young children.

College of Pharmacists of British Columbia

Training

- Pharmacists in BC do not typically receive training on how to administer an injection to a child under 5 years of age.
- Based on the BC Immunization Manual, no significant difference for patients aged 5 compared to patients 4 years of age, in:
  - recommended immunization technique,
  - location of administration, and
  - needle size.
- Differences in muscle mass must be considered.

College of Pharmacists of British Columbia

Training

- Should a pharmacist determine they need additional training, Canadian Council on Continuing Education in Pharmacy (CCCEP) accredited training programs are available for pharmacists to enhance their knowledge about pediatric injection.
- Programs include learning objectives on
  - selecting appropriate needle and syringe sizes,
  - positioning techniques, and
  - pain management strategies.

College of Pharmacists of British Columbia

Need for Policy Change

- Access to health care services, including vaccine access, is the responsibility of the Ministry of Health.
- The College has not received a request from the Ministry of Health to change the Standards, Limits and Conditions.
- A change to the College's requirements could have a beneficial impact on public health and safety.

College of Pharmacists of British Columbia

Need for Policy Change

- Pharmacists in BC have been involved in administering publicly funded vaccines to patients 5 years and up for many years, including participating in health authority-run vaccine “catch-up” programs for children.
- Reducing the age limit to capture 4-year-old children could have a beneficial impact for children accessing school-entry vaccines from a pharmacy.

College of Pharmacists of British Columbia

November 1, 2021 Meeting of the DAC

- The DAC met on November 1, 2021 to consider the College's findings.
- The DAC recommended that the Standards, Limits and Conditions be amended to reduce the patient age limit for drug administration by injection to 4 years of age

College of Pharmacists of British Columbia

Approved In-Principle Standards

- In 2020, the Board was presented with proposed general updates to the Standards, Limits and Conditions, which also included the removal of the restriction that limits pharmacists to administering “immunizations-only”.
- In November 2020, the Board approved the updates as recommended by the DAC, however the updated Standards, Limits and Conditions were not approved for filing with the Ministry of Health due to the ongoing bylaw moratorium and ongoing work with the Ministry.

College of Pharmacists of British Columbia

Approved In-Principle Standards

- The general updates to the Standards, Limits and Conditions approved by the Board were informed by
  - Relevant standards from other provincial regulatory authorities;
  - Internal review; and,
  - Clarification needs.
- The updates included amendments to existing standards, as well as the addition of new standards in the interest of patient safety, and are described on the following slides.

College of Pharmacists of British Columbia

Approved In-Principle Standards

- New standard requiring pharmacists to act in best interest of the patient, and take all appropriate steps to ensure the drug is administered safely
- New standard requiring pharmacists who administer a drug to do so within the scope of their education, training and competence
- Added requirement to ensure the patient is appropriately monitored
- Added requirement for safe and appropriate disposal of devices, supplies and remaining drug, following administration

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Approved In-Principle Standards

- Added documentation requirements, including documenting the expiry date of the drug, the identification of pharmacist who administered the drug, and the patient response to drug administration
- New requirement to ensure there is access to the drugs and supplies needed to manage adverse reactions, and removal of specific examples of emergency measures
- Broadened requirement to respond appropriately to complications and emergencies if they arise

College of Pharmacists of British Columbia

Bylaw Moratorium Update

- The Ministry of Health announced a partial lifting of the bylaw moratorium in the summer of 2021.
- Bylaw changes will be prioritized by the Ministry based on several factors, including alignment with Government priorities and those that address BC's public health emergencies.
- Work with the Ministry regarding the removal of the limit on "immunizations-only" is ongoing, and it's recommended this part of the approved standards not be moved forward at this time.
- The Ministry also requested that there not be a change to the "15-30 minute" wait period, at this time.

College of Pharmacists of British Columbia

Recommendation

- The Board approve the proposed amendments to the Standards, Limits and Conditions and file with the Ministry of Health, to lower the patient age limit for drug administration by injection to 4 years of age, and
- Include the other minor updates for filing as previously approved by the Board, but not to remove the limit that restricts pharmacists to administering immunizations only.
- Consider the Ministry request to College staff that there not be a change to the “15-30 minute” wait period, at this time.

College of Pharmacists of British Columbia

Next Steps

- If approved by the Board, amendments to the Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions will be submitted for filing with the Ministry of Health, for a period of 60 days.

College of Pharmacists of British Columbia

9. Amendments to the HPA Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions

MOTION:

Approve the following resolution to amend the Health Professions Act Bylaws Schedule F Part 4 – Certified Practice – Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions to lower the patient age limit for drug administration by injection to 4 years of age, and to include other minor updates as previously approved by the Board, but not remove the limit that restricts pharmacists to administering immunizations only nor the 15-30 minute wait period, as circulated.

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

College of Pharmacists of British Columbia

Questions

College of Pharmacists of British Columbia

BOARD MEETING
November 26, 2021

10. Governance Committee
b) Board Meeting Guidelines: Robert Rule's to BCCNM Meeting Guidelines

DECISION REQUIRED

Recommended Board Motion

Direct the Registrar to bring forward Board meeting guidelines, based on those from the British Columbia College of Nurses and Midwives, and associated bylaw amendments for the February 2022 meeting.

Purpose

To seek Board approval to give direction to the Registrar to:

- Develop a modified version of the British Columbia College of Nurses and Midwives' ("BCCNM") Board Meeting Guidelines document; and,
- Develop bylaw amendments to remove Robert's Rules or Order as the document that governs the procedures of Board meetings.

Background

Relevant Legislative and Bylaw Authority

Section 19 (1)(c) of the *Health Professions Act* ("the HPA") states that the Board may make bylaws to, *"regulate the time, place, calling and conduct of meetings of the board and general meetings of the registrants".* Bylaws made under this authority are not required to be publicly posted, and only need to be filed for a 60-day period with the Ministry of Health, prior to taking effect.

Currently, College Board meeting procedures are governed by the most recent edition of Robert's Rules of Order. This is required under s.13,(15) of the *Health Professions Act Bylaws* ("the Bylaws"), which states:

> *"Except as otherwise provided in the Act, the regulations, or these bylaws, the most recent edition of Robert's Rules of Order governs the procedures at meetings of the Board."*

College of Pharmacists of British Columbia

BOARD MEETING
November 26, 2021

Robert's Rules of Order is a manual of parliamentary procedure to help guide meeting conduct and group decision-making.

BCCNM Meeting Guidelines
The Board of the BCCNM uses a set of guidelines as a key mechanism to govern their meeting procedures. The BCCNM Board Meeting Guidelines outlines how their meetings are structured and planned, and how balanced, unbiased, and relevant decisions can be made to support their college's mandate. The BCCNM's Board Meeting Guidelines are attached in Appendix 1.

The BCCNM Board Meeting Guidelines is a plain language document outlining relevant information and procedural rules under the following topics:

- Types of Meetings
- Ways to Meet
- Meeting Materials and Logistics
- Decision-Making
- The Role of the Chair

The BCCNM Meeting Guidelines has a particular focus on consensus decision-making. In fact, it states that, "*The Board has agreed that its decisions will be achieved through consensus whenever possible*." It highlights that reaching consensus can be challenging, and at times, not appropriate. However, it is a type of decision-making that works best where there is openness and trust, and the group has a common goal, a clear process, and a strong commitment to finding a balanced solution.

Discussion

The Governance Committee ("the Committee") has been discussing whether Robert's Rules of Order is still the most applicable guideline for governing College Board meetings. The most recent edition of the manual is about 700 pages, containing formal parliamentary rules and procedures, which is considered appropriate for larger group settings. Since the College Board is generally a small group (e.g., consisting of 12 members, with possible fluctuations in size) it may be unnecessary and cumbersome for the Board to use Robert's Rule of Order to guide its meeting procedures and management.

The Committee has stated an interest in adopting BCCNM's Board Meeting Guidelines as they may be better suited for the intended purposes of Board meetings.

To implement an adapted version of BCCNM's Board Meeting Guidelines, HPA Bylaw amendments must be made to reference the meeting guidelines approved by the Board, and remove the reference to the Robert's Rules of Order. Any subsequent updates to the meeting guidelines could be implemented with Board approval only, thereby removing the need to continually amend the HPA Bylaws regarding this matter.

College of Pharmacists of British Columbia

BOARD MEETING
November 26, 2021

Options

Option 1
Continue using Robert's Rule of Order to govern meeting procedures and conduct of the Board.

Pros

- No bylaw amendments are needed.
- No change management needs to be considered for new Registrar or Board members.
- Robert's Rule of Order's formal structure and rules promotes efficient meeting procedures and decision-making.

Cons

- Robert's Rule of Order is lengthy and was developed as a parliamentary manual, which may be unnecessary and cumbersome for an organization governed by a smaller group of directors, such as the College Board.
- May limit discussion at the Board table as Robert's Rules of Order generally promotes a quite formal approach to decision-making.
- If the HPA Bylaws regarding Board meeting procedures stays current, there will remain no real flexibility in deviating from the use Robert's Rule of Order.

Option 2
Direct the Registrar to develop a modified version of BCCNM's Board Meeting Guidelines to govern the procedures of Board meetings with an aim to no longer use Robert's Rules of Order. The modified meeting guideline document along with associated HPA Bylaw amendments would be brought forward for consideration at the February 2022 Board meeting.

Pros

- The BCCNM Board Meeting Guidelines may be better suited for smaller groups, such as the College Board.
- The BCCNM Board Meeting Guidelines may be easier to follow and understand, as they are written in plain language and not as lengthy as Robert's Rules.
- The BCCNM Meeting Guidelines focus on a consensus-decision making model, which may enable more discussion around the Board table.
- Amending the HPA Bylaws to refer to guidelines approved by the Board enables the Board to make future changes to the guideline document, without going through the bylaw amendment process.

Cons

- With a new set of meeting rules, change management processes will have to be considered.
- Shifting from a more formal structure meeting process to one focused on a consensus model of decision-making may be less efficient and consensus may be difficult to reach.

Recommendation

The Governance Committee recommends Option 2, which is to direct the Registrar to adopt a modified version of BCCNM's Board Meeting Guidelines and bring forward associated bylaw amendments to the February 2022 Board meeting. This option is recommended for the following reasons:

- Robert's Rule of Order is better suited for parliamentary bodies that need to follow a quite formal and rigid set of rules to enable efficient decision-making.
- A modified version of BCCNM's Board Meeting Guidelines focuses on consensus-based decision-making, which may better enable thorough discussion around the Board table.
- Amending the HPA Bylaws to refer to Board-approved meeting guidelines, will enable flexibility should the Board wish to make future changes to the guidelines. To do so, the Board would merely approve the meeting guideline changes, and it would not need to amend the HPA Bylaws.

Guiding Questions

1. Is Robert's Rules of Order the most appropriate and applicable meeting guidelines to govern Board meetings?
2. Are BCCNM's Board Meeting Guidelines more applicable and better suited for the Board?

Appendix

College of Pharmacists of British Columbia

BOARD MEETING
November 26, 2021

1	BCCNM Board Meeting Guidelines

British Columbia College of Nurses & Midwives

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BCCNM STRATEGY AND GOVERNANCE

Board Meeting Guidelines

Approved by BCCNM Board on July 28, 2020

Effective September 1, 2020

Introduction

The BC College of Nurses and Midwives (BCCNM) is committed to ensuring its board members are well-informed, engaged in a culture of trust and respect, empowered to contribute freely, and able to participate in positive and robust interactions with their peers. Board meetings serve as the primary forum for board discussions and decision-making. An effective meeting is defined as "*the assembly of people gathering to discuss ideas and make decisions that produce an outcome of value*" and BCCNM builds on this through its drive to cultivate meeting space that is safe, unoppressive, and inclusive.

These guidelines are intended to help board members understand how their meetings are structured and planned, and how balanced, unbiased, and relevant decisions can be made to support the fulfilment of BCCNM's legislated authority as set out in the *Health Professions Act* (the "Act"). The guidelines work in conjunction with the duties and responsibilities of board members as established in the Oath of Office, BCCNM Bylaws, and the Code of Conduct, and are grounded by a clear mandate, strong values, and coherent strategic priorities.

These guidelines reference regulatory trends as well as best practices across the realm of governance. They are also informed by agreements that extend beyond the college, notably the Declaration of Commitment to Cultural Safety and Humility, signed by all provincial health regulators in March 2017 that sets out a vital pledge to increase the level of cultural safety and humility, health literacy, and relationship-based care to improve health outcomes for First Nations people.

These guidelines do not apply to general college meetings such as the annual general meeting or special general meetings (as defined in the bylaws). Separate procedural rules govern those types of meeting.

Types of Meeting

There are several types of meeting that board members can expect to attend during their tenure. The agenda will indicate the type of meeting and, depending on the nature of the discussion, items can be moved between open and closed agendas.

1. Open

This type of meeting is open to all staff, registrants, and the public. Meeting dates and guidelines for those who wish to attend an open session are posted on the BCCNM website and interested parties can register in advance (space is usually limited). Minutes are recorded for these meetings and published on the college's website.

2. Closed

This type of meeting is open to staff involved in discussion items but closed to registrants and the public. Minutes are recorded for these meetings but are not published on the college's website. Section 19(2) of the bylaws establishes the conditions under which a meeting can be closed, as follows:

> *"19(2) The board may exclude any person who is not a board member from any board meeting or part of a board meeting if the person's attendance at the board meeting is disruptive or if the board is satisfied that one or more of the following matters will be discussed:*
>
> *(a) financial or personal or other matters of such a nature that the interest of any affected person, or the public interest in avoiding disclosure of those matters, outweighs the public interest in board meetings being open to the public;*
>
> *(b) information concerning an application by any individual for registration under section 20 of the Act or a certified practice designation under section 151 [Certified practice designations], or reinstatement or renewal thereof, the disclosure of which would be an unreasonable invasion of the applicant's personal privacy;*
>
> *(c) information concerning a complaint against, or investigation of, any individual under Part 3 of the Act, the disclosure of which would be an unreasonable invasion of the individual's personal privacy;*
>
> *(d) information concerning an assessment of the professional performance of a registrant under section 26.1 of the Act or the registrant's compliance with competency or quality assurance requirements established under Part 6 [Quality Assurance and Professional Responsibilities], the disclosure of which would be an unreasonable invasion of the individual's personal privacy;*

(e) information the disclosure of which may prejudice the interests of any person involved in (i) a proceeding under the Act, including a disciplinary proceeding under Part 3 of the Act or a review under Part 4.2 of the Act, or (ii) any other criminal, civil or administrative proceeding;

(f) information described in section 75 [Disclosure of education program review information];

(g) personnel matters;

(h) property acquisitions;

(i) the contents of examinations;

(j) information concerning the scoring or results of examinations, a report of the registrar under section 87(6) [Examinations] or a request for approval to take an examination again under section 87(11) or (12) [Examinations], the disclosure of which would be an unreasonable invasion of any individual's personal privacy;

(k) communications with the Office of the Ombudsperson;

(l) instructions given to or opinions received from legal counsel, or any other matter which is subject to solicitor-client privilege;

(m) information that the college would be required or authorized to refuse to disclose to an applicant making a request for records under Part 2 of the Freedom of Information and Protection of Privacy Act;

(n) information that the college is otherwise required by law to keep confidential."

3. In-Camera

This type of meeting is a subset of a closed meeting and therefore must meet the criteria set out in section 19(2) of the bylaws. It may be open to certain staff at the invitation of the Board depending on the matter under discussion but is closed to registrants and the public.

An example of an in-camera meeting would be an update from the Chief Officer or HR consultant supporting the registrar evaluation process, or a discussion where the Board wishes to speak to the Registrar in private.

Minutes are recorded for these meetings by the staff member in the meeting but are secured with limited access. These minutes are not published on the college's website but are available on request only to those who attended the in-camera meeting.

4. Board-Only Session

This type of meeting is closed to all but board members. It too is a subset of a closed meeting and must meet the criteria of section 19(2) of the bylaws. No college business is conducted during this session, no formal action can be taken, and no minutes are recorded; because of this, the Board needs to be rigorous with respect to what is discussed in this forum.

The purpose of a board-only meeting is self-reflection. For example, the Board may wish to use this time to evaluate its own effectiveness or the effectiveness of meetings, to foster board culture by having an open discussion about behaviours, examine its relationship with management, or reinforce good practices. If the Board finds itself having conversations that are broader than self-reflection, it must determine if minutes are required and, if so, which members of staff should be included to support and record the discussion.

5. Strategy Session

This type of meeting might be embedded within another scheduled meeting or at a separate time. Its purpose is for the Board to work with management to set the mandate, vision, and strategic direction for the college, and proactively review and assess future-facing issues that may affect or guide college business. Notes are usually kept for this type of meeting to assist management in developing strategy or plans, but no formal minutes are kept.

6. Education Session

The purpose of an education session is to ensure that board members have the knowledge, information, and tools to be most effective in their roles. No minutes are recorded for this type of meeting, but educational support materials are kept for future reference.

Ways to Meet

How and where a meeting takes place are important considerations. Technology provides greater flexibility than ever, so multiple channels can be made available to board members wherever possible to help manage time, availability, cost, and quorum.

1. In-Person

In-person meetings are the preferred type of meeting for board members, predominantly because board meetings involve significant discussion, planning, problem solving and decision-making. This is the best type of meeting to hold when it is important to reduce distractions and fully engage board members; being face-to-face with colleagues helps build shared understanding, co-operation, and empathy.

2. Teleconference/Videoconference

Videoconferencing has recently become the norm for board meeting format due to the global pandemic. However, the option to attend a meeting remotely – either by teleconference or videoconference– is available to anyone unable to participate in person. Remote meetings tend to work best for straightforward discussions, where no group work is taking place or controversial decisions being made.

3. By Email

Email meetings are convened for one specific purpose only, either when information needs to be disseminated quickly, or an urgent decision is required that cannot wait until the next scheduled board meeting.

Meeting Material and Logistics

1. Agenda

Agendas are prepared by staff in consultation with the Chair and Vice-Chair, based upon the annual work plan for the Board and emerging issues. Any board member may propose an agenda item for consideration by the Board Chair and Registrar in advance of the meeting.

Agendas follow a standard template, which includes the time, date, location and type of meeting, the names of board members who have confirmed their attendance or forwarded their regrets, the names of staff and guests attending the meeting, and a formal acknowledgment of the unceded First Nations territory on which the meeting is taking place. The agenda will list each matter that will be brought forward to the Board, the time estimated for each discussion, whether the Board is receiving the item for information, discussion, or decision, and the material that will be provided to the Board to support its consideration of a matter.

When developing agendas, staff and board leadership need to be confident that:

- the Board is spending the most amount of time on the most important issues;
- the Board will have the information and time to have an appropriate discussion for each agenda item;
- the agenda is not too ambitious for the time allocated;
- the right people will be in the room for each discussion;
- staff are making the best use of the time they have with the Board when face-to-face;
- staff are sure the topics under discussion during a closed or in-camera meeting are appropriately flagged as confidential and properly fall under section 19(2) of the bylaws;
- staff ensure the design of the meeting aligns with the board members' level of engagement and capacity (e.g. deep discussion is not happening at a time when the board members might be tired or distracted).

2. Consent Agenda

On occasion, a consent agenda may be used. This is a technique for addressing multiple decision requests as a single agenda item so the Board can manage its meeting time. Only items that are routine or non-controversial in nature will appear on a consent agenda, or an item that requires perfunctory approval because the Board has already reached consensus in previous discussions.

Board members are expected to have carefully reviewed the items on a consent agenda prior to the meeting. The Chair will ask at the outset of the meeting if any items from the consent agenda need to be moved to the regular agenda for further discussion. Any reason provided by a board member is sufficient to have the item moved. The Chair may then decide to discuss the matter immediately or move the discussion to an appropriate time on the agenda.

If an item is moved but other matters remain on the consent agenda, the Chair will ask for a motion for the consent agenda to be approved as amended. The Chair will subsequently ask for a motion for the regular agenda to be approved as amended (as it will include the new matter for discussion). If no items are moved from the consent agenda, the Chair will ask for a motion for the consent agenda as a whole to be approved. Whenever the consent agenda is approved, each item appearing on it will have its resolution recorded separately in the minutes.

3. Meeting Package

Briefing notes, with supplemental documents, form the basis of the meeting package. Along with the agenda, the meeting package provides board members with the information they need to understand the goal of each discussion, as well as background information, context, and analysis. Management will also be present during the meeting or on call to address any questions that arise.

The meeting package is posted on the college's secure document management system (Collaborations) at least one week prior to the meeting in order to give board members time to read and consider the material. This allows greater time for discussion at the meeting itself. Any changes made to the agenda or meeting package will be communicated to board members either by email in advance of the meeting, or in person by the Chair at the beginning of the meeting.

Upon notification that the meeting package has been posted, and prior to the actual meeting, board members should:

- check they can access the meeting package;
- review the agenda and notify the Chair and Registrar if a conflict of interest is identified (the Chair will also ask board members to declare potential conflicts at the outset of each meeting);
- read the material carefully; and
- submit significant concerns or questions to the Chair ahead of the meeting so that a response can be formulated in time for the meeting.

4. Conduct and Logistics

Board members are referred to section 3 of the Code of Conduct which sets out the requirements for their conduct during the meeting, specifically:

- accountability and integrity;
- active participation and respect;
- diversity and inclusion; and
- cultural safety and humility.

To maximize meeting effectiveness, board members are advised to:

- notify staff in advance if they are unable to attend a meeting or, if the meeting is being held in-person, plan to attend remotely;
- inform the Chair in advance if they plan to join the meeting late or leave early;
- test equipment ahead of time to make sure internet access is available and working and, if possible, to have a contingency in place in the event of system glitches;
- arrive on time, with materials and notes ready to participate in the meeting; and
- turn off any notifications and put away any devices not in use or explain at the outset to the group that an interruption might occur during the meeting.

Board members attending by video- or teleconference are further advised to:

- consider how they might appear on camera, for example, avoiding stripes or bold patterns which can be visually distracting, adjusting lighting to minimize shadows, and reducing background noise;
- have the dial-in number, access codes, or log-in details ready and join the meeting at least 10 minutes early to resolve technical issues;
- if the meeting is late to begin, email the meeting organizer to say they are ready to join the call;
- give full attention to the meeting as they would if in the same room;
- identify themselves if they wish to speak;
- wait to be acknowledged by the Chair before speaking;
- speak clearly and address board members by name if asking specific questions;
- ask for clarity if any part of the discussion is unclear;
- be patient if there is a slight delay in transmission; and
- mute the line when not speaking and not place the call on hold to avoid silence fillers (i.e. news or music) being broadcast to the room.

When the meeting concludes, board members must remember to end the call or connection or, if present in person, ensure that all written meeting material is left in the room for secure disposal.

If there have been any logistical problems with the meeting, board members should provide feedback to staff as soon as possible so these can be addressed.

Staff will ensure that any action items or communications are attended to following the meeting, consulting with the Chair and Vice-Chair where necessary. The Chair will also follow up with board members separately after the meeting if a commitment to discuss matters offline was made. Where a decision needs to be revised, this will generally be addressed by an additional teleconference, email meeting or at the next scheduled board meeting.

Decision Making

1. Staff/Committee Recommendations

Depending on the nature of the decision, staff or committees may include a recommendation in the briefing note. Sometimes a draft resolution will also be provided to support the Board's deliberations. However, at times, staff may lay out the various options without a recommendation or draft resolution if they feel this is more appropriately left to the Board.

Recommendations are never brought forward in isolation: previous discussions, analysis of strategic priorities, consideration of external factors, consultation with stakeholders, and previous board discussions, for example, will have been captured when preparing the briefing note. Additionally, a full review of the issues may have already been completed by committees delegated with such authority by the Board, in which case the Board will get a summary of the process the committee engaged in and a recommendation.

2. Types of Decision

Board members can expect to see four types of decision in their work, each triggering a different decision-making process intended to support strong outcomes and meet the public interest mandate. These types of decision are:

- *Standard Decisions*
  Where information is static, the context is well understood, less background information is required, and minimal discussion is necessary.

- *New Decisions*
  Where an issue has never been addressed, more information may be necessary, and greater discussion and context is required in order for the Board to understand why it is being asked to make a decision at all.

- *Significant Decisions*
  Where issues involve major transactions or commitment to a long-term plan or an action with far-reaching effects that may require longer timeframes for deliberation.

- *Crisis Decisions*
  Where an emergency or significant issue arises, which has a very short timeframe in which to act or respond, and often requires concise information to support efficient decision-making.

3. Decision-making Process

The Chair is responsible for the meeting and makes sure that it runs on time. Decisions are made predominantly by consensus with a confirmation vote (see further below). Depending on the nature of the discussion and the timelines involved, the Chair may consider other processes that support informed decision-making and may hire an external facilitator to support the process.

Currently, the standard process for moving through discussion to decision includes the following:

- Each item on the agenda will be introduced by an identified member of staff, a committee chair or anyone else invited by the Chair to introduce the topic.
- The Chair will open the floor for any questions and discussion arising from the briefing note and background materials.
- The Chair will ensure that every member of the Board has an opportunity to share their perspective.
- For the sake of efficiency and effectiveness, the Chair will ensure that discussion is confined to issues that fall within the Board's authority and are relevant to the issue being discussed.
- Throughout the discussion, the Chair will highlight important points, clarify misunderstandings, and keep the discussion focused on the matters at hand.
- When board members believe they have received the information necessary to consider the issue fully and are ready to move to a decision on the matter, the Chair will request a motion for resolution on which the Board will vote (see section 6 below).
- The Chair will check in with each board member to ensure they have had an opportunity to share their opinion, ask questions, and, upon voting, are comfortable with the decision reached.

4. Consensus Decision-Making

The Board has agreed that its decisions will be achieved through consensus whenever possible. Under circumstances where consensus is not achieved, a vote will take place. Even where consensus has been reached, all decisions of the Board are confirmed with a vote in accordance with section 22 of the bylaws.

What is consensus?

Consensus means finding a decision, solution or proposal acceptable enough that all members can support it, no member opposes it, and all can see that the decision meets their fiduciary duty to make decisions in the best interest of the college and therefore the public.

When does it work best?

This type of decision-making works best when a group has a common goal, a clear process, and a strong commitment to finding the most balanced solution possible. It works best in an environment

that is open and trusting, where board members are actively engaged, clear information is available to the decision-makers, and a skilled Chair is facilitating the discussion.

When doesn't it work?

Consensus is not easy. It takes time, patience, concentration and the co-operation of each participant, and the absence of any of these elements may derail the process. It is for the Chair to assess the wisdom in employing a consensus model, based on the significance of the decision before the group and the dynamics of its board members. There will be times when the Chair realizes that consensus is not appropriate, and a vote will proceed.

Process

A consensus process needs to incorporate the following elements:

Step 1: Clarity of the issue that needs to be resolved
Step 2: Open, but coordinated, discussion where everyone is able to voice their initial perspectives
Step 3: Formation of a proposal based on perspectives and information
Step 4: Test for agreement and amend proposal if required
Step 5: Clarity of the decision for the minutes and actions required

The bylaws do require that some board decisions must have a specific number of votes in order for a resolution to pass. Ordinary resolutions must pass with a majority of votes as cast by board members. Special resolutions require not less than two-thirds of board members to agree before a resolution is passed.

5. Important considerations for Board Members

For a regulatory board, the primary test for any decision will always be whether the outcome serves and protects the public. Board members should keep the scope of the college's mandate and objects uppermost in mind, and may wish to ask themselves the following questions:

- Why are we having this discussion/making this decision?
  - Is it in our mandate?
  - Is it tied to our strategic priorities?
- Do we trust the decision-making process in light of the importance of the decision (risk implications, strategic importance, budget implications, and impact on stakeholders)? If not, what needs to change?
- Are the right people with the right experience and knowledge in the room to support a good decision?
- Have we understood all the necessary facts and information?
- Is there additional information we need to make a good decision?
- Are the assumptions made reasonable?

- Is there more than one possible course of action?
- Do we have agreement on the outcome?
- Would it be better to defer making a decision now, until we have further information or additional time to continue the discussion?

Timeliness of decisions is a key consideration for the Board. An annual calendar/work plan is drawn up at the beginning of the board year, which carefully sets out the various decisions the Board must make at its meetings throughout the year (for example, approval of the budget or financial statements).

When possible, staff will bring items to the Board incrementally, with information, education sessions and smaller decisions leading up to the final request for a decision. This ensures the Board is fully informed and comfortable with the subject matter before a decision is required. Therefore, when the Board decides to defer a decision, it is best practice to think about what the unintended consequences of that deferment might be.

6. Resolutions

A resolution is a written statement of an action approved by the Board. It usually deals only with single or directly related issues, and has two main components:

- the preamble, which begins with the word "WHEREAS", being a brief, concise sentence about the nature of, or the reason for, the request for a resolution; and
- the proposed action or remedy, which begins with the words "BE IT RESOLVED".

Once a decision has been reached, the Chair will call for a motion for resolution. If a draft resolution has been set out in the briefing note, the Chair or member of staff will read it to the Board, making any adjustments, as necessary. Following any further discussion, the Chair will ask the Board to indicate, usually by a show of hands, or verbal acknowledgment for board members attending remotely, acceptance of the resolution. For the sake of clarity, the Chair will then restate the decision that has been approved, so it can be captured correctly for the minutes.

As per section 22(1) of the bylaws, no resolution proposed at a board meeting needs to be seconded (i.e. a demonstration that there is at least more than one board member interested in seeing the decision before the Board). However, the Board has agreed that any resolution proposed by a board member that (i) has not been considered by staff, (ii) is not supported with a briefing note, and (iii) is not placed on the written agenda, must be supported by a seconder. Under such circumstances, the Chair will determine how best to deal with the proposed resolution, by:

- allocating time at the meeting for the discussion;
- deferring the discussion to a future meeting and directing staff to prepare a briefing note with respect to the issue; or
- deferring the discussion to a committee, with a recommendation for decision to come to the Board as appropriate.

7. Recording decisions

Once finalized, resolutions should be explicit so there is no room for misinterpretation or misunderstanding, and to ensure that anyone reviewing the resolution in the future can understand its meaning and intent.

Individual votes are not recorded unless the Board has agreed to record the vote, or unless an individual board member requests that their vote be noted.

The minutes are the official record of the meeting. Much like agendas, they follow a standard template to record the time, date, location and type of meeting, the names of board members who attended the meeting or forwarded their regrets, the names of staff and guests in attendance, and a formal acknowledgment of the unceded First Nations territory on which the meeting is taking place. The minutes state the nature of the matter before the Board, the reason the Board was asked to consider it, a note of the questions asked, and what action was taken by the Board, if any.

The draft minutes are added to the next meeting agenda for review and approval by the Board. The minutes do not need to be signed once approved.

A log of all resolutions is kept by staff and is a resource to the Board if required.

The Chair

As meeting facilitator, the Chair is responsible for setting the tone of the meeting and ensuring good governance practices are adhered to. It is an active role to keep board members engaged while building a safe, cohesive, and collaborative forum in which discussions can take place and clear decisions can be made.

The Chair may wish to adopt the following suggested practices when conducting the meeting:

1. Before the meeting

- If there are sensitive issues to discuss on the agenda, check in with board members to ensure they have the information they need to engage fully in the board meeting, and also consider whether the Board would benefit from using an external party to facilitate the discussion.
- Walk through the agreed final agenda and develop a plan for each agenda item with respect to process, timing and outcome.
- Check with First Nations or Indigenous colleagues to ensure the correct pronunciation for the names of territories, and ask whether there are other protocols or traditional knowledge that may help to purposefully promote learning or enhance culturally safe, humble and respectful practices during the meeting, beyond that which is already expected from board members under the Code of Conduct.

2. During the Meeting

- For remote board members, check they are available to start the meeting and have the relevant material.
- Verify that remote board members can see and hear properly and review the general guidelines with them (e.g. muting the line when not speaking, identifying themselves, etc.).
- At the outset of the meeting, verbally name and identify the unceded First Nations territory on which the meeting is taking place.
- At the outset of the meeting (or, if need be, at any time during), ask board members if they know of any conflicts of interest with agenda items under discussion.
- During the meeting, if a conflict of interest is identified by a board member, allow time for them to leave the room, log off or disconnect their call, and then later rejoin the meeting.
- Remember that every agenda item has a purpose. Create space for board members to express their opinions but make sure that any decision reached is based on facts, and close the discussion ensuring that either its purpose is achieved or another process has been triggered.
- Take time to seek views from each board member. If discussion stalls, ask questions to unearth why, to ensure there are no gaps in understanding that need to be addressed.
- Actively promote good debate by asking for alternative or dissenting views when decisions are not straightforward.

- Give space to board members to ask and address uncomfortable questions or to those who continue to ask questions because they are not yet satisfied or comfortable with the response.
- Draw attention back to the college mandate to ensure board members stay on track.
- If a question is asked, allow board members a moment to think of an answer, perhaps even giving board members the opportunity to spend time formulating questions on their own or in small groups.
- Go around the table, asking board members by name for their comments or answers.
- Make sure there are sufficient pauses after asking a question to board members attending remotely.
- Ask a specific board member a specific question rather than asking open-ended questions to the group (to avoid multiple board members speaking up at once).
- Read the room: if energy is low or conversation is waning, call a break.
- When a resolution has been put forward, make sure that board members understand what is being asked of them.
- Keep a list of issues that are more appropriately discussed offline or at another meeting.
- Remember to formally close the meeting, thanking all board members, including those attending remotely.
- Most importantly, inject warmth, humour and fun into the meeting wherever appropriate. The work is important, board members do this work as an act of service, but it need not be dull!

3. At End of Meeting

The Chair may also wish to ask the following questions when debriefing the Board, either with or without staff as appropriate:

- Do you trust the decision-making process of the Board?
- Did we have the right people in the room?
- Was the meeting purpose and agenda clear?
- Was there sufficient information available to the Board to make good, informed decisions?
- Was it easy for each member to contribute to the discussion?
- Are there any outstanding concerns which still need to be addressed?

4. After the meeting

It is always good practice for the Chair to debrief regularly with management as soon as possible after the board meeting to maintain strong and trusting relationships, and ensure that meetings continue to be managed effectively, especially if the Board has a board-only session without management present.

If board members have feedback or concerns following a board meeting or have other board-related issues which they may not wish to share with the whole Board, they are encouraged to communicate directly and confidentially with the Chair or Vice-Chair. Contact information for the Board is available on the Board Resource site in Collaborations.

Review

These guidelines will be reviewed annually by the Governance Committee to ensure they are kept current and remain relevant to the work of the Board and BCCNM. The Board is responsible for approving these guidelines on an annual basis.

These guidelines were approved by the Board on July 28, 2020 (ratified on September 1, 2020).

Supporting Documents

- BCCNM Bylaws
- Code of Conduct for Board Members and Committee Members
- Declaration of Commitment to Cultural Safety and Humility

College of Pharmacists of British Columbia

10. Governance Committee

Anne Peterson

Chair, Governance Committee

College of Pharmacists of British Columbia

10 a) Appointment of Board Members to Committees

Audit and Finance Committee

- Reappoint Steven Hopp as a Committee Chair
- Reappoint Alex Dar Santos as Committee Vice-Chair
- Reappoint Steven Hopp, newly elected Board Chair as a Member
- Appoint Andrea Silver, newly elected Board Vice-Chair as a Member
- Reappoint Alex Dar Santos as a Member
- Reappoint Anca Cvaci as a Member
- Reappoint Tracey Hagkull as a Member

Governance Committee

- Appoint Claire Ishoy as a Member, for a 3-year term
- Appoint Alex Dar Santos as a Member, for a 3-year term
- Appoint Anca Cvaci as Committee Vice-Chair

Legislation Review Committee

- Appoint Eric Sletmoen as a Member, for a 3-year term

Past Chairs Advisory Committee

- Appoint Claire Ishoy as a Member, for a 3-year term

Registrar Evaluation & Succession Planning Committee

- Appoint Steven Hopp as Committee Chair
- Reappoint Steven Hopp, newly elected Board Chair as a Member
- Appoint Andrea Silver, newly elected Board Vice-Chair as a Member
- Appoint Terri Gibson as a Member
- Reappoint Justin Thind as a Member
- Reappoint Claire Ishoy as a Member

All recommended appointments are for terms beginning on November 26, 2021 for one year term, unless stated otherwise.

College of Pharmacists of British Columbia

10 a) Appointment of Board Members to Committees

MOTION:

Approve College committee member appointments for terms beginning on November 26, 2021, as presented.

College of Pharmacists of British Columbia

10 b) Board Meeting Guidelines: Robert's Rules to BCCNM Meeting Guidelines

College of Pharmacists of British Columbia

Purpose

- To seek Board approval to give direction to the Registrar to:
  - Develop a modified version of the British Columbia College of Nurses and Midwives ("BCCNM") Board Meeting Guidelines document; and,
  - Develop bylaw amendments to remove Robert's Rules of Order as the document that governs the procedures of Board meetings.

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Background

- Section 19(1)(c) of the HPA allows the Board to make bylaws to, *"regulate the time, place, calling and conduct of meetings of the board and general meetings of the registrants."*
- The College's HPA-Bylaws require that Board meeting procedures are governed by Robert's Rules of Order.

College of Pharmacists of British Columbia

Robert's Rule of Order

Potential Issues

- The most recent edition is about 700 pages, containing formal parliamentary rules and procedures.
- It's considered more appropriate for larger group settings, whereas the College Board is a small group (about 12 members).
- It may be unnecessary and too cumbersome to have so many formal rules governing our meeting procedures.

College of Pharmacists of British Columbia

BCCNM Meeting Guidelines

- The Committee has stated an interest in adopting BCCNM's Board Meeting Guidelines to govern College Board meeting procedures.
- BCCNM's Board Meeting Guidelines is a plain language document outlining relevant information and procedural rules for Board meetings.
- It focuses on consensus decision-making.

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Options

There are two options for the Board's consideration:

Option 1:

Continue using Robert's Rule of Order

Option 2:

Adapt BCCNM's Board Meeting Guidelines and amend the HPA-Bylaws accordingly.

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Recommendation – Option 2

- BCCNM Board Meeting Guidelines are better suited for smaller groups, such as the College Board:
  - The guidelines are easier to understand and use.
  - A consensus-decision making model may enable more discussion around the Board table.
  - Amending the HPA bylaws to refer to the Board approved guidelines enables more flexibility for future changes.

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Next Steps

- If Option 2 is approved:
  - A modified version of BCCNM's Board Meeting Guidelines and HPA-Bylaw amendments will be developed.
    - These bylaws do not require public posting. However, they do need to be filed for a 60-day period prior to taking effect.
- The meeting guidelines and associated bylaw amendments will be brought forward to the Board's February 2022 meeting.
- Pending approval, the new guidelines and bylaws can be in effect for the April 2022 Board meeting.

College of Pharmacists of British Columbia

10 b) Board Meeting Guidelines: Robert's Rules to BCCNM Meeting Guidelines

MOTION:

Direct the Registrar to bring forward Board meeting guidelines, based on those from the British Columbia College of Nurses and Midwives, and associated bylaw amendments for the February 2022 meeting.