College of Pharmacists of British Columbia

Board Meeting
September 18, 2020
Via Video Conference

MINUTES

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

Staff:
Bob Nakagawa, Registrar
Ashifa Keshavji, Director of Practice Reviews and Quality Assurance
Doreen Leong, Director of Registration and Licensure
Mary O'Callaghan, Chief Operating Officer
Christine Paramonczyk, Director of Policy and Legislation
Gillian Vrooman, Director of Communications and Engagement
Kimberly Hilchie, Pharmacy Policy Consultant
Stephanie Kwok, Executive Assistant and Board Coordinator
Anu Sharma, Senior Policy and Legislation Analyst
James Van, Community Pharmacy Compliance Officer

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

Guests Presenters:
Gabriella Wong, BC Representative, Pharmacy Examining Board of Canada's Board of Directors
Joanne Archer, Education and Practice Coordinator, Provincial Infection Control Network of BC (PICNet)

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1. **WELCOME & CALL TO ORDER**
   Chair Antler called the meeting to order at 9:40am on September 18, 2020.

   Chair Antler acknowledged the Coast Salish People on whose unceded traditional territories the meeting is being chaired from, the Coast Salish, Squamish and Tsleil-Waututh First Nations. She also recognized that attendees of the videoconference are joining the call from other First Nations territories across BC.

College of Pharmacists of British Columbia

Board member Michael Ortynsky indicated that he has a perceived conflict of interest with item 7b. Implementation of the National Association of Pharmacy Regulation Authorities' Model Standards for Pharmacy Compounding and would recuse himself from the discussion and vote for that item.

2. CONFIRMATION OF AGENDA (Appendix 1)

Chair Antler made a request to amend the agenda by adding a break after item 3. Drug Administration Committee: Amendments to the HPA Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions and to move the consent agenda to item 9.

It was moved and seconded that the Board:
Approve the September 18, 2020 Draft Board Meeting Agenda as amended.

CARRIED

3. DRUG ADMINISTRATION COMMITTEE: *AMENDMENTS TO THE HPA DRUG ADMINISTRATION BY INJECTION AND INTRANSAL ROUTE STANDARDS, LIMITS AND CONDITIONS* (Appendix 2)

It was moved and seconded that the Board table the motion for the November Board meeting:
Accept the amendments to the Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions, as circulated.

DEFERRED

It was moved and seconded that the Board:
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.

CARRIED

4. AUDIT AND FINANCE COMMITTEE: COVID-19 BUDGET REVIEW AND FEE INCREASE CONSIDERATIONS (Appendix 3)

Steven Hopp, Chair of the Audit and Finance Committee provided an overview to the Board of the impact of the COVID-19 pandemic on the finances of the College. Models of projected College finances were reviewed, including one that used the fee increases that were approved by the Board in February 2020 and a reduced fee increase model.

It was moved and seconded that the Board:
Direct the Registrar to implement the annual fee increases as stated in the 2020-21 budget, 5.25% increase effective November 2020 for pharmacists and pharmacy technicians, and 5.5% increase effective approximately April 2021 for pharmacies.

CARRIED

5. PHARMACY EXAMINING BOARD OF CANADA UPDATE (Appendix 4)

Gabriella Wong, BC Representative of the Board of Directors of the Pharmacy Examining Board of Canada (PEBC) provided the Board with an update regarding the implications of COVID-19 on the PEBC assessments and examinations.

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6. INFLUENZA SEASON AND COVID …NOW WHAT? (Appendix 5)

Joanne Archer, Education and Practice Coordinator, Provincial Infection Control Network of BC, provided the Board with updated guidance on the challenges posed by COVID-19 on immunization administration during the upcoming influenza season.

7. LEGISLATION REVIEW COMMITTEE (Appendix 6)

a) Removal of Natural Health Products from the *Drug Schedules Regulation*

*Appendix 1 "*NHPs in NDS Confirmed Removals and Changes (by Date of Removal) – July 30, 2020"* of item 7a is removed as it contains confidential information.

It was moved and seconded that the Board:
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.

CARRIED

b) Implementation of the National Association of Pharmacy Regulation Authorities' Model Standards for Pharmacy Compounding

*District 5 Board Member, Michael Ortynsky recused himself from the discussion due to a perceived conflict of interest.

It was moved and seconded that the Board:
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.

CARRIED

c) *Health Professions Act* Fee Amendments

It was moved and seconded that the Board:
Approve the following resolution:

RESOLVED THAT, in accordance with the authority established in section 19(1) of the Health Professions Act, and subject to filing with the Minister as required by section 19(3) of the Health Professions Act, the Board amend the bylaws of the College of Pharmacists of British Columbia to amend the Fee Schedule to operationalize the College's 2020/2021 budget, as set out in the schedule attached to this resolution.

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d) *Pharmacy Operations and Drug Scheduling Act* Fee Amendments

It was moved and seconded that the Board:
Approve the following resolution:

RESOLVED THAT, in accordance with the authority established in section 21(8) of the Pharmacy Operations and Drug Scheduling Act, the Board approve the proposed draft bylaws of the College of Pharmacists of British Columbia to amend the Fee Schedule to operationalize the College's 2020/2021 budget, for public posting, as circulated.

CARRIED

8. PRACTICE REVIEW COMMITTEE: PRACTICE REVIEW PROGRAM ANNUAL REPORT (Appendix 7)

Tracey Hagkull, Chair of the Practice Review Committee and James Van, Community Pharmacy Compliance Officer presented to the Board the Practice Review Program Annual Report for the 2019-2020 fiscal year to the Board.

9. CONSENT AGENDA

a) Items for further discussion

District 8 Board Member, Bal Dhillon requested that item 2b.viii Recommendations to Modernize the Provincial Health Profession Regulatory Framework be removed from the Consent Agenda and placed onto the regular Agenda for further discussion; specifically the opportunity to revisit the College name change. As no briefing material for this item was prepared, Chair Antler suggested that this item be added to the November Board meeting agenda to which Board Member Dhillon agreed.

b) Approval of Consent Items (Appendix 8)

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

CARRIED

10. ITEMS BROUGHT FORWARD FROM CONSENT AGENDA

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

ADJOURNMENT

Chair Antler adjourned the meeting at 3:03pm on September 18, 2020.

College of Pharmacists of British Columbia

BOARD MEETING
September 18, 2020

2. Confirmation of Agenda

DECISION REQUIRED

Recommended Board Motion:

Approve the September 18, 2020 Draft Board Meeting Agenda as circulated, or amended.

Appendix	
1	September 18, 2020 Draft Board Meeting Agenda

College of Pharmacists of British Columbia

Board Meeting
Friday, September 18, 2020

AGENDA

9:15am - 9:20am	5	**1.**	Call to Order *Land Acknowledgement*	Chair Antler
		2.	Confirmation of Agenda **[DECISION]**	Chair Antler
9:20am - 10:00am	40	**3.**	Drug Administration Committee: Amendments to the *Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions* **[DECISION]**	Alex Dar Santos
10:00am - 10:15am	15		***BREAK***	
10:15am - 10:45am	45	**4.**	Audit and Finance Committee: COVID-19 Budget Review and Fee Increase Consideration **[DECISION]**	Steven Hopp Mary O'Callaghan
10:45am - 11:00am	30		In-Camera Session	
11:00am - 11:15am	15		***BREAK***	
11:15am - 11:45am	30	**5.**	Pharmacy Examining Board of Canada Update	Gabriella Wong
11:45am - 12:15pm	30	**6.**	Influenza Season and COVID …. Now What?	Joanne Archer
12:15pm - 1:15pm	60		***LUNCH***	
1:15pm - 2:00pm	45	**7.**	Legislation Review Committee: a) Removal of Natural Health Products from the *Drug Schedules Regulation* **[DECISION]** b) Implementation of the National Association of Pharmacy Regulatory Authorities' Model Standards for Pharmacy Compounding **[DECISION]** c) *Health Professions Act* Fee Amendments **[DECISION]** d) *PODSA Operations and Drug Scheduling Act* Fee Amendments **[DECISION]**	Justin Thind
2:00pm - 2:15pm	15		***BREAK***	
2:15pm - 3:00pm	60	**8.**	Practice Review Committee: Practice Review Program Annual Report	Tracey Hagkull James Van
3:00pm - 3:10pm	10	**9.**	Consent Agenda a) Items for Further Discussion b) Approval of Consent Items **[DECISION]**	Chair Antler
		10.	Items Brought Forward from Consent Agenda	Chair Antler

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 1

College of Pharmacists of British Columbia

Pharmacist Drug Administration
May 26, 2020

Pharmacist Drug Administration

FOR INFORMATION

Purpose

To provide the Ministry of Health, Professional Regulation and Oversight Branch, with an overview of the status of the College of Pharmacists of BC's (CPBC's) removal of restrictions on pharmacist drug administration.

Background

The *Pharmacists Regulation*[1] 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, 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.

The Standards, Limits and Conditions governing pharmacists' administration of drugs by injection or intranasal route are established in Schedule "F", Part 4 under the *Health Professions Act* Bylaws.[2] The existing limits placed on drug administration are such that a practising pharmacist must not administer a drug by injection or intranasal route unless it is for the purpose of immunization.

In 2018, the DAC met to review CPBC's restrictions on pharmacist drug administration in relation to patient safety and public protection. The DAC discussed options for removing restrictions, as conferred by the *Pharmacists Regulation*. The DAC also considered the experience of other pharmacy regulatory authorities in order to formulate evidence-based recommendations for the CPBC Board. In recent years, the CPBC Board has approved several Delegation of a Medical Act requests to allow medical practitioners to delegate drug administration by injection to pharmacists. This was also considered in the DAC's recommendation.

At its February 2019 meeting, based on the recommendations of the DAC, the CPBC Board directed the Registrar to remove current restrictions on pharmacist injection and intranasal administration of medications as follows:

[1] http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/417_2008
[2] http://library.bcpharmacists.org/6_Resources/6-1_Provincial_Legislation/5099-HPA_Bylaws_Drug_Administration_Injection_Intranasal.pdf

- Amend the "Limits" to allow for injection and intranasal administration of any Schedule I and II medication with the exception of Schedule IA[3];
- Amend the "Limits" to restrict pharmacists from administering injections for cosmetic purposes; and
- Maintain the existing "Limits" on the age restrictions for injection and intranasal drug administration.

On April 10, 2019, CPBC received a letter addressed to the Board Chair from Mark Armitage, Assistant Deputy Minister, Ministry of Health (MoH) inviting CPBC to work with the Professional Regulation and Oversight Branch to establish a working group, comprised of representatives of regulatory colleges of health professions with prescribing authority, to determine the impacts of removing the restrictions on pharmacist injection and intranasal administration of medications. The College worked collaboratively with the MoH to draft the Terms of Reference and Timeline and Activities for the Safe Drug Administration by Pharmacists Working Group ("Working Group") (see Appendix 1).

First Meeting of the Working Group
The first meeting of the Working Group occurred on October 28, 2019, and an update was provided to the Board at the November 2019 Board meeting. Key items were discussed, and included the following:

- Reframing the removal of the restrictions using the principles of Right-touch regulation;
- Outlining the impacts of removing the restrictions, including defining the specific drugs or drug classes which would be included or excluded from the authority;
- Determining the potential impacts on the broader healthcare system; and
- In the future, consider existing drug administration issues that could be potentially addressed by pharmacists, including expanding pharmacist administration to include intravenous infusions.

Additional issues were raised concerning pharmacist communication with the prescriber, management of adverse reactions including anaphylaxis, and maintenance of a patient record. The current Standards, Limits and Conditions do address each of these concerns, as pharmacists are required to notify and provide relevant information to other health care professionals, pharmacists must implement appropriate emergency measures including CPR and first aid, and pharmacists are required to document the administration of a drug in the patient record.

The Working Group raised specific questions regarding the accreditation of training programs for pharmacist drug administration and the range of drugs that pharmacists would be permitted to inject after the removal of restrictions. Despite these questions, there was general

[3] Note: no changes were proposed to the routes of administration currently permitted under the *Pharmacists Regulation.*

support from the other regulatory colleges for removing restrictions on pharmacist drug administration.

Second Meeting of the Working Group (Cancelled)
A second meeting of the Working Group was scheduled to take place on February 12, 2020, but cancelled after staff from the Professional Regulation and Oversight Branch indicated they were unable to participate.

A presentation for the second meeting of the Working Group was prepared by CPBC staff to address the key issues raised at the first meeting (see Appendix 2). This included reframing the removal of the CPBC's restrictions on pharmacist drug administration using the elements of Right-touch regulation and presentation of data from the MoH on injectable drugs dispensed from community pharmacies over a one-year period. A joint presentation by the BC Pharmacy Association (BCPhA) and the UBC Faculty of Pharmaceutical Sciences on their drug administration training programs for pharmacists was also planned, along with discussion on NAPRA's competency 15 *Essential Competencies for Injection of other Substances* (see Appendix 3).

1. Right-Touch Regulation

There are eight elements of Right-touch regulation, including identifying the problem before the solution, quantifying and qualifying the risks, using regulation only when necessary, and checking for unintended consequences. Right-touch regulation requires that regulation aims to be proportionate to the risk posed, and is able to adapt and anticipate change.[4] The draft presentation for the second meeting of the Working Group includes a synopsis of how CPBC's removal of restrictions aligns with the elements of Right-touch regulation (see Appendix 2).

2. Injectable Drugs Dispensed from Community Pharmacies

The Working Group expressed an interest in the range of drugs that pharmacists would be permitted to inject once the current restrictions are removed. To objectively quantify this, data on Schedule I and II injectable drugs dispensed from community pharmacies over a one-year period (August 1, 2018 – July 31, 2019) was obtained. The data was limited to those products that could be injected by the intramuscular (IM) or subcutaneous (SC) route, and represents dispenses of drugs, and not the quantity of drug dispensed. Schedule IA and cosmetic drugs were excluded from the data, as they are restricted under the current recommendation of the DAC.

[4] https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/right-touch-regulation-2015.pdf?sfvrsn=eaf77f20_20

The data indicates that there were approximately 2,859 different drugs dispensed in BC during the one-year period. Of the different drugs dispensed, 93% were not IM or SC injectable drugs, and 9.6% were IM or SC injectable drugs (see Appendix 2, slide 15).[5]

CPBC was also provided with the number of dispenses of each injectable drug. To summarize the dispensing information, drugs were grouped into categories based on clinical experience, and visualized on slide 17 of Appendix 2. Vaccines, which pharmacists are permitted to inject, make up 42% of IM and SC injectable drug dispenses. Insulins, which are typically self-injected by patients, make up 22% of IM and SC injectable drug dispenses.

Schedule IA Drugs – Emerging Issue
Buprenorphine extended-release injection is a new Schedule IA drug available in Canada for the management of moderate-to-severe opioid use disorder. It was recently listed by PharmaCare as a limited coverage benefit.[6] This injectable drug is unique in that it must not be dispensed directly to a patient, and must be administered by health care provider, due to significant risks if incorrectly administered.

The current recommendation of the DAC excludes injection of Schedule IA drugs; however, buprenorphine extended-release injection was not available and therefore not considered in the DAC's recommendation to remove restrictions on pharmacist drug administration made to the CPBC Board in February 2019.

3. Pharmacist Drug Administration Training Programs

The Canadian Council on Continuing Education in Pharmacy (CCCEP) provides accreditation of drug administration training programs for pharmacists through a competency-mapped accreditation process.[7] CCCEP accreditation ensures programs meet established Standards and Guidelines, and is recognized by all provinces and territories. The required competencies to obtain authorization to administer immunizations and injections are outlined in the *Supplemental Competencies on Injection for Canadian Pharmacists by the National Association of Pharmacy Regulatory Authorities* (Appendix 3), and programs must meet these competencies in order to be accredited by CCCEP. The competencies set forth by the National Association of Pharmacy Regulatory Authorities include competencies for both immunization, and also essential competencies for injection of other substances in addition to vaccines.

In order to obtain certification to provide drug administration, pharmacists must complete an CPBC approved drug administration training program.
In order to obtain certification to provide drug administration in BC, pharmacists must complete a drug administration training program approved by CPBC. Drug administration

[5] The total percentage is slightly more than 100%, as drugs could be counted in both categories if they had a route of administration that was non-injectable and injectable, for example furosemide which is available in injectable and oral formulations.
[6] https://www2.gov.bc.ca/assets/gov/health/health-drug-coverage/pharmacare/newsletters/news20-008.pdf
[7] https://www.cccep.ca/pages/immunization_and_injections.html

training programs approved by CPBC are accredited by CCCEP and therefore should already meet the required competencies set out by the National Association of Pharmacy Regulatory Authorities for injection of both vaccines and other substances by the intramuscular and subcutaneous routes.[8]

Discussion

To determine the steps forward in removing restrictions on pharmacist drug administration, the DAC reconvened on May 25, 2020. The meeting was originally planned for March 19, 2020, but was postponed due to competing priorities related to COVID-19.

At the meeting of the DAC, the DAC was presented with an update of events since the last DAC meeting in December 2018. Issues raised at the first Working Group meeting were presented to the DAC for consideration and discussion. The DAC was presented with two options for moving forward.

The first option is to proceed with the original DAC recommendations as approved by the CPBC 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 is to reschedule the second Working Group meeting when the Professional Regulation and Oversight Branch staff are available and bylaw moratorium has been lifted (date unknown). The Working Group would then present findings to the DAC, and the DAC would review and present the findings to the CPBC Board, if changes to the original recommendation result from the findings.

In considering these options, the DAC was informed of the meeting between the MoH and CPBC held on May 22, 2020. The DAC was made aware that the MoH advised they would be providing a response to CPBC on a timeline within one week.

Additionally, the DAC expressed interest in re-examining their previous recommendation to exclude schedule IA drugs from pharmacist drug administration authority in light of the newly available buprenorphine extended-release injection.

Decision

- Due to the advisement from the Ministry of Health, Professional Regulation and Oversight Branch, that a timeline for moving forward on this file would be presented to CPBC by the end of the week, the DAC decided to postpone their decision and wait for the response from the MoH on a collaborative path forward.

[8] https://www.cccep.ca/ckfinder/userfiles/files/Immunization-Injection%20Programs%202020-05-12.pdf

Next Steps

- The DAC will reconvene in early June to review the timeline presented by the MoH, to consider removing the restriction on schedule IA drugs, and to discuss the next steps moving forward.
- The DAC will provide an update to the Board at the June 12, 2020 meeting of the Board.

Appendix	
1	Safe Drug Administration by Pharmacists Working Group Terms of Reference and Timeline *(Appendix not included, previously provided to the Board)*
2	Draft Presentation for the second Working Group meeting *(Appendix included)*
3	Supplemental Competencies on Injection for Canadian Pharmacists by the National Association of Pharmacy Regulatory Authorities *(Appendix not included, available online: https://napra.ca/sites/default/files/2017-09/Supplemental_Competencies_on_Injection_for_Canadian_Pharmacists2012.pdf)*

Appendix 1

College of Pharmacists of British Columbia

We acknowledge that the land on which we gather today is the unceded and traditional territories of the Coast Salish peoples – sḵwx̱wú7mesh (Squamish), seĺílwitulh (Tsleil-Waututh), and xʷməθkʷəy̓əm (Musqueam) nations.

Appendix 1

College of Pharmacists of British Columbia

Drug Administration by Pharmacists

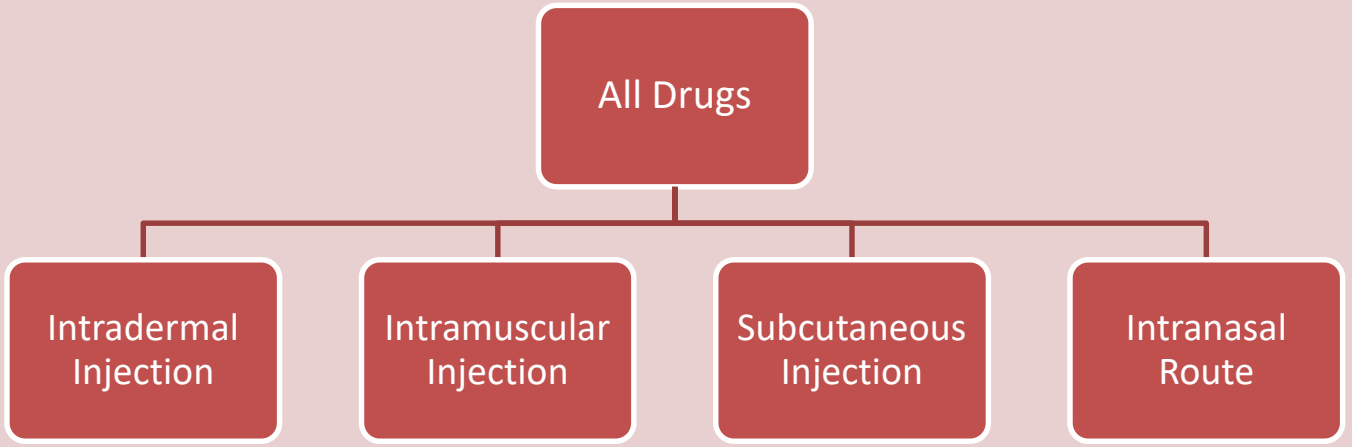
College of Pharmacists of British Columbia

February 12, 2020

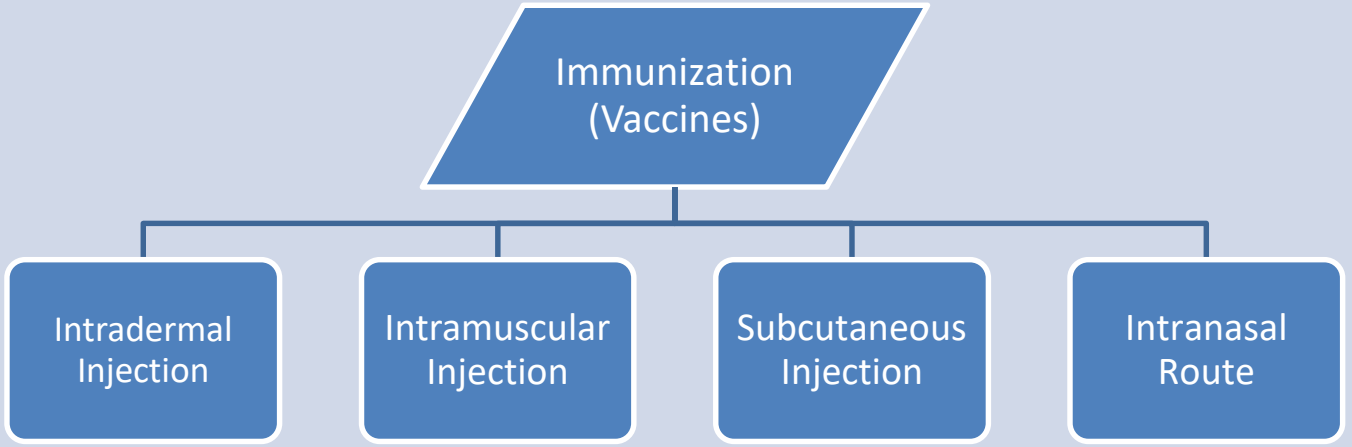
Appendix 1

College of Pharmacists of British Columbia

Provincial *Pharmacist Regulation*



CPBC *Standards, Limits and Conditions*



College of Pharmacists of British Columbia

Safe Drug Administration by Pharmacists Working Group

- Purpose is to consider the patient safety risks and potential benefits of changing the authority of pharmacists to administer drugs or substances via intradermal, intramuscular or subcutaneous injection or intranasal routes
- Activities will culminate in documented findings regarding patient safety risks, mitigation strategies and benefits of changing pharmacists' drug administration authority
- Findings will be provided to the Drug Administration Committee, Ministry of Health and other health professional regulatory colleges for consideration

College of Pharmacists of British Columbia

Working Group Timeline and Activities

- First meeting – October 28, 2019
- Second meeting – February 12, 2020
- Findings to be finalized March 2020
  - Working group to prepare summary of findings for consideration for the Ministry of Health, CPBC and the Drug Administration Committee, and other regulatory colleges

College of Pharmacists of British Columbia

Safe Drug Administration by Pharmacists Working Group

- Key items discussed at October 28, 2019 Meeting:
  - ❑ Defining the need for removal of the restrictions using the principles of Right-touch regulation;
  - ❑ Outlining the impacts of removing the restrictions, including defining the specific drugs or drug classes which would be included or excluded from the authority;
  - ❑ Determining the potential impacts on the broader healthcare system; and
  - ❑ In the future, consider existing drug administration issues that could be potentially addressed by pharmacists, including expanding pharmacist administration to include intravenous infusions.

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Purpose of Presentation

- To provide the Safe Drug Administration by Pharmacists Working Group with an overview of the College of Pharmacist of BC's (CPBC) proposed removal of restrictions on drug administration authority, in the context of Right-touch regulation.

Appendix 1

College of Pharmacists of British Columbia

CURRENT STATE: DRUG ADMINISTRATION BY PHARMACISTS IN BC

Appendix 1

College of Pharmacists of British Columbia

Presentation: Administration of Injections Training in Pharmacy

College of Pharmacists of British Columbia

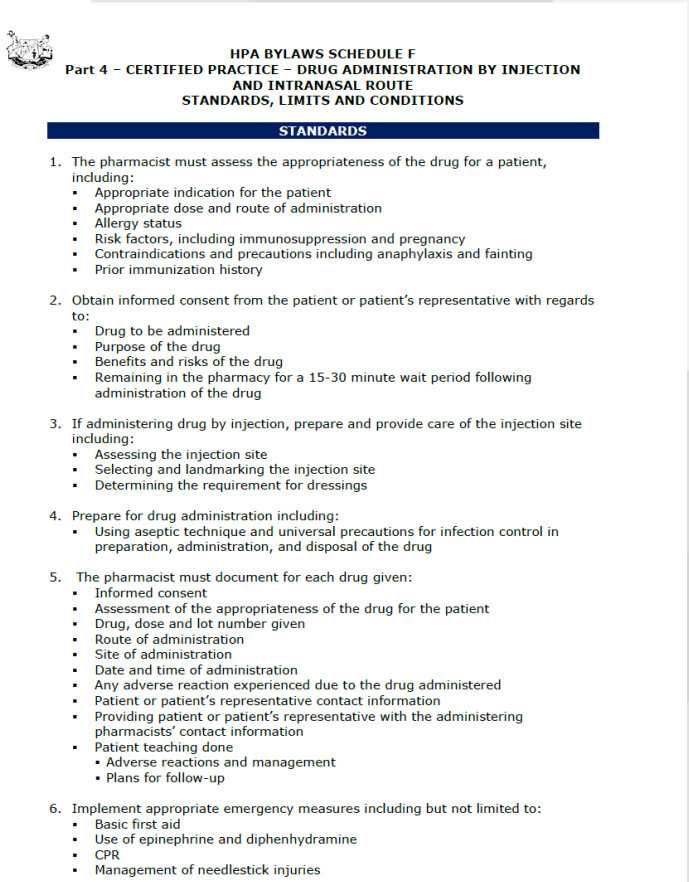
Drug Administration Certification Requirements

- CPBC *Health Professions Act Bylaws*
  - Be a practising pharmacist registered with CPBC
  - Complete a CPBC approved accredited program in drug administration
  - Hold a current certificate in CPR and first aid from a program approved by the Board, declared annually
  - Submit application to CPBC
- Registered pharmacists (full and limited) with injection authority as of February 2020: 4,399 (69.3%)

Appendix 1

College of Pharmacists of British Columbia

Current Drug Administration Standards



HPA BYLAWS SCHEDULE F
Part 4 – CERTIFIED PRACTICE – DRUG ADMINISTRATION BY INJECTION AND INTRANASAL ROUTE
STANDARDS, LIMITS AND CONDITIONS

STANDARDS

1. The pharmacist must assess the appropriateness of the drug for a patient, including:
   - Appropriate indication for the patient
   - Appropriate dose and route of administration
   - Allergy status
   - Risk factors, including immunosuppression and pregnancy
   - Contraindications and precautions including anaphylaxis and fainting
   - Prior immunization history
2. Obtain informed consent from the patient or patient's representative with regards to:
   - Drug to be administered
   - Purpose of the drug
   - Benefits and risks of the drug
   - Remaining in the pharmacy for a 15-30 minute wait period following administration of the drug
3. If administering drug by injection, prepare and provide care of the injection site including:
   - Assessing the injection site
   - Selecting and landmarking the injection site
   - Determining the requirement for dressings
4. Prepare for drug administration including:
   - Using aseptic technique and universal precautions for infection control in preparation, administration, and disposal of the drug
5. The pharmacist must document for each drug given:
   - Informed consent
   - Assessment of the appropriateness of the drug for the patient
   - Drug, dose and lot number given
   - Route of administration
   - Site of administration
   - Date and time of administration
   - Any adverse reaction experienced due to the drug administered
   - Patient or patient's representative contact information
   - Providing patient or patient's representative with the administering pharmacists' contact information
   - Patient teaching done
     - Adverse reactions and management
     - Plans for follow-up
6. Implement appropriate emergency measures including but not limited to:
   - Basic first aid
   - Use of epinephrine and diphenhydramine
   - CPR
   - Management of needlestick injuries

1. The pharmacist must assess the appropriateness of the drug for a patient
2. Obtain informed consent from the patient or patient's representative
3. If administering drug by injection, prepare and provide care of the injection site
4. Prepare for drug administration including
5. The pharmacist must document for each drug given
6. Implement appropriate emergency measures including but not limited to:
   - Basic first aid
   - Use of epinephrine and diphenhydramine
   - CPR
   - Management of needle stick injuries

College of Pharmacists of British Columbia

Current Drug Administration Standards

7. Develop, maintain and review, at least annually, a policy and procedure manual including:
   - Emergency procedure and treatment protocol
   - Precautions required for patients with latex allergies
8. Maintain a setting within which the drug is to be administered that is clean, safe, comfortable and appropriately private and furnished for the patient
9. Notify and provide relevant information to other health professionals, as appropriate

Appendix 1

College of Pharmacists of British Columbia

Current Drug Administration Limits

LIMITS

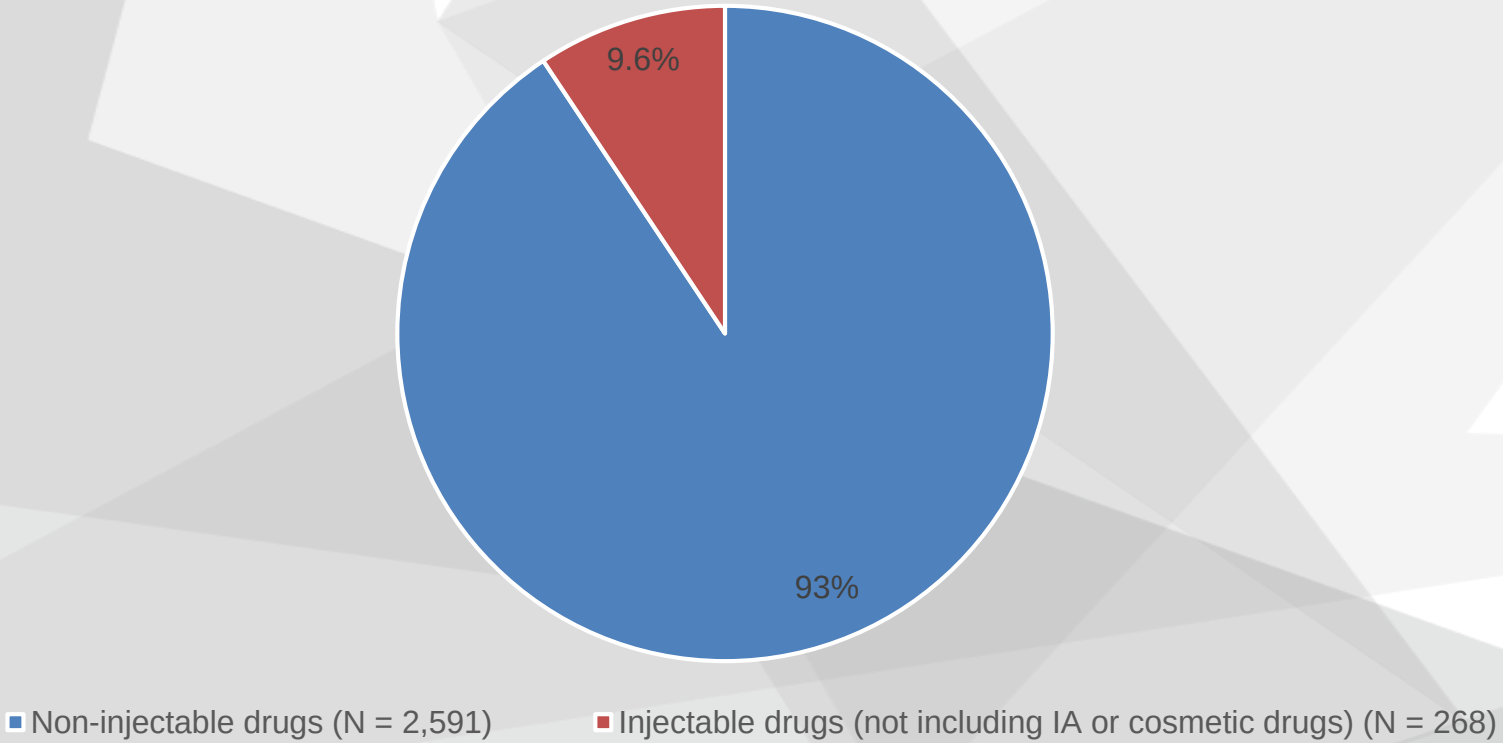
1. A practising pharmacist must not administer a drug by injection or intranasal route unless it is for the purpose of immunization.
2. A practising pharmacist must not administer an injection to a child under 5 years old.
3. A practising pharmacist must not administer a drug by intranasal route to a child under 2 years old.

Appendix 1

College of Pharmacists of British Columbia

Current Status: Injectable Drugs in BC

Drugs dispensed at least once from a community pharmacy in BC, August 1, 2018 to July 31, 2019 (PharmaNet data provided by Ministry of Health).



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Injectable Drugs Dispensed from Community Pharmacies

Summary and Limitations:

- List of DINS/PINS provided to MoH based on all marketed Schedule I and II IM & SC drugs listed in Health Canada's Drug Database and publicly funded vaccines
  - Does not include Schedule IA drugs or cosmetic drugs/substances
  - Does not include compounded products
- Captures *dispensing* events, and does not reflect *quantity* dispensed
  - E.g. a single influenza vaccine dispense and 30 day supply of dalteparin dispensed (i.e. 30 syringes) are both counted as 1 dispense
- Date range: August 1, 2018 – July 31, 2019
- Likely an overestimation of drugs that pharmacists would administer, as some drugs
  - Can also be administered by intravenous (IV), intra-articular, or oral routes
  - May have been dispensed for veterinary use
  - Are dispensed directly to hospice or residential care, or through home IV programs

Appendix 1

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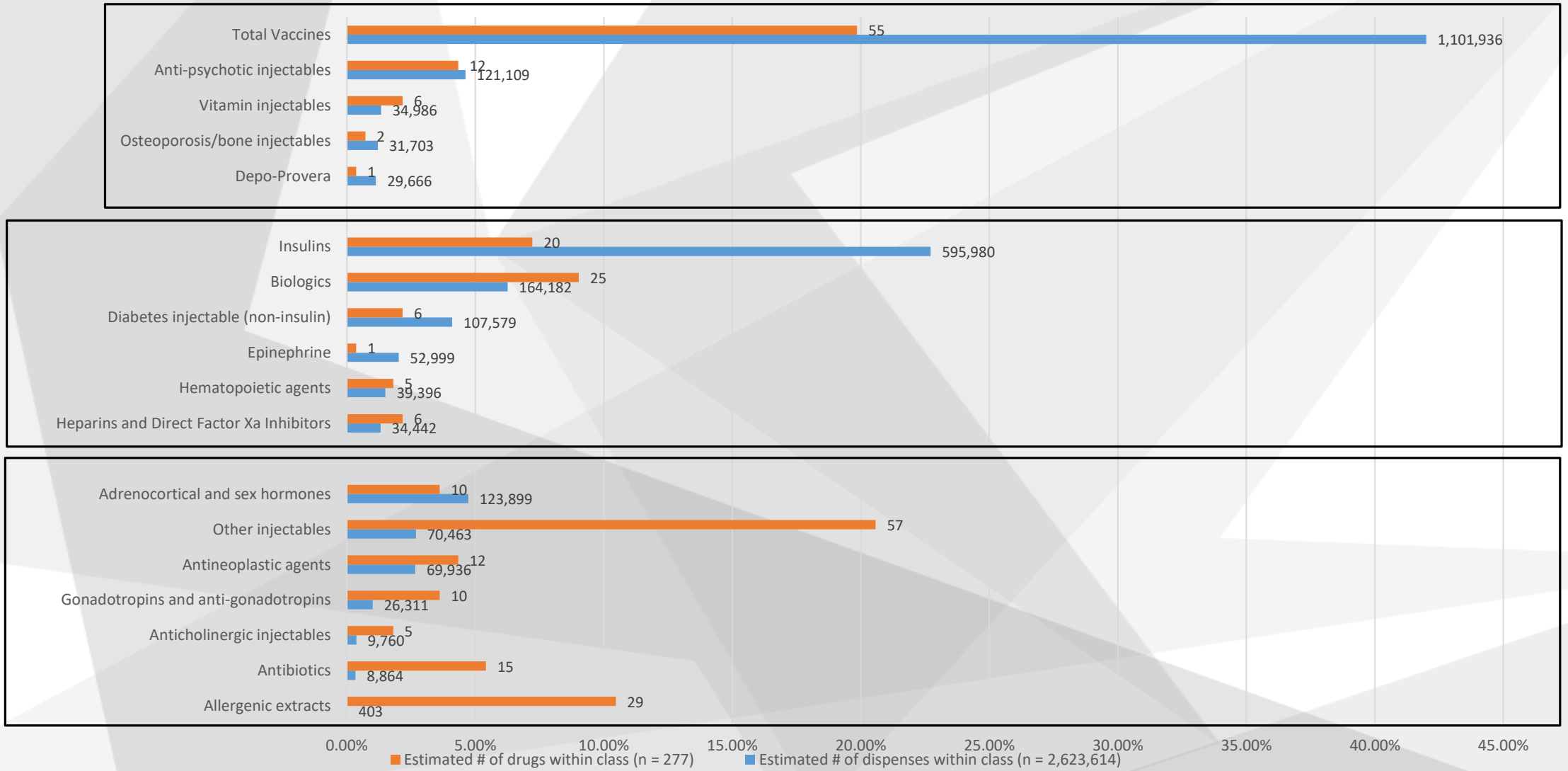
Injectable drugs dispensed from community pharmacies in BC, August 1, 2018 to July 31, 2019 (not including schedule IA and cosmetic drugs).
Raw data provided by the Ministry of Health, analysis by CPBC.



Appendix 1

College of Pharmacists of British Columbia

RIGHT-TOUCH REGULATION AND THE PROPOSED REMOVAL OF RESTRICTIONS ON DRUG ADMINISTRATION

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Right-Touch Regulation Elements

1. Identify the problem before the solution
2. Quantify and qualify the risks
3. Get as close to the problem as possible
4. Focus on the outcome
5. Use regulation only when necessary
6. Keep it simple
7. Check for unintended consequences
8. Review and respond to change

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1. Identify the problem before the solution

What we are hearing:

- Patients have difficulty receiving injections due to systemic barriers (e.g., clinic location, clinic opening time, availability of practitioner)
- Patients ask why pharmacists can administer vaccines, but not other injectable medications when technique is the same
- Pharmacists are expected to teach patients to self-inject medications, but cannot administer that same injection to a patient
- Some patients have vision or dexterity difficulties, making self-injection challenging

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2. Quantify and qualify the risks

If patients do not receive adequate or timely treatment…

- Medical conditions are not adequately treated
- Risk varies, depending on disease state
- Worse outcomes for patients and increased health service utilization

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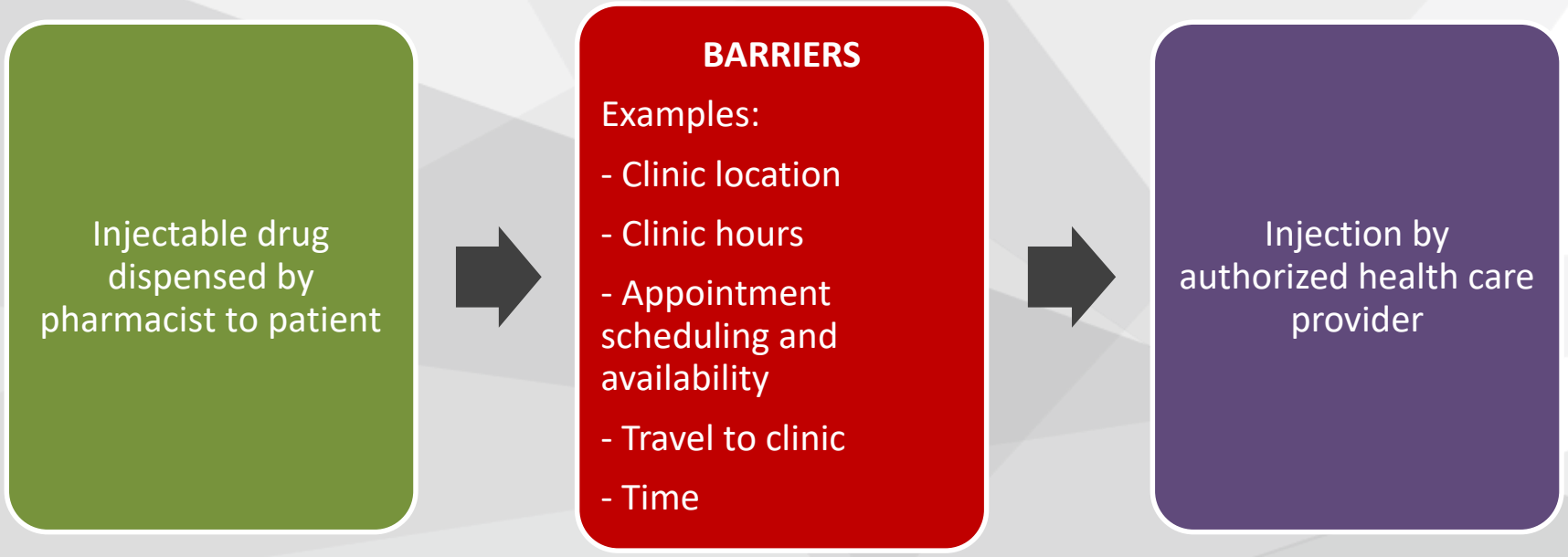
2. Quantify and qualify the risks

- Risks are caused by steps required between dispensing at the pharmacy and administration by authorized provider



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3. Get as close to the problem as possible

"Look for a solution as close to the problem as possible"

- Pharmacists are at the point of dispensing, and could conveniently provide injection
- Pharmacists are accessible
- Pharmacists are trained to give IM & SC injections
- Physicians are requesting pharmacists do this through Delegation of a Medical Act

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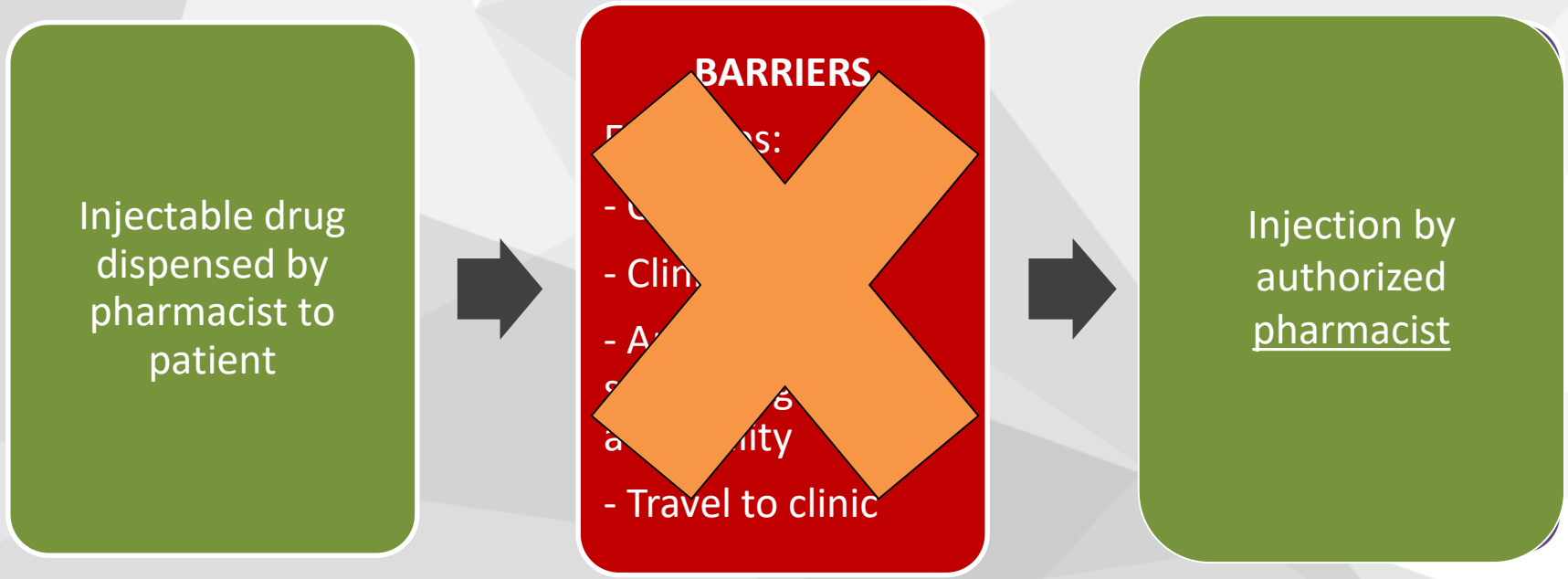
3. Get as close to the problem as possible



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4. Focus on the outcome

- What we expect
  - Patient receives drug when and where they need it
  - Improved medication adherence
  - Improved efficacy and safety of treatment (i.e. reduced harms for the public)
  - Improved patient outcomes and patient care

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5. Use regulation only when necessary

- *Standards, Limits and Conditions* are used to ensure patient safety
- This change can only be implemented through regulatory change to CPBC's *Standards, Limits and Conditions*
- Six other pharmacy regulatory authorities in Canada have enabled broad injection authority for pharmacists for any drug or vaccine (AB, SK, MB, NB, PEI, NL)

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6. Keep it simple

Removal of restrictions on pharmacist drug administration authority will be simple, and will include

- Minor amendments to the *Standards, Limits and Conditions*
- Minor adaptations to current training programs

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7. Check for unintended consequences

Concerns raised at last Working Group meeting:

- Communication with prescriber
  - Mitigated by current standard that requires pharmacist to notify and provide relevant information to other health care professionals
- Management of adverse reactions, including anaphylaxis
  - Mitigated by current standard that requires certified pharmacist to implement appropriate emergency measures including CPR, first aid and use of epinephrine and diphenhydramine
- Maintenance of patient record
  - Mitigated by current standard that requires certified pharmacist to document drug, dose, and lot number given, route and site of administration, date and time of administration, any adverse reaction experienced, etc.
  - Dispensed drug is documented on PharmaNet

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7. Check for unintended consequences

- CPBC developed a questionnaire to learn from the experiences of other jurisdictions
- Questionnaire was sent to the six PRAs with broad injection authority
- Questions included:
  - What has been your experience to-date, since implementing broad injection authority, of the following:
    - Has it been beneficial to public safety? Why or Why not?
    - Have you had any discipline or public/patient safety issues?
  - If you could start over, would you do anything differently?

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7. Check for unintended consequences

Questionnaire Results:

- None used a step-wise approach in removing restrictions on injection authority
- All concluded it was safe and in the public interest
- Very few complaints shared specific to pharmacist administered injections
  - Of these, the results suggest none were directly due to broad injection authority (e.g., relate to cold chain, documentation, adverse events)
- None indicated they would make an substantive changes to this broad authority, if they could start over

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7. Check for unintended consequences

Drug Administration Committee:

- Multidisciplinary committee discussed potential patient safety risks
- Identified potential patient safety implications of restriction removal
  - Injection of cosmetic drugs and substances
    - Pharmacists lack of experience with craniofacial muscles
    - General lack of knowledge of these substances
    - Potential conflict of interest & deviation from expertise
    - Recommended excluding these drugs and substances

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8. Review and respond to change

- Practice Review Program
  - In-person review of a pharmacy professional's practice
  - Program aims to protect public safety by improving compliance with CPBC Bylaws and Professional Practice Policies
- Complaints
  - Patients and members of the public who feel they've received unsafe or otherwise poor-quality care can submit complaints to CPBC
  - CPBC investigates complaints related to practices conducted by pharmacy professionals that present a risk to public safety
- Opportunity for post-implementation external evaluation

College of Pharmacists of British Columbia

Questions

Appendix 2

College of Pharmacists of British Columbia

9. Drug Administration Committee – Pharmacists' Injection Authority Update

FOR INFORMATION

Purpose

To provide the Board with an update on the Drug Administration Committee, and the status of the recommendation made by the Drug Administration Committee to the Board on February 15, 2019.

Background

The *Pharmacists Regulation*[1] 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, 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.

The Standards, Limits and Conditions governing pharmacists' administration of drugs by injection or intranasal route are established in Schedule "F", Part 4 under the *Health Professions Act* Bylaws.[2] The existing limits placed on pharmacist drug administration are such that a practising pharmacist must not administer a drug by injection or intranasal route unless it is for the purpose of immunization.

In 2018, the DAC met to review the College of Pharmacists of BC (the College) restrictions on pharmacist drug administration in relation to patient safety and public protection. The DAC discussed options for removing restrictions, as conferred by the *Pharmacists Regulation*. The DAC also considered the experience of other pharmacy regulatory authorities in order to formulate evidence-based recommendations for the Board.

[1] http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/417_2008
[2] http://library.bcpharmacists.org/6_Resources/6-1_Provincial_Legislation/5099-HPA_Bylaws_Drug_Administration_Injection_Intranasal.pdf

Appendix 2

At its February 2019 meeting, based on the recommendations of the DAC, the Board directed the Registrar to remove current restrictions on pharmacist injection and intranasal administration of medications as follows (see Appendix 1):

- Amend the "Limits" to allow for injection and intranasal administration of any Schedule I and II medication with the exception of Schedule IA;
- Amend the "Limits" to restrict pharmacists from administering injections for cosmetic purposes; and
- Maintain the existing "Limits" on the age restrictions for injection and intranasal drug administration.

On April 10, 2019, the College received a letter addressed to the Board Chair from Mark Armitage, Assistant Deputy Minister, Ministry of Health (MoH) inviting the College to work with the Professional Regulation and Oversight Branch of the MoH to establish a working group, comprised of representatives of regulatory colleges of health professions with prescribing authority, to determine the impacts of removing the restrictions on pharmacist injection and intranasal administration of medications. College staff worked collaboratively with the MoH to draft the Terms of Reference and Timeline and Activities for the Safe Drug Administration by Pharmacists Working Group (see Appendix 2).

First Meeting of the Working Group
The first meeting of the Working Group occurred on October 28, 2019, and an update was provided to the Board at the November 2019 Board meeting (see Appendix 3). Key items were discussed, and included the following:

- Reframing the removal of the restrictions using the principles of "Right-touch regulation"[3];
- Outlining the impacts of removing the restrictions, including defining the specific drugs or drug classes which would be included or excluded from the authority;
- Determining the potential impacts on the broader healthcare system; and
- In the future, consider existing drug administration issues that could be potentially addressed by pharmacists, including expanding pharmacist administration to include intravenous infusions.

The Working Group raised specific questions regarding the accreditation of training programs for pharmacist drug administration and the range of drugs that pharmacists would be permitted to inject after the removal of restrictions. Despite these questions, there was general support from the other regulatory colleges for the removal of restrictions on pharmacist drug administration.

[3] https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/right-touch-regulation-2015.pdf?sfvrsn=eaf77f20_20

Second Meeting of the Working Group (Cancelled)
A second meeting of the Working Group was scheduled to take place on February 12, 2020, but was cancelled after staff from the Professional Regulation and Oversight Branch indicated they were unable to participate. An update was provided to the Board in April 2020 (see Appendix 4).

A presentation for the second meeting of the Working Group was prepared by College staff to address the key issues raised at the first meeting. This included reframing the removal of the College's restrictions on pharmacist injection authority using the elements of "Right-touch regulation" and presentation of data from the MoH on injectable drugs dispensed from community pharmacies over a one-year period. The purpose of obtaining data on injectable drugs dispensed was to determine in an objective way what drugs pharmacists would be permitted to inject once the restrictions on pharmacist drug administration are removed.

A joint presentation by the BC Pharmacy Association and the University of British Columbia's Faculty of Pharmaceutical Sciences on their drug administration training programs for pharmacists was also planned, along with discussion on the National Association of Pharmacy Regulatory Authorities' (NAPRA's) *Supplemental Competencies on Injection for Canadian Pharmacists* competency 15: *Essential Competencies for Injection of other Substances*.[4] Drug administration training programs for pharmacists approved by the College are accredited by the Canadian Council on Continuing Education in Pharmacy, and therefore should already meet the required competencies set out by NAPRA for injection of both vaccines and other substances by the intramuscular and subcutaneous routes.[5]

Discussion

To determine the steps forward in removing restrictions on pharmacist drug administration, the DAC reconvened on May 25, 2020. The meeting was originally planned for March 19, 2020, but was postponed due to competing priorities related to the COVID-19 public health emergency.

At the meeting of the DAC, the DAC was presented with an update of events since the last DAC meeting in December 2018. Issues raised at the first Working Group meeting were presented to the DAC for consideration and discussion, and the DAC was presented with two options for moving forward.

The first option 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.

[4] https://napra.ca/sites/default/files/2017-09/Supplemental_Competencies_on_Injection_for_Canadian_Pharmacists2012.pdf
[5] https://www.cccep.ca/ckfinder/userfiles/files/Immunization-Injection%20Programs%202020-05-12.pdf

The second option was to reschedule the second Working Group meeting when the Professional Regulation and Oversight Branch staff are available. 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.

In considering these options, the DAC was informed of a meeting between the Registrar, Bob Nakagawa, and the Assistant Deputy Minister of the Ministry of Health, Mark Armitage, held on May 22, 2020 to discuss the status of the removal of restrictions on pharmacist drug administration. At the meeting, the Ministry of Health advised the College that they would provide the College with information on a plan to move forward in a collaborative manner as soon as possible. The meeting of the DAC on May 25, 2020 was arranged prior to the meeting between the Registrar and the Assistant Deputy Minister.

Due to the advisement from the Ministry of Health that a timeline for moving forward on this file would be presented to the College in a timely manner, the DAC decided to postpone their decision and wait for the response from the Ministry of Health on a collaborative path forward.

Additionally, the DAC expressed interest in re-examining their previous recommendation to exclude Schedule IA drugs from pharmacist drug administration authority in light of buprenorphine extended-release injection, a limited coverage drug now available in BC for the management of moderate-to-severe opioid use disorder. This drug must be administered by a health care professional.

Next steps

The DAC will reconvene in early June to review the timeline presented by the Ministry of Health, and to discuss the options and next steps moving forward.

Appendix	
1	February 2019 Board Briefing Note (without appendices)
2	September 2019 Board Briefing Note (with appendices – ToR & Timeline)
3	November 2019 Board Briefing Note (without appendices)
4	April 2020 Board Briefing Note (without appendices)

Appendix 3

Drug Administration by Pharmacists – Jurisdictional Scan Summary

Jurisdictions with broad drug administration authority and links to relevant standards:

- Alberta College of Pharmacy (AB)
- Saskatchewan College of Pharmacy Professionals (SK)
- College of Pharmacists of Manitoba (MB)
- New Brunswick College of Pharmacists (NB)
- Newfoundland and Labrador Pharmacy Board (NL)
- Nova Scotia College of Pharmacists (NS)
- Prince Edward Island College of Pharmacists (PEI)
- Yukon (YT)

Table 1. Summary of Drug Administration Provisions – Overarching Themes

	BC	AB	SK	MB	NB	NL	NS	PEI	YT
Assess patient and/or appropriateness of administration	✓	✓	✓	✓	✓	✓	✓	✓	✓
Have proper regard for the interest of the patient	Code of ethics	✓	X	X	✓	X	✓	✓	✓
Obtain informed consent	✓	✓	✓	✓	✓	✓	✓	✓	✓
Take all appropriate/necessary steps to ensure that the injection is administered safely[1]	Code of ethics	✓	✓	X	✓	X	✓	X	✓
Prepare the drug for administration	✓	✓	✓	✓	✓	✓	✓	✓	✓
Use universal precautions for infection control	✓	✓	✓	✓	✓	✓	✓	✓	✓
Prepare and provide care of the injection site	✓	X	X	✓	✓	✓	✓	X	X
Following the administration of a drug, ensure the patient is appropriately monitored	X	✓	X	✓	✓	✓	✓	✓	✓
Implement appropriate emergency measures	✓	✓	X	✓	✓	✓	✓	✓	✓
Safe and appropriate disposal of devices, equipment, and remaining drug	Code of Ethics	✓	✓	✓	✓	✓	✓	✓	✓
The pharmacist must document for each drug given	✓	✓	✓	✓	✓	✓	✓	✓	✓
Develop and maintain a policy and procedure manual[2]	✓	✓	✓	✓	✓	✓	✓	✓	✓
Maintain a setting within which the drug is to be administered that is appropriate[3]	✓	✓	✓	✓	✓	✓	✓	✓	✓
Notify and provide relevant health information	✓	✓	✓	✓	✓	✓	✓	✓	✓

[1] NAPRA Model Standard: Administer medications by injection only: the pharmacist can take all appropriate steps to ensure that the injection is administered safely

[2] NAPRA Model Standard: Administer medications by injection only when there are policies and procedures established for handling emergencies

[3] NAPRA Model Standard: Administer medications by injection only: the environment in which the injection is to be administered is appropriate

Appendix 4

Summary of Additional Proposed Amendments to the *Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions*

Eight other pharmacy regulatory authorities (PRAs) allow pharmacists to administer drugs by injection, and do not restrict administration to vaccines only (see Appendix 3). A cross-jurisdictional scan of their drug administration regulations, standards, and practice directions was completed, and an analysis was undertaken to understand where the College's *Standards, Limits and Conditions* may have gaps. Overall, the *Standards, Limits and Conditions* align well with the drug administration standards of other PRAs (see Appendix 3). Despite this, some areas were identified where the *Standards, Limits and Conditions* may benefit from additional provisions or clarification. Based on this analysis, as well as an internal consultation with College staff with drug administration experience, additional amendments to the *Standards Limits and Conditions* are proposed and are summarized below.

1. *New standard requiring pharmacist to act in the best interest of the patient and take all appropriate steps to ensure the drug is administered safely*
    - Similar provisions exist within the Code of Ethics, but it may be beneficial to have a provision outlining this expectation within the *Standards, Limits and Conditions* as well.

2. *New standard requiring pharmacists to administer a drug within the scope of their education training and experience*
    - A provision requiring pharmacists to practice within the scope of their education, training and competence exists within the Code of Ethics. However, having a similar provision in the *Standards, Limits and Conditions* clarifies requirements for pharmacists with respect to drug administration. As intradermal administration and intramuscular injection sites other than the deltoid are not routinely taught in drug administration training programs, it may be beneficial to have a standard that requires pharmacists to only administer a drug if they are competent to do so.

3. *Amendments to assessment of appropriateness requirements*
    - A new standard was added that requires a pharmacist to assess the appropriateness of the time for administration, as all of the other "seven rights" of administration[1] are already embedded within the *Standards, Limits and Conditions*, but this was not explicitly included.
    - Assessing prior immunization status may not always be necessary with the new range of administered drugs. So, it was clarified that this requirement is only necessary "as applicable."

[1] The "seven rights" of drug administration: right product, right client, right dose, right time, right route, right reason, and right documentation (https://napra.ca/sites/default/files/2017-09/Supplemental_Competencies_on_Injection_for_Canadian_Pharmacists2012.pdf)

Appendix 4

4. *Amendments to informed consent requirements*
    - Many PRAs require pharmacists to discuss the expected reaction with the patient or patient's representative as part of the informed consent process. This was not deemed to be embedded within existing requirements, and its addition may ensure patients receive this information to aid in making an informed decision.
    - To align with a principle-based approach and to accommodate for a wider range of drugs, the requirement to obtain informed consent with respect to a "15-30 minute wait period" was amended to "an appropriate wait period." Additionally, the reference to waiting in the pharmacy was removed, as pharmacists are not prohibited from administering drugs in other settings (e.g. multidisciplinary clinics).

5. *Amendments to drug preparation requirements*
    - A new standard was added requiring that pharmacists ensure the drug to be administered is stable and has been stored and labelled appropriately prior to administration. This may be important for scenarios where a pharmacist administers a drug that was previously dispensed and/or brought in by a patient. This requirement is also common among other PRAs.

6. *New standard on requirements following administration*
    - A new standard outlining requirements following drug administration was added. In this section, new provisions were added requiring a pharmacist to appropriately monitor a patient following drug administration, and to dispose of drugs, devices and supplies in a safe and appropriate manner. Currently, the *Standards, Limits and Conditions* only speak to safe disposal from an infection control standpoint; however, proper disposal of sharps and remaining drug should also be considered. This is also required by many other PRAs.

7. *Amendments to notification and providing relevant information requirements*
    - To align with workflow, this standard was rearranged to fall within the "following administration" standard.
    - A new standard was added outlining existing requirements to report adverse events and reactions to the applicable government agency. Adverse events following immunization must be reported as per section 5(3) in the *Reporting Information Affecting Public Health Regulation.*[2] Community pharmacists are also required to report adverse drug reactions as per s.12(7) of the *HPA Bylaws Schedule F Part 1 – Community Pharmacy Standards of Practice.*[3] To make the *Standards, Limits and Conditions* more principle-based, the reference to the Adverse Event Following Immunization (AEFI) form was removed.

[2] https://www.bclaws.ca/civix/document/id/lc/statreg/167_2018#section5
[3] http://library.bcpharmacists.org/6_Resources/6-1_Provincial_Legislation/5078-HPA_Bylaws_Community.pdf

Appendix 4

8. Amendments to documentation requirements

- A new requirement to document the identification of the pharmacist who administered the drug was added, as this is important for accountability and traceability.
- New requirements to document the patient response to drug administration, and to document the management provided if an adverse event occurs were added. These are important for a complete record of the administration of the drug, as the absence of documentation may not be sufficient to demonstrate that the patient tolerated the drug administration well. Documentation of the patient response and management provided are required by most other PRAs.
- A new requirement to document the expiry date of the drug was added. This is required by many other PRAs and documenting the expiry date ensures that the pharmacist has checked it prior to administration. This may be of importance when administering a drug that was previously dispensed and/or brought in by a patient.

9. Amendments to requirement to implement emergency measures

- To align with a principle-based format, the examples of emergency measures were removed. In their place, a new standard was added requiring pharmacists to ensure there is access to the drugs, devices, and other necessary equipment and supplies used to treat reactions to administered drugs. Another new standard was added requiring pharmacists to respond appropriately to complications and emergencies if they arise.

10. Additional minor amendments

- "Application" section added to link to other relevant legislation.
- Bulleted lists under each standard changed to lettered lists to allow for easier referencing.
- Minor housekeeping and typographical corrections.

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 under the *Health Professions Act*, and in conjunction with sections 43, 43.1 and 46(5.1) of the 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 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, if applicable

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) Ensuring the drug is stable, and has been stored and labelled appropriately prior to administration
    (b) 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 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. A practising pharmacist must not administer an injection to a child under 5 years old.
4. 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 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 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.

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 under the *Health Professions Act*, and in conjunction with sections 43, 43.1 and 46(5.1) of the 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.

~~1.~~3. ~~The~~ 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
   ~~(b)~~(c) Appropriate time for administration
   ~~(c)~~(d) Allergy status
   ~~(d)~~(e) Risk factors, including immunosuppression and pregnancy
   ~~(e)~~(f) Contraindications and precautions including anaphylaxis and fainting
   ~~(f)~~(g) Prior immunization history, if applicable

~~2.~~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
   ~~(c)~~(d) Expected reaction
   ~~(d)~~(e) Remaining ~~in the pharmacy~~ for an appropriate ~~15-30 minute~~ wait period following administration of the drug, if applicable

~~3.~~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

~~4.~~6. Prepare for drug administration including:
   (a) Ensuring the drug is stable, and has been stored and labelled appropriately prior to administration
   ~~(a)~~(b) Using aseptic technique and universal precautions for infection control in preparation, administration, and disposal of the drug

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4. xAppendix 5 - HPA_Bylaws_Drug_Administration_Injection_Intranasal 2020_v.7 (Track Changes)~~HPA_Bylaws_Drug_Administration_Injection_Intranasal v2019.1 (Track Changes)5099-HPA_Bylaws_Drug_Administration_Injection_Intranasal v2016.1~~ 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
   ~~(a) , including:~~
      ~~(i) The Adverse Event Following Immunization (AEFI) form~~
   (d) Report adverse events or reactions to the applicable government agency, as required

~~5.~~8. ~~The~~ A pharmacist must document for each drug given:
   ~~—~~Informed consent
   (a)
   (b) Assessment of the appropriateness of the drug for the patient
   (c) Drug and ~~,~~ dose ~~and lot number given~~administered
   ~~(c)~~(d) Lot number and expiry date of the drug
   ~~(d)~~(e) Route of administration
   ~~(e)~~(f) Site of administration
   (g) Date and time of administration
   (h) The identification of the pharmacist who administered the drug
   ~~(f)~~(i) Patient response
   ~~(g)~~(j) Any adverse reaction experienced due to the drug administered and management provided
   ~~(h)~~(k) Patient or patient's representative contact information
   ~~(i)~~(l) Providing patient or patient's representative with the administering pharmacist's~~'~~ contact information
   ~~(j)~~(m) Patient teaching done, including adverse reactions and management and plans for follow-up
   ~~• Adverse reactions and management~~
   ~~• 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.

~~6. Implement appropriate emergency measures including but not limited to:~~
   ~~• Basic first aid~~
   ~~• Use of epinephrine and diphenhydramine~~
   ~~• CPR~~
   ~~• Management of needlestick injuries~~

~~7.~~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

~~8.~~12. Maintain a setting within which the drug is to be administered that is clean,

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4. xAppendix 5 - HPA_Bylaws_Drug_Administration_Injection_Intranasal 2020_v.7 (Track Changes)~~HPA_Bylaws_Drug_Administration_Injection_Intranasal v2019.1 (Track Changes)5099-HPA_Bylaws_Drug_Administration_Injection_Intranasal v2016.1~~ Posted 2016-06-06

safe, comfortable and appropriately private and furnished for the patient.

~~9.~~1. ~~Notify and provide relevant information to other health professionals, as appropriate, including:~~
- ~~The Adverse Event Following Immunization (AEFI) form~~

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.
~~2.~~3. A practising pharmacist must not administer an injection to a child under 5 years old.
~~3.~~4. 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~~Schedule I and II drugs by injection or intranasal route within 1 year of successful completion of the required certification program.

~~1.~~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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1173509

August 20, 2020

Christine Antler, RPh
Chair,
College of Pharmacists of British Columbia
200 – 1765 W 8th Ave
Vancouver BC V6J 5C6

Dear Ms. Antler:

I hope that you are staying well during this unprecedented time.

I write to you regarding the email and information package on Pharmacist Drug Administration that I received from Registrar Bob Nakagawa on May 26, 2020, his subsequent email received on July 28, 2020 (see attachments), and the unfinished work of the Safe Drug Administration by Pharmacists Working Group (the Working Group).

While I know the subject of pharmacist injecting has been a topic of discussion for a number of years, the Ministry is concerned with the direction the College of Pharmacists of British Columbia (CPBC) is presently considering. Mr. Nakagawa's July 28 email indicated that he will be seeking approval at the September 18, 2020 Board meeting to move forward with public consultation on bylaw amendments that would expand pharmacist drug administration authority. In our view this would be premature prior to completion of the work we previously agreed to undertake collaboratively. To that end, we agreed to work together with other regulators to review the impacts (benefits and risks) and policy considerations of an expanded drug administration authority. The findings of this work were to be shared with the Drug Administration Committee, the Ministry and relevant regulators.

At the Working Group's first and only meeting on October 28, 2019, key questions were raised regarding:

- the identified need for pharmacists to provide additional injections;
- the types of drugs contemplated;
- the conditions under which expanded injection authority would be appropriate;
- how that authority would fit with team-based and/or other models for health services delivery; and
- how the service would be reimbursed.

Following this initial meeting and to help facilitate further discussions, the CPBC committed to provide to the Ministry a list of contemplated drugs with accompanying rationale for

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Ministry of Health
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Health Sector Workforce and Beneficiary Services Division
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consideration prior to the second meeting originally planned for February 2020. The Ministry was therefore pleased to receive a drug categories list as part of the May 26, 2020 information package.

This drug categories list provides a starting point to help identify what the CPBC considers appropriate for pharmacists to inject. It is based on raw data for community pharmacy dispensing in BC from 2018-2019.

It is the Ministry's view that considerable work remains before being able to consider moving forward with an expanded injecting authority. This includes:

- defining the underlying problem which expanded pharmacist injecting authority may solve; and
- considering the respective merits of a pharmacist-based model, models involving other injecting professionals, and/or a hybrid model.

On December 12, 2019 the Ministry communicated to regulators the difficult decision to put a temporary moratorium on bylaw changes, largely due to the volume, complexity and urgency of the modernization work. Since then, the COVID-19 pandemic has resulted in considerable work for the Ministry to support the provincial emergency response. This work continues, as does work to restart many of the health services which were impacted by the acute COVID-19 response. Also, of concern, the province has seen an increase in the number of deaths from opioid overdose.

These factors have resulted in the following areas being identified by the Ministry and executive as our top priorities:

- COVID-19 response;
- opioid overdose emergency response;
- restarting health services to address the needs of the broader population; and
- modernization of the regulation of health professionals.

Despite this prioritization, the Ministry remains committed to a collaborative approach with the CPBC and our continued participation on the Working Group. As time allows over the coming months, the Ministry intends to take more of a lead role on key pieces of the work, including internal consultation (e.g. with primary care and public health divisions, the Ministry of Mental Health and Addictions, and other areas as appropriate), to determine whether there is an identified need to:

- adjust the way in which patients receive regular and/or intermittent injections; and
- identify barriers and/or potential solutions.

Please confirm with Mark MacKinnon, Executive Director, Professional Regulation and Oversight, the Board's continued support for the CPBC to collaborate on the remaining

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necessary work, as well as support for postponing the posting of draft bylaw amendments for public consultation. To reiterate, in our view posting would be premature until the work has been completed and findings are available for consideration by the Drug Administration Committee, Ministry and regulatory colleges. You can reach Mark MacKinnon by email at Mark.MacKinnon@gov.bc.ca.

Sincerely,

Mark Armitage
Assistant Deputy Minister
Health Sector Workforce and Beneficiary Services

Attachments

Pc: Bob Nakagawa, Registrar, College of Pharmacists of British Columbia
Honourable Adrian Dix, Minister of Health
Stephen Brown, Deputy Minister, Ministry of Health
David Byres, Associate Deputy Minister, Ministry of Health
Mitch Moneo, Assistant Deputy Minister, Pharmaceutical Services
Mark MacKinnon, Executive Director, Professional Regulation and Oversight

College of Pharmacists of British Columbia

3. 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

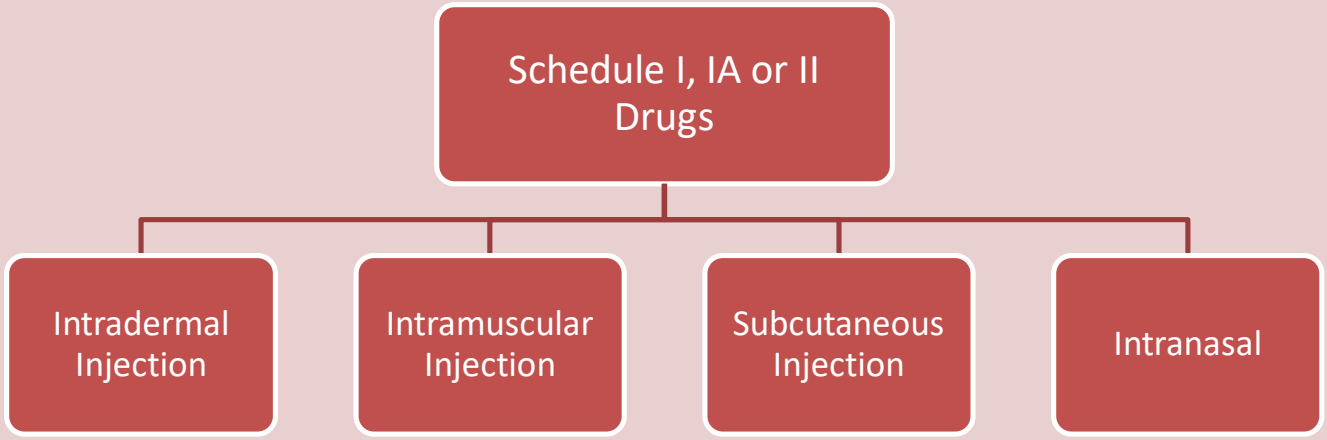
College of Pharmacists of British Columbia

Purpose of Presentation

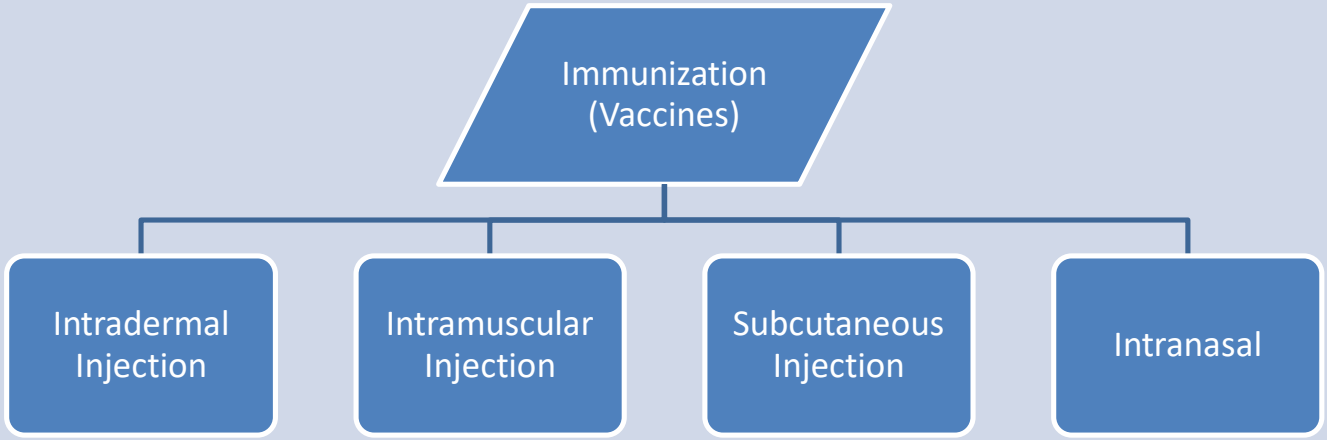
- To propose amendments to the *Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions* ("*Standards, Limits and Conditions*").
- To provide the Board with potential next steps in the removal of certain restrictions on pharmacist drug administration authority.

College of Pharmacists of British Columbia

Provincial *Pharmacists Regulation*



CPBC *Standards, Limits and Conditions*



College of Pharmacists of British Columbia

Drug Administration Committee

- The Drug Administration Committee (DAC) is established in accordance with the Provincial *Pharmacists Regulation*, s. 4.1 (1).
- The purpose of the DAC is to review, develop and recommend the standards, limits and conditions under which a registrant may administer a drug or substance to patients.
- The DAC is an inter-professional committee and includes, at a minimum, one full pharmacist, one medical practitioner, one registered nurse, and one person nominated by the Ministry of Health.

College of Pharmacists of British Columbia

DAC Recommendations to CPBC Board – Feb. 2019

- Amend the “Limits” to allow for injection and intranasal administration of any Schedule I and II medication, with the exception of Schedule IA.
- Amend the “Limits” to restrict administering injections for cosmetic purposes.
- Maintain the existing “Limits” on the age restrictions.
- Amend the “Conditions” to outline new training requirements for injecting drugs and substances beyond immunizations, if required.

College of Pharmacists of British Columbia

Drug Administration Timeline

February 2019	April 2019	June 2019	October 2019	December 2019
• The DAC presented its recommendations to the Board. • The Board directed the Registrar to remove certain restrictions on pharmacist injection and intranasal administration of medications.	• The College received a letter from Mark Armitage, Assistant Deputy Minister, Ministry of Health. • The letter invited the College to work with the Ministry of Health to establish a working group. • The aim of the working group was to determine the impacts of removing the restrictions on pharmacist drug administration.	• The College and Ministry of Health staff developed the Working Group's terms of reference and action plan.	• First meeting of the Working Group was held at the College.	• The Ministry of Health announces a temporary bylaw moratorium. • The end date of the moratorium is unknown.

College of Pharmacists of British Columbia

Drug Administration Timeline

February 2020	March 2020	May 2020	June – July 2020	August 2020
• Second meeting of the Working Group was scheduled. • That Working Group meeting was cancelled, as key Ministry of Health staff could no longer participate.	• A DAC meeting was scheduled to provide an update on the activities of the Working Group. • That DAC meeting was cancelled due to COVID-19 related competing priorities.	• College staff met with the Mark Armitage, Assistant Deputy Minister. The Ministry of Health was to provide a response on a collaborative path forward within one week. • A DAC meeting was held to provide an update on the activities of the Working Group and provide a recommendation to the Board on next steps. The DAC decided to wait to provide a recommendation on next steps until the response from the Ministry of Health was received.	• Development of proposed amendments to the *Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions.*	• Hearing no response from the Ministry of Health, the DAC met to review proposed amendments and recommend next steps to the Board.

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Proposed Amendments to the *Standards, Limits and Conditions*

- The College did not receive a response from the Ministry of Health on a timeline or collaborative path forward in June 2020, as anticipated.
- In light of this, the College continued working on proposed amendments to the *Standards, Limits and Conditions,* and presented them to the DAC on August 14, 2020.

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Proposed Amendments to the *Standards, Limits and Conditions*

- The proposed amendments to the *Standards, Limits and Conditions* align with the DAC's previous recommendation and the direction of the Board:
  - Allow administration of Schedule I and II drugs with the exception of Schedule IA
  - Prohibit injection of cosmetic drugs and substances
  - Maintain existing age limits

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Proposed Amendments to the *Standards, Limits and Conditions*

- In addition to the amendments directed by the Board, other changes were informed by:
  - Relevant standards from other provincial regulatory authorities;
  - Internal review; and,
  - Clarification needs.
- These amendments are described in the following slides.

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Proposed Amendments – New Safety and Competence Requirements

	Brief Description	Rationale
1.	New standard requiring pharmacists to act in best interest of the patient, and take all appropriate steps to ensure the drug is administered safely	• Similar provisions exist within the Code of Ethics • It may be beneficial to have a provision outlining this expectation within the *Standards, Limits and Conditions* as well
2.	New standard requiring pharmacists who administer a drug to do so within the scope of their education, training and competence	• A similar provision exists in the Code of Ethics • Intradermal administration and intramuscular sites other than the deltoid are not routinely taught in drug administration training programs for pharmacists • Including this provision clarifies that pharmacists may only administer a drug if they are competent to do so

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Proposed Amendments – Assessment of Appropriateness

	Brief Description	Rationale
3.	Add requirement for pharmacist to assess that the *timing* of the administration is appropriate	• The Standards already embed the “seven rights” of drug administration, but don’t explicitly include “right time” • “Seven rights" of medication administration: right medication, right client, right dose, right time, right route, right reason and right documentation
	Add “if applicable” to requirement to assess immunization history	• Assessing prior immunizations may not always be necessary with the new range of administered drugs

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Proposed Amendments – Informed Consent

	Brief Description	Rationale
4.	Add a requirement for pharmacists to discuss the expected reaction with a patient as part of informed consent	• Many PRAs require pharmacists to discuss the expected reaction with the patient or patient's representative as part of the informed consent process • This was not deemed to be embedded within existing requirements, and its addition may ensure patients receive this information to aid in making an informed decision
	Change"15-30 minute" wait period to "an appropriate" wait period	• Aligns with a principle-based approach • Accommodates for a wider range of drugs
	Remove reference to waiting in "the pharmacy"	• The *Standards, Limits and Conditions* do not limit a pharmacist to providing drug administration within a pharmacy

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Proposed Amendments – Drug Preparation

	Brief Description	Rationale
5.	Add requirement to ensure the drug is stable, and has been stored and labelled appropriately prior to administration	• This requirement is common among all other PRAs • This may be important for scenarios where a pharmacist administers a drug that was previously dispensed and/or brought in by a patient.

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Proposed Amendments – New Requirements Following Administration

	Brief Description	Rationale
6.	Add requirement for safe and appropriate disposal of devices, supplies and remaining drug, following administration	• The *Standards, Limits and Conditions* only speak to safe disposal from an infection control standpoint • Safe and appropriate disposal goes beyond this, and includes proper disposal of sharps and remaining drug, etc. • Similar provision exists within the Code of Ethics
	Add requirement to ensure the patient is appropriately monitored	• The standards don't explicitly require this (indirectly require) • This is important for patient safety and required by all other PRAs
	Rearrangement of other sections	• Move requirement for notification of other health care professionals into this section to align with workflow

College of Pharmacists of British Columbia

Proposed Amendments – Notification

	Brief Description	Rationale
7.	New provision added outlining existing requirements to report adverse events and reactions to the applicable government agency	• Adverse events following immunization must be reported as per section 5(3) in the *Reporting Information Affecting Public Health Regulation* • Pharmacists are also required to report adverse drug reactions as per the *Community Pharmacy Standards of Practice* and *Residential Care Facilities and Homes Standards of Practice*
	Remove reference to the Adverse Events Following Immunization form	• Aligns with a principle-based approach

College of Pharmacists of British Columbia

Proposed Amendments – Documentation

	Brief Description	Rationale
8.	Add requirement to document expiry date	• Ensures pharmacist checks expiry date prior to administration • This may be of particular importance when administering a drug that was previously dispensed and/or brought in by a patient
	Add requirement to document identification of pharmacist who administered the drug	• Important for traceability and accountability
	Add requirement to document patient response to drug administration and any management provided if an adverse event occurs, if required	• These are important for a complete record of the administration of the drug, as the absence of documentation may not be sufficient to demonstrate that the patient tolerated the drug administration well • Documentation of the patient response and management provided are required by most other PRAs

College of Pharmacists of British Columbia

Proposed Amendments – Emergency Measures

	Brief Description	Rationale
9.	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	• To align with a principle-based approach, the examples of emergency measures were removed and replaced with a broader requirement for the pharmacist to ensure there is access to the drugs, devices, equipment and supplies necessary to treat reactions to administered drugs
	Broadened requirement to respond appropriately to complications and emergencies if they arise	• Added in wording requiring pharmacist to respond to emergencies and *complications* as not all adverse events may be emergencies

College of Pharmacists of British Columbia

Additional Proposed Amendments

- "Application" section added at the beginning of the *Standards, Limits and Conditions* to link to other relevant legislation.
- Bulleted lists under each standard change to lettered lists to allow for easier referencing.
- Minor housekeeping and typographical corrections.

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DAC Approval of Proposed Amendments

- The DAC recommends that the Board moves forward with the proposed amendments, as circulated.

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Options for Moving Forward

- The DAC was presented with options for moving forward with the proposed amendments to the *Standards, Limits and Conditions.*
- The DAC discussed whether to recommend that the Board:
  - File the amendments with the Ministry of Health;
  - Wait for a Working Group meeting and for the Ministry of Health bylaw moratorium to end; or,
  - Post the amendments for public comment.
- However, deciding on the next step was seen as a Board decision.
- Important to note: posting amendments to standards, limits and conditions for public comment is not required under the HPA.

College of Pharmacists of British Columbia

Engagement with the Ministry of Health

- On August 28, 2020, the College received a letter from Mark Armitage, Assistant Deputy Minister, Ministry of Health. It noted:
  - A request that the College not engage publicly on the S*tandards, Limits and Conditions* at this time, and continue to collaborate with the Working Group.
  - That the temporary bylaw moratorium is still in effect.
  - That there is no clear Ministry of Health timeline on a path forward, due to other pressing matters.

College of Pharmacists of British Columbia

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.
- It is recommended that the Board direct the Registrar to engage with the Ministry of Health to move the amendments forward.

College of Pharmacists of British Columbia

3. Amendments to the HPA *Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions*

MOTION 1:

Accept the amendments to the *Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions*, as circulated.

College of Pharmacists of British Columbia

3. Amendments to the HPA *Drug Administration by Injection and Intranasal Route Standards, Limits and Conditions*

MOTION 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.

College of Pharmacists of British Columbia

Questions

College of Pharmacists of British Columbia

BOARD MEETING
September 18, 2020

4. COVID-19 Budget Review and Fee Increase Considerations

DECISION REQUIRED

Recommended Motion:

Direct the Registrar to implement the annual fee increases as stated in the 2020-21 budget, 5.25% increase effective November 2020 for pharmacists and pharmacy technicians, and 5.5% increase effective approximately April 2021 for pharmacies.

Purpose

To review the impact of the COVID-19 health pandemic on the 2020/21 budget and approve the implementation of annual fee increases. As any fee increase decision primarily generates revenues for future years due to timing of renewals and the earning of revenue over the twelve months of registration, finance has prepared multi-year plans to review.

Background

The Board approved the 2020/21 budget at the February Board meeting. At the April Board meeting, the Board directed the Registrar to review the impact of the pandemic before proceeding with the fee increases that had been included in the approved budget.

Discussion

With four months of operations in this fiscal year, much of it with adjusted operations due to the pandemic, we have updated the Latest Estimates of the 2020/21 Financial Reports to reflect our current assumptions. As projected in the June 2020 update, the College's financial situation shows sufficient funding and reserve balances for this year and next year. It is during the 2022/23 and 2023/24 fiscal years that the closing Reserve balances become a serious concern due to continued deficits. It was concern for these years that led to the February budget planned fee increases.

2020/21 Latest Estimate and Projections for 2021/22

Finance prepared for this report by meeting with College directors and managers to gather information concerning operational changes and future plans.

COVID-19 Generated Savings

As discussed in previous reports, the savings are primarily seen in:

- Travel and accommodations (staff, conference, committees and Board);
- Professional development (programs cancelled, reduced fees for virtual sessions, no travel required);
- Strategic Plan projects (delay in project management costs);
- Staffing (a few positions are vacant, and hiring is currently frozen); and,
- Reduction in health benefit premiums.

As of July 31st, these combined impacts have resulted in expenses being 16% below budget.

COVID-19 Impact on Revenues

The health pandemic has had a few negative impacts on the College's revenues:

- Delayed implementation of budgeted fee increases (a future impact).
- As discussed during the budget presentation, the fee increases were scheduled to come into effect late in the fiscal year, so primarily impact 2021/22 and 2022/23 revenues.
- Cancellation of planned Jurisprudence Exams (now to be held virtually in fall 2020).
- Cancellation of Pharmacist's Objective Structured Clinical Examinations (OSCE), resulting in the 2020 UBC grads being unable to register as full pharmacists. (these exams are scheduled for November 8, 2020).
- Cancellation of Pharmacy Technician's Objective Structured Performance Examinations (OSPE), resulting in pharmacy technicians being unable to register (these exams are scheduled for September 20, 2020).

As of July 31st, these combined impacts have resulted in revenues being 4% below budget.

Points for Consideration

Key questions for the Board to consider are:

- Historical context regarding planned deficits: These deficits were first planned to reduce a large accumulated surplus. However, they were extended to the point where the College will have little surplus remaining due to the loss of revenue from the PharmaNet contract in order to avoid a large fee increase all at once. (The PharmaNet contract had contributed considerable income for the College for many years.)
- The Board-approved Reserve balance was reduced to $2,000,000.

- The College has a very healthy cash / investment (GICs) balance with the Deferred Revenue from registrants (fees paid but being allocated over the upcoming year).
- The College also has a 30% ownership of the College Place building.
- This year's results will be much higher than anticipated.
- Today's decision is only to approve this year's fee increase. The College is beginning to start the 2021/22 budget planning process. The Board will be approving that budget in February 2021.

Multi-year Impact of the Fee Increase

Although this discussion is about this year's fee increase, fee increases can take almost three years to be fully earned[1]. Therefore, it takes time for the revenue generated by fees to show up in the College's revenue.

Note: The College receives the payment at the beginning of the renewal period. This cash is on hand, available for use but tracked in the account "Deferred Revenue".

Finance has prepared three scenarios to show the future year impact of different fee increases.

The following table highlights the difference between the models.

Scenario And Current Fee	**Year 1 2020-21 Latest Estimate**	**Year 2 2021-22**	**Year 3 2022-23**	**Year 4 2023-24**
Model 1 Fees PH - $739 PT - $492 PY - $2,345	 PH - $18 (2.5%) PT - $12 PY - n/a	 PH - $40 (5.25%) PT - $26 PY - $129 (5.5%)	 PH - $20 (2.5%) PT - $14 PY - $62 (2.5%)	 PH - $21 (2.5%) PT - $14 PY - $65 (2.5%)
Model 1 Reserve Balance	$1,752,88	$995,558	$298,338	$264,690
Model 2 Fees PH - $739 PT - $492 PY - $2,345	 PH - $39 (5.25%) PT - $26 PY - n/a	 PH - $19 (2.5%) PT - $13 PY - $129 (5.5%)	 PH - $20 (2.5%) PT - $14 PY - $62 (2.5%)	 PH - $21 (2.5%) PT - $14 PY - $64 (2.5%)
Model 2 Reserve Balance	$1,758,681	$1,121,997	$469,133	$431,724

[1] In years 1 and 2: fees need to be approved and filed and then takes 12 months for all renewals to be billed. In years 2 and 3: the fees are earned 1/12th each month of the year of the registrant or pharmacy's renewal term.

Scenario And Current Fee	Year 1 2020-21 Latest Estimate	Year 2 2021-22	Year 3 2022-23	Year 4 2023-24
Model 3 Fees PH - $739 PT - $492 PY - $2,345	 PH - $39 (5.25%) PT - $26 PY - n/a	 PH - $41 (5.25%) PT - $27 PY - $129 (5.5%)	 PH - $21 (2.5%) PT - $14 PY - $62 (2.5%)	 PH - $21 (2.5%) PT - $14 PY - $64 (2.5%)
Model 3 Reserve Balance	$1,758,681	$1,134,596	$626,611	$797,127

Note: Model 3 is included to show that next year's budget will also impact year 3 and 4's reserve balance.

Note: All three models plan for the pharmacist and pharmacy technicians fee increases to come into effect November each year as usual. However, as pharmacy fee increases must be posted as well as filed, they would come into effect April 2021. This would require a special Board meeting in January, in order to approve that it be filed and come into effect April 2021.

As discussed previously, Year 4 is the concern as this is the year where the Reserve balance drops the lowest for Models 1 and 2.

Guiding Questions

Key questions for the Board to consider are:

1. What impact will this recommendation have on the financial health of the College?
2. What level of reserve balance is acceptable?
3. What are the implications for next year, including no or limited travel?

Recommendation

The Audit and Finance Committee recommends Model 2. It implements the budget fee increases approved in this year's budget (although the PODSA increase would take place early next fiscal year).

Model 2 does not maintain the minimum Reserve balance of $500,000 that had been identified at the February budget discussions. However, that could be still reached with the 2021-22 budget.

Appendix	
1	Board approved 2020-21 Multi-year Plan
2	Model 1
3	Model 2
4	Model 3

College of Pharmacists of BC
Budget 2020-21 & Multi-Year Plan
Board Approved Copy

Fee Assumptions:

5.5% increase (Years 1 - 2) for Pharmacy
5.25% increase (Years 1 - 2) for Pharmacist & Pharmacy Technician
1.5% increase for all categories (Years 3 - 6)

	CURRENT			YR 1	MULTI-YEAR PLAN				
	2019-20			2020-21	2021-22	2022-23	2023-24	2024-25	2025-26
	BUDGET	LATEST EST.	9-MO ACTUAL	BUDGET (DRAFT)	PROJECTED				
Revenue deferred	8,744,240	8,701,834	6,486,974	9,173,978	9,879,723	10,765,126	11,438,815	11,964,763	12,529,757
Revenue licensure other	515,366	489,905	313,205	554,113	595,037	631,009	652,863	675,122	699,574
Revenue other	574,329	508,573	416,270	487,475	486,087	497,726	508,384	519,249	530,324
Revenue	9,833,935	9,700,311	7,216,449	10,215,565	10,960,847	11,893,861	12,600,062	13,159,134	13,759,655
Total Expenditures	10,838,668	10,571,459	7,717,985	11,329,901	11,766,786	11,968,810	12,260,124	12,276,873	12,493,783
OpEx	3,727,820	3,800,376	3,611,876	3,793,788	4,008,411	4,055,267	4,188,311	4,043,623	4,095,868
Labour	7,110,848	6,771,083	4,106,109	7,536,113	7,758,375	7,913,543	8,071,813	8,233,250	8,397,915
Excess (Deficiency) of Revenue over Expenditures	(1,004,733)	(871,148)	(501,536)	(1,114,329)	(805,939)	(74,949)	339,937	882,261	1,265,872

	CURRENT			YR 1	YR 2	YR 3	YR 4	YR 5	YR 6
	2019-20			2020-21	2021-22	2022-23	2023-24	2024-25	2025-26
	BUDGET	LATEST EST.	9-MO ACTUAL	BUDGET (DRAFT)	PROJECTED				
Reserves, Opening Balance [1]	3,368,879	3,368,879	3,368,879	2,497,731	1,383,402	577,463	502,515	842,452	1,724,713
Add *: Excess of Revenue over Expenditures*							339,937	882,261	1,265,872
Less *: Deficiency of Revenue over Expenditures*	(1,004,733)	(871,148)	(501,536)	(1,114,329)	(805,939)	(74,949)			
Reserves, Closing Balance	2,364,146	2,497,731	2,867,343	1,383,402	577,463	502,515	842,452	1,724,713	2,990,585
Approved Reserve Balance	2,000,000	2,000,000	2,000,000	2,000,000	2,000,000	2,000,000	2,000,000	2,000,000	2,000,000
Excess (Deficiency) of Reserves	364,146	497,731	867,343	(616,597)	(1,422,537)	(1,497,485)	(1,157,548)	(275,287)	990,585

FEE TYPE	CURRENT 2019-20	YR 1 2020-21 BUDGET (DRAFT)	YR 2 2021-22	YR 3 2022-23	YR 4 2023-24	YR 5 2024-25	YR 6 2025-26
			PROJECTED				
Pharmacy ***(licensure renewal)***	***$2,345.*** *Increased from* ***$2,299*** *effective Dec 1, 2019*	$2,474 effective Dec 1, 2020 ($129 incr. or 5.5%)	$2,610 ($136 incr. or 5.5%)	$2,650 ($40 incr. or 1.5%)	$2,690 ($40 incr. or 1.5%)	$2,731 ($41 incr. or 1.5%)	$2,772 ($41 incr. or 1.5%)
Pharmacist ***(full renewal)***	***$739.*** *Increased from* ***$724*** *effective Nov 1, 2019*	$778 effective Nov 1, 2020 ($39 incr. or 5.25%)	$819 ($41 incr. or 5.25%)	$832 ($13 incr. or 1.5%)	$845 ($13 incr. or 1.5%)	$858 ($13 incr. or 1.5%)	$871 ($13 incr. or 1.5%)
Pharmacy Technician ***(full renewal)***	***$492.*** *Increased from* ***$482*** *effective Nov 1, 2019*	$518 effective Nov 1, 2020 ($26 incr. or 5.25%)	$545 ($27 incr. or 5.25%)	$554 ($9 incr. or 1.5%)	$563 ($9 incr. or 1.5%)	$572 ($9 incr. or 1.5%)	$581 ($9 incr. or 1.5%)

*****Remarks*****

[1] *Opening 2019/20 reserve balance based on closing balance of audited 2018/19 financial statements.*

College of Pharmacists of BC
2020-21 & Multi-Year Plan

Model 1

COVID-19: Return to Travel March 2022*

Information as of: August 13, 2020

	CURRENT (YR 1)		MULTI-YEAR PLAN				
	2020-21		YR 2	YR 3	YR 4	YR 5	YR 6
			2021-22	2022-23	2023-24	2024-25	2025-26
	BUDGET	LATEST EST.	PROJECTED				
Revenue deferred	9,173,978	8,990,056	9,544,605	10,321,237	11,060,222	11,657,822	12,292,307
Revenue licensure other	554,113	364,965	714,034	612,469	639,852	668,157	699,124
Revenue other	487,475	487,011	484,667	496,399	507,523	519,124	530,962
Revenue	10,215,565	9,842,032	10,743,306	11,430,105	12,207,597	12,845,102	13,522,393
Total Expenditures	11,329,901	10,522,222	11,500,636	12,127,325	12,241,245	12,382,692	12,500,729
OpEx	3,793,788	3,290,953	3,804,954	4,221,802	4,172,711	4,147,786	4,096,020
Labour	7,536,113	7,231,268	7,695,682	7,905,523	8,068,534	8,234,906	8,404,709
Excess (Deficiency) of Revenue over Expenditures	**(1,114,329)**	**(680,189)**	**(757,330)**	**(697,220)**	**(33,648)**	**462,410**	**1,021,664**

	CURRENT (YR 1)		YR 2	YR 3	YR 4	YR 5	YR 6
	2020-21		2021-22	2022-23	2023-24	2024-25	2025-26
	BUDGET	LATEST EST.	PROJECTED				
Reserves, Opening Balance [1]	**2,497,731**	**2,433,077**	**1,752,888**	**995,558**	**298,338**	**264,690**	**727,100**
Add *: Excess of Revenue over Expenditures*						**462,410**	**1,021,664**
Less *: Deficiency of Revenue over Expenditures*	**(1,114,329)**	**(680,189)**	**(757,330)**	**(697,220)**	**(33,648)**		
Reserves, Closing Balance	**1,383,402**	**1,752,888**	**995,558**	**298,338**	**264,690**	**727,100**	**1,748,763**
Approved Reserve Balance	**2,000,000**	**2,000,000**	**2,000,000**	**2,000,000**	**2,000,000**	**2,000,000**	**2,000,000**
Excess (Deficiency) of Reserves	**(616,597)**	**(247,112)**	**(1,004,442)**	**(1,701,662)**	**(1,735,310)**	**(1,272,900)**	**(251,237)**

FEE TYPE	CURRENT (YR 1)	YR 2	YR 3	YR 4	YR 5	YR 6
	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26
		PROJECTED				
Pharmacy ***(licensure renewal)***	***No fee increase. Fee remains at $2,345. Timing of increase changed from Dec 1, 2020 to April 1, 2021.***	**$2,474 ($129 incr. or 5.5%)**	**$2,536 ($62 incr. or 2.5%)**	**$2,600 ($64 incr. or 2.5%)**	**$2,665 ($65 incr. or 2.5%)**	**$2,732 ($67 incr. or 2.5%)**
Pharmacist ***(full renewal)***	***$757. Increased $18 or 2.50% from $739 effective Nov 1, 2020***	**$797 ($40 incr. or 5.25%)**	**$817 ($20 incr. or 2.5%)**	**$838 ($21 incr. or 2.5%)**	**$859 ($21 incr. or 2.5%)**	**$881 ($22 incr. or 2.5%)**
Pharmacy Technician ***(full renewal)***	***$504. Increased $12 or 2.50% from $492 effective Nov 1, 2020***	**$530 ($26 incr. or 5.25%)**	**$544 ($14 incr. or 2.5%)**	**$558 ($14 incr. or 2.5%)**	**$572 ($14 incr. or 2.5%)**	**$587 ($15 incr. or 2.5%)**

Remarks*

[1] *Opening 2020-21 reserve balance based on closing balance of audited 2019-20 financial statements.*

College of Pharmacists of BC

2020-21 & Multi-Year Plan

Model 2

COVID-19: Return to Travel March 2022*

Information as of: August 13, 2020

	CURRENT (YR 1)		MULTI-YEAR PLAN				
	2020-21		YR 2	YR 3	YR 4	YR 5	YR 6
			2021-22	2022-23	2023-24	2024-25	2025-26
	BUDGET	LATEST EST.	PROJECTED				
Revenue deferred	9,173,978	8,993,147	9,659,073	10,371,018	11,062,157	11,659,844	12,294,410
Revenue licensure other	554,113	367,203	719,265	607,045	634,156	662,202	692,886
Revenue other	487,475	487,475	485,614	496,399	507,523	519,124	530,962
Revenue	10,215,565	9,847,825	10,863,951	11,474,462	12,203,836	12,841,170	13,518,258
Total Expenditures	11,329,901	10,522,222	11,500,636	12,127,325	12,241,245	12,382,692	12,500,729
OpEx	3,793,788	3,290,953	3,804,954	4,221,802	4,172,711	4,147,786	4,096,020
Labour	7,536,113	7,231,268	7,695,682	7,905,523	8,068,534	8,234,906	8,404,709
Excess (Deficiency) of Revenue over Expenditures	**(1,114,329)**	**(674,396)**	**(636,684)**	**(652,863)**	**(37,409)**	**458,478**	**1,017,529**

	CURRENT (YR 1)		YR 2	YR 3	YR 4	YR 5	YR 6
	2020-21		2021-22	2022-23	2023-24	2024-25	2025-26
	BUDGET	LATEST EST.	PROJECTED				
Reserves, Opening Balance [1]	**2,497,731**	**2,433,077**	**1,758,681**	**1,121,997**	**469,133**	**431,724**	**890,202**
Add *: Excess of Revenue over Expenditures*						**458,478**	**1,017,529**
Less *: Deficiency of Revenue over Expenditures*	**(1,114,329)**	**(674,396)**	**(636,684)**	**(652,863)**	**(37,409)**		
Reserves, Closing Balance	**1,383,402**	**1,758,681**	**1,121,997**	**469,133**	**431,724**	**890,202**	**1,907,731**
Approved Reserve Balance	**2,000,000**	**2,000,000**	**2,000,000**	**2,000,000**	**2,000,000**	**2,000,000**	**2,000,000**
Excess (Deficiency) of Reserves	**(616,597)**	**(241,319)**	**(878,003)**	**(1,530,867)**	**(1,568,276)**	**(1,109,798)**	**(92,269)**

FEE TYPE	CURRENT (YR 1)	YR 2	YR 3	YR 4	YR 5	YR 6
	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26
		PROJECTED				
Pharmacy ***(licensure renewal)***	***No fee increase. Fee remains at $2,345. Timing of increase changed from Dec 1, 2020 to April 1, 2021.***	**$2,474 ($129 incr. or 5.5%)**	**$2,536 ($62 incr. or 2.5%)**	**$2,600 ($64 incr. or 2.5%)**	**$2,665 ($65 incr. or 2.5%)**	**$2,732 ($67 incr. or 2.5%)**
Pharmacist ***(full renewal)***	***$778. Increased $39 or 5.25% from $739 effective Nov 1, 2020***	**$797 ($19 incr. or 2.5%)**	**$817 ($20 incr. or 2.5%)**	**$838 ($21 incr. or 2.5%)**	**$859 ($21 incr. or 2.5%)**	**$881 ($22 incr. or 2.5%)**
Pharmacy Technician ***(full renewal)***	***$518. Increased $26 or 5.25% from $492 effective Nov 1, 2020***	**$531 ($13 incr. or 2.5%)**	**$545 ($14 incr. or 2.5%)**	**$559 ($14 incr. or 2.5%)**	**$573 ($14 incr. or 2.5%)**	**$588 ($15 incr. or 2.5%)**

Remarks*

1 *Opening 2020-21 reserve balance based on closing balance of audited 2019-20 financial statements.*

College of Pharmacists of BC

2020-21 & Multi-Year Plan

Model 3

COVID-19: Return to Travel March 2022*

Information as of: August 13, 2020

	CURRENT (YR 1)		MULTI-YEAR PLAN				
	2020-21		YR 2	YR 3	YR 4	YR 5	YR 6
			2021-22	2022-23	2023-24	2024-25	2025-26
	BUDGET	LATEST EST.	PROJECTED				
Revenue deferred	9,173,978	8,993,147	9,662,402	10,498,113	11,251,271	11,857,289	12,507,574
Revenue licensure other	554,113	367,203	728,061	623,260	651,122	679,849	711,241
Revenue other	487,475	487,475	486,087	497,967	509,368	521,004	532,877
Revenue	10,215,565	9,847,825	10,876,551	11,619,340	12,411,761	13,058,141	13,751,691
Total Expenditures	11,329,901	10,522,222	11,500,636	12,127,325	12,241,245	12,382,692	12,500,729
OpEx	3,793,788	3,290,953	3,804,954	4,221,802	4,172,711	4,147,786	4,096,020
Labour	7,536,113	7,231,268	7,695,682	7,905,523	8,068,534	8,234,906	8,404,709
Excess (Deficiency) of Revenue over Expenditures	**(1,114,329)**	**(674,396)**	**(624,085)**	**(507,985)**	**170,516**	**675,449**	**1,250,962**

	CURRENT (YR 1)		YR 2	YR 3	YR 4	YR 5	YR 6
	2020-21		2021-22	2022-23	2023-24	2024-25	2025-26
	BUDGET	LATEST EST.	PROJECTED				
Reserves, Opening Balance [1]	**2,497,731**	**2,433,077**	**1,758,681**	**1,134,596**	**626,611**	**797,127**	**1,472,576**
***Add** : Excess of Revenue over Expenditures*					**170,516**	**675,449**	**1,250,962**
***Less** : Deficiency of Revenue over Expenditures*	**(1,114,329)**	**(674,396)**	**(624,085)**	**(507,985)**			
Reserves, Closing Balance	**1,383,402**	**1,758,681**	**1,134,596**	**626,611**	**797,127**	**1,472,576**	**2,723,538**
Approved Reserve Balance	**2,000,000**	**2,000,000**	**2,000,000**	**2,000,000**	**2,000,000**	**2,000,000**	**2,000,000**
Excess (Deficiency) of Reserves	**(616,597)**	**(241,319)**	**(865,404)**	**(1,373,389)**	**(1,202,873)**	**(527,424)**	**723,538**

FEE TYPE	CURRENT (YR 1) 2020-21	YR 2 2021-22	YR 3 2022-23	YR 4 2023-24	YR 5 2024-25	YR 6 2025-26
		PROJECTED				
Pharmacy *(licensure renewal)*	***No fee increase. Fee remains at $2,345. Timing of increase changed from Dec 1, 2020 to April 1, 2021.***	**$2,474 ($129 incr. or 5.5%)**	**$2,536 ($62 incr. or 2.5%)**	**$2,600 ($64 incr. or 2.5%)**	**$2,665 ($65 incr. or 2.5%)**	**$2,732 ($67 incr. or 2.5%)**
Pharmacist *(full renewal)*	***$778. Increased $39 or 5.25% from $739 effective Nov 1, 2020***	**$819 ($41 incr. or 5.25%)**	**$840 ($21 incr. or 2.5%)**	**$861 ($21 incr. or 2.5%)**	**$883 ($22 incr. or 2.5%)**	**$906 ($23 incr. or 2.5%)**
Pharmacy Technician *(full renewal)*	***$518. Increased $26 or 5.25% from $492 effective Nov 1, 2020***	**$545 ($27 incr. or 5.25%)**	**$559 ($14 incr. or 2.5%)**	**$573 ($14 incr. or 2.5%)**	**$588 ($15 incr. or 2.5%)**	**$603 ($15 incr. or 2.5%)**

Remarks*

1 *Opening 2020-21 reserve balance based on closing balance of audited 2019-20 financial statements.*

College of Pharmacists of British Columbia

4. Audit and Finance Committee: COVID-19 Budget Review and Fee Increase Consideration

Steven Hopp

Chair, Audit and Finance Committee

Mary O'Callaghan

Chief Operating Officer

College of Pharmacists of British Columbia

Background

- COVID-19 Generated Savings as of July 2020 are almost $400,000 compared to budget.
- Expenses are 16% below budget due to savings in:

Travel and Accommodations	$190,000
Strategic Plan timing	$ 53,000
Staffing – gapping	$120,000
Professional development	$ 15,000

College of Pharmacists of British Columbia

Background continued

- However, revenues are 4% below budget at July 2020 due to impacts from:

Jurisprudence Exam postponement	$54,000
Pharmacy renewals and fees	$34,000
Injection fees	$ 7,700
Pharmacists fees and renewals	$25,500

College of Pharmacists of British Columbia

Background continued

- Although this year's final results will be better than budgeted for, the multi-year projections still show the need for the fee increase.
- As the decision was made to phase in fee increases to replace the lost revenue from the College's former PharmaNet contract with the Ministry of Health, the multi-year projections show continued deficits that deplete the reserves to a very low level in 2023/24 before starting to slowly build again.
- This is due to the length of time for fee increases to be billed (over a year to account for varying renewal times) and to be earned (one month at a time).

College of Pharmacists of British Columbia

Approved budget 2020/21

The 2020/21 budget was approved in February 2020.

The budget was based upon the assumption that fees would be increased as follows:

- Pharmacists - $39 (5.25%) in November 2020
- Pharmacy Technicians - $26 (5.25%) in November 2020
- Pharmacies - $129 (5.5%) in December 2020
- At the April Board meeting, the Board recommended reviewing the impact of COVID-19 prior to implementing the fee increases.

College of Pharmacists of British Columbia

Scenarios

The scenarios all include:

- The same expenditure assumptions (latest projections based upon June actuals)
- Fee increases for registrants come into effect November of each year as usual
- Pharmacy fee increases must be posted as well as filed, so will come into effect April 2021 and continue with April each year after.

College of Pharmacists of British Columbia

Scenario – Model One

Model One includes:

- Delaying the approved budget's fee increase until next year, but
  - Implementing a reduced fee increase this year
- This delay of one year results in projections of a concerning small amount of Reserve funds in 2023/24

College of Pharmacists of British Columbia

Model One

Model One	Year 1 2020-21 Latest Estimate	Year 2 2021-22	Year 3 2022-23	Year 4 2023-24
Current Fees: PH - $739 PT - $492 PY - $2,345	PH - $18 (2.5%) PT - $12 (2.5%) PY – n/a	PH - $40 (5.25%) PT - $26 (5.25%) PY - $129 (5.5%)	PH - $20 (2.5%) PT - $14 (2.5%) PY - $62 (2.5%)	PH - $21 (2.5%) PT - $14 (2.5%) PY - $65 (2.5%)
Reserve Balance	$1,752,888	$995,558	298,338	**264,690**

College of Pharmacists of British Columbia

Scenario – Model Two

Model Two includes:

- Implementing the 2020/21 budget fee increases this year (for registrants) and as soon as possible (April 2021) for Pharmacies.
- The Reserves in 2023/24 are still low but considerably better than in Model One.

College of Pharmacists of British Columbia

Model Two

Model Two	Year 1 2020-21 Latest Estimate	Year 2 2021-22	Year 3 2022-23	Year 4 2023-24
Current Fees: PH - $739 PT - $492 PY - $2,345	PH - $39 (5.25%) PT - $26 (5.25%) PY – n/a	PH - $19 (2.5%) PT - $13 (2.5%) PY - $129 (5.5%)	PH - $20 (2.5%) PT - $14 (2.5%) PY - $62 (2.5%)	PH - $21 (2.5%) PT - $14 (2.5%) PY - $64 (2.5%)
Reserve Balance	$1,758,681	$1,121,997	469,133	**431,724**

College of Pharmacists of British Columbia

Scenario – Model Three

- Model Three is included solely to show that decisions made concerning next year's budget will impact future years' Reserve levels as well.
- At this point the decision is only concerned with approving fee increases related to this year's budget.
- The 2021/22 budget will begin to be prepared this fall and will be brought to the February 2021 Board meeting for approval.

College of Pharmacists of British Columbia

Model Three

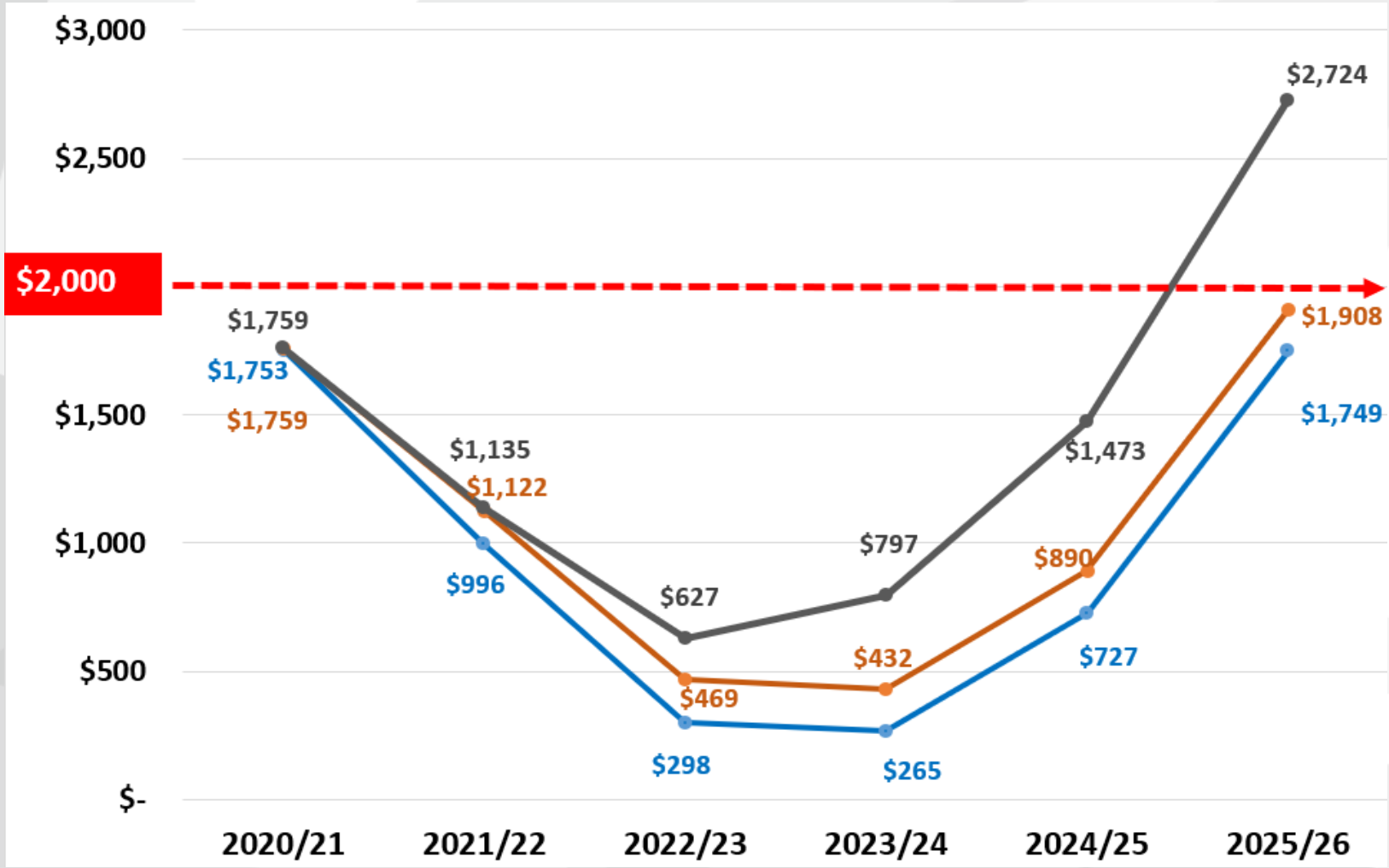
Model Three	Year 1 2020-21 Latest Estimate	Year 2 2021-22	Year 3 2022-23	Year 4 2023-24
Current Fees: PH - $739 PT - $492 PY - $2,345	PH - $39 (5.25%) PT - $26 (5.25%) PY – n/a	PH - $41 (5.25%) PT - $27 (5.25%) PY - $129 (5.5%)	PH - $21 (2.5%) PT - $14 (2.5%) PY - $62 (2.5%)	PH - $21 (2.5%) PT - $14 (2.5%) PY - $64 (2.5%)
Reserve Balance	$1,758,681	$1,134,596	**626,611**	797,127

College of Pharmacists of British Columbia

Projected Impact on Reserves

(in thousands)

Approved Reserve Balance



College of Pharmacists of British Columbia

4. Audit and Finance Committee: COVID-19 Budget Review and Fee Increase Consideration

MOTION:

Direct the Registrar to implement the annual fee increases as stated in the 2020-21 budget, 5.25% increase effective November 2020 for pharmacists and pharmacy technicians, and 5.5% increase effective approximately April 2021 for pharmacies.

College of Pharmacists of British Columbia

Questions

PRESENTATION TO
COLLEGE OF PHARMACISTS OF BC BOARD

September 18, 2020

Gabriella Wong, BSc(Pharm), RPEBC, RPh

Board Director, Pharmacy Examining Board of Canada

PRESENTATION AGENDA

- Brief overview of PEBC and PEBC Board
- Introduction to various assessments and examinations
- Implications of COVID-19 on assessments and examinations

THE PHARMACY EXAMINING BOARD OF CANADA (PEBC)

- National certification body for the pharmacy profession
- Not-for-profit, self-supporting organization
- Established by a Special Act of Parliament
  - December 21, 1963
- Over 50 years of experience in assessing the qualifications and competence of candidates for licensing by pharmacy provincial regulatory authorities

PURPOSE OF PEBC

Purpose:

- To assess candidates and certify that new pharmacist and pharmacy technician registrants have the necessary knowledge, skills and abilities to practice at an entry-level

Responsibility:

- To ensure achievement of a minimum level of competence to practice at an entry-level, in the interest of public protection
- To ensure that PEBC exams are valid, reliable, legally defensible and administered in a standardized manner

PEBC BOARD

One appointee from:

- Each provincial licensing bodies (10)
- Canadian Society of Hospital Pharmacists (CSHP)
- Canadian Pharmacists Association (CPhA)
- Canadian Association of Pharmacy Technicians (CAPT)

Two appointees from:

- Canadian Pharmacy Technician Educators Association (CPTEA)
- Association of Faculties of Pharmacy of Canada (AFPC)

PEBC BOARD

Term of Office:

- 3 years, renewable for 1 term

Duties and Responsibilities:

- Control and direction of:
  - all activities of the Board and its committees
  - disbursement of its funds
  - determination of its policies and strategic direction

Committees:

Nominating Committee
Executive Committee
By-Laws Committee
Committee on Examinations
Finance Committee
Public Relations Committee
Committee on Specialties

OBJECTS OF THE CORPORATION

- to establish qualifications for entry-to-practice pharmacists and pharmacy technicians, acceptable to participating regulatory authorities;
- to establish and certify the qualifications for pharmacists in pharmacy practice specialities;
- to assess and/or certify pharmacists for continuing competence, re-entry to practice, readiness to undertake advanced or expanded pharmacy practice roles including but not limited to disease prevention and management functions;

OBJECTS OF THE CORPORATION

- to assess and certify the qualifications for entry-to-practice pharmacy technicians and pharmacy assistants;
- to issue certificates of qualification to pharmacy specialists and for advanced or expanded pharmacy practice roles;
- to issue certificates of qualification to entry-to-practice pharmacy technicians and pharmacy assistants; and …

PROVINCIAL REGULATORY AUTHORITIES' REQUIREMENTS FOR PHARMACISTS

- All provinces except Quebec require PEBC certification for all pharmacist applicants for licensure

- PEBC certification is only one of several requirements

- In addition to the PEBC Certificate of Qualification, each province has additional licensing requirements. These may include practical experience, English or French language skills, and jurisprudence examinations.

Assessment and Examinations

International Pharmacy Graduates	Canadian Pharmacy Graduates	International Pharmacy Technician Candidates *New for 2020*	Direct-Entry Candidates
Pharmacist Document Evaluation	Pharmacist Qualifying Examination • Part I MCQ • Part II OSCE	Documents Evaluation	Pharmacy Technician Qualifying Examination • Part I MCQ • Part II OSPE
Pharmacist Evaluating Examination		Portfolio Assessment	
Pharmacist Qualifying Examination • Part I MCQ • Part II OSCE		Pharmacy Technician Qualifying Examination • Part I MCQ • Part II OSPE	

Entry-to-Practice Examinations for Pharmacists

ASSESSMENT OF INTERNATIONAL PHARMACY GRADUATES

Two step evaluation process

Step 1: Document Evaluation

Step 2: Evaluating Examination

PHARMACIST DOCUMENT EVALUATION

Purpose:

- Ensure international pharmacist applicant (trained outside Canada and U.S.) has acquired a legitimate university degree in pharmacy acceptable to the Board

PHARMACIST EVALUATING EXAMINATION

Purpose:

- Determine the comparability of education of candidates from international pharmacy programs to graduates of Canadian programs
- Evaluate candidate's knowledge and skills in major areas of Canadian pharmacy curriculum

PHARMACIST QUALIFYING EXAMINATION (QE)

Purpose:

- Assess entry-level competence in the practice of pharmacy
- Designed to assess competencies required for safe and effective practice
- Examines ability of candidates to apply their knowledge, skills and abilities to solve practice-based problems and meet patients' needs

QE EXAMINATION STRUCTURE

Part I – computer based - multiple choice (MCQ)

- Tests understanding and application of knowledge
- Tests ability to make judgments in situations relevant to practice

Part II - performance assessment - *Objective, Structured, Clinical Exam* (OSCE)

- Tests ability to communicate
- Tests ability to perform professional functions
- Tests ability to problem-solve and make judgments
- Consists of 7-minute ‘stations’ based on common/critical practice situations

Entry-to-Practice Examinations for Pharmacy Technicians

PT EVALUATING EXAMINATION

- Discontinued transitional pathway in 2018
- Pharmacy Technician Evaluation Process for International Candidates for 2020
  - Documents Evaluation
  - Portfolio Assessment for International Candidates:
    - Assess Education and Practice Portfolio

Pharmacy Technician Qualifying Examination for Entry-to-Practice

- Purpose: to assess and certify the competence of Pharmacy Technicians at entry to practice
- Format: two parts
  - written multiple-choice question exam (MCQ)
  - performance-based exam (OSPE)
- Number of attempts:
  - maximum of four attempts for each part
  - remediation required after the third attempt
  - must complete both parts within 3 years of passing one part

QE Examination Structure

Part I - written exam -

multiple choice (MCQ)

- tests understanding and application of knowledge
- tests ability to make judgments in situations relevant to practice

Part II - performance assessment

Objective, Structured, Performance Exam (OSPE)

- tests ability to communicate
- ability to perform professional functions in simulated practice contexts
- tests technical skills (compounding and prescription checking
- tests ability to problem-solve and make judgments

PRE-COVID

EXAMINATION CENTRES AND SCHEDULE

Spring

- **Part I (MCQ)** - Computerized testing sites at Prometric Testing Centres (approx. 17)
  - All Part I sites offer English and French
- **Part II (OSCE)** - Vancouver, Edmonton, Calgary, Saskatoon, Winnipeg, Toronto, Hamilton, Kingston, London (ON), Ottawa, Waterloo, Montreal (bilingual), Halifax, St. John's

Fall

- **Part I (MCQ)** – Computerized testing sites at Prometric Testing Centres (approx. 17)
- **Part II (OSCE)** - Vancouver, Edmonton, Calgary, Toronto, Hamilton, London(ON), Ottawa, Waterloo, Montreal (bilingual)

IMPLICATIONS OF COVID-19 ON EXAMINATIONS

- March 2020
  - Cancelled April 2020 PEBC Pharmacy Technician Qualifying Examination Part I (MCQ) and Part II (OSPE) across Canada
  - Postponed May 2020 PEBC Pharmacist Qualifying Examination Part I (MCQ) and Part II (OSCE) across Canada
- April 2020
  - Rescheduled Pharmacist Qualifying Examination Part I (MCQ) rescheduled for August 4 & 5, 2020
    - Accepting new applications for November 2020 Part I (MCQ)
  - Cancelled Pharmacist Qualifying Examination Part II (OSCE) to hold next administration of exam in November 2020
    - Delayed opening of new applications to determine available capacity

IMPLICATIONS OF COVID-19 ON EXAMINATIONS

- May 2020
  - Board approved use of remote proctoring as additional examination delivery modality for MCQ exams
- June 2020
  - Rescheduled Pharmacist Evaluation Examination from June to July 2020

SUMMARY

International Pharmacy Graduates	Canadian Pharmacy Graduates	International Pharmacy Technician Candidates *New for 2020*	Direct-Entry Candidates
Pharmacist Document Evaluation – DELAYED	Pharmacist Qualifying Examination • Part I MCQ – MAY → AUGUST * • Part II OSCE – MAY → NOVEMBER	Documents Evaluation	Pharmacy Technician Qualifying Examination • Part I MCQ— APRIL→SEPTEMBER* • Part II OSPE— APRIL→SEPTEMBER
Pharmacist Evaluating Examination – JUNE → JULY *		Portfolio Assessment	
Pharmacist Qualifying Examination • Part I MCQ – MAY → AUGUST * • Part II OSCE – MAY → NOVEMBER		Pharmacy Technician Qualifying Examination • Part I MCQ • Part II OSPE	

* REMOTE PROCTORING OPTION AVAILABLE

Thank You

PICNet
PROVINCIAL INFECTION CONTROL NETWORK OF BRITISH COLUMBIA
A program of the Provincial Health Services Authority

Influenza Season and COVID…. Now what?

September 2020
Joanne Archer RN Btech MA
Education and Practice Coordinator

Objectives

- Overview of PICNet
- What We Have Learned So Far
  - Virus attributes
  - Epidemiology
  - Treatments
  - Antibody Testing
  - Vaccinations and COVID
- COVID-19 Resources

Who is the Provincial Infection Control Network (PICNet)?

- Established in 2005 by the Ministry of Health following an Auditor Generals report
- A program under PHSA
- Mandated to provide infection control leadership and standardize practices and surveillance and function as a knowledge collaborative
- Links nationally and internationally

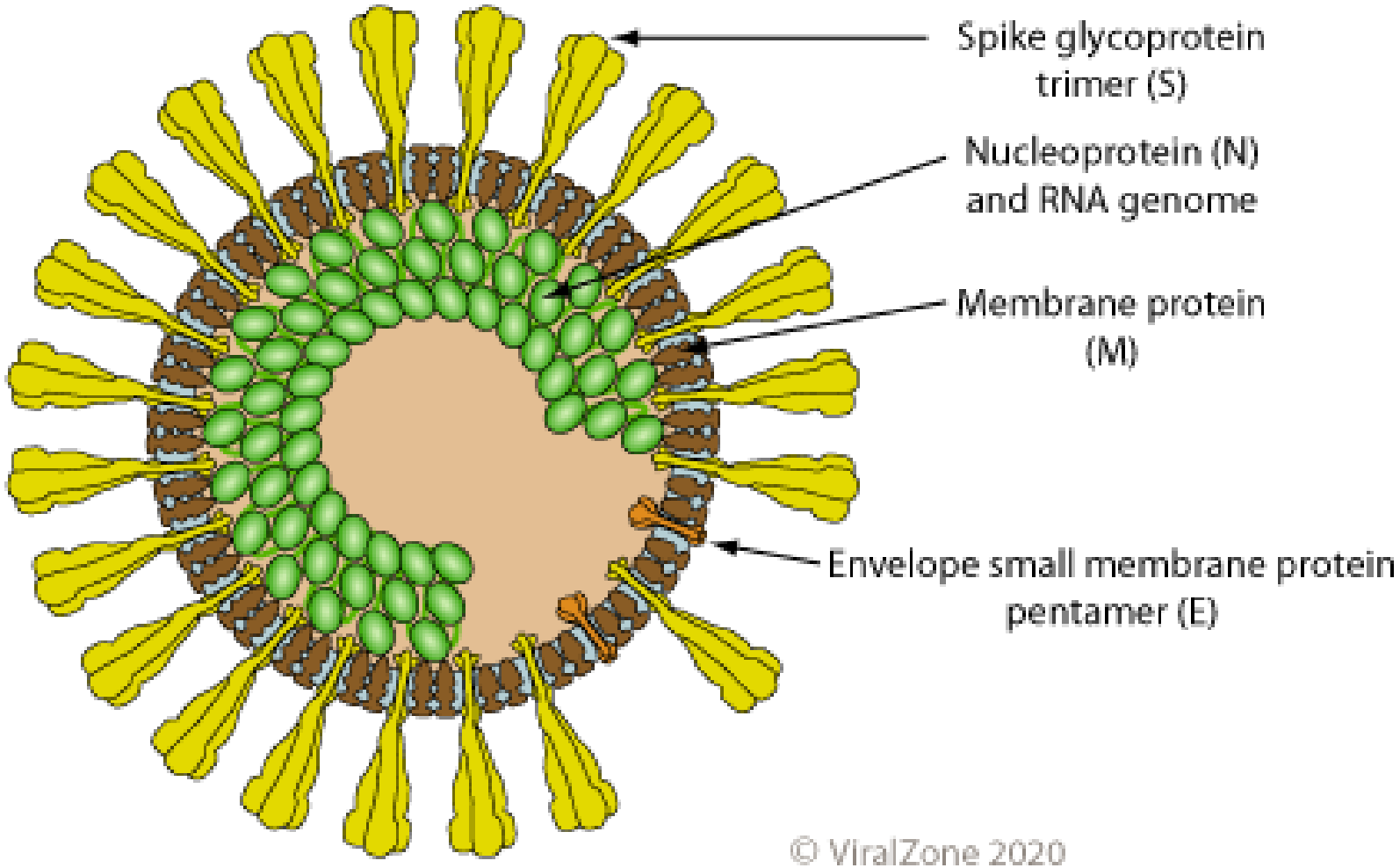
Who is PICNet?

PICNet's three key areas of focus are:

- Guidelines that provide provincial guidance in infection prevention and control practices
- Surveillance of healthcare-associated infections in BC hospitals
- Education of infection control and healthcare professionals

Our community of practice includes public health and workplace health

COVID-19 Virus



What We've Learned So Far

- Not hardy in the environment; deactivated by common household cleaners
- Most significant mode of transmission is via large respiratory droplets during close (< 2 meter) face to face contact
- Some hard, non-porous (e.g. metal) surfaces may play a much less significant role (person picks virus off surface and self-innoculates)
- Porous surfaces (e.g. paper, cloth) do not play a significant role in transmission

What We've Learned So Far

- Vast majority of transmission (78-85%) has occurred within settings of close prolonged contact.
- Secondary attack rate in households not consistent with airborne spread
- Reproduction number 2.2-2.7 (comparable to influenza)
  - R_0 for measles >10
- Only 1 study has found viable viral particle in health care unit air samples (no differentiation in particle sizes, time/density of droplets unknown)

What We've Learned So Far (Airborne vs Droplet, Surface contamination)

Read articles with caution because:

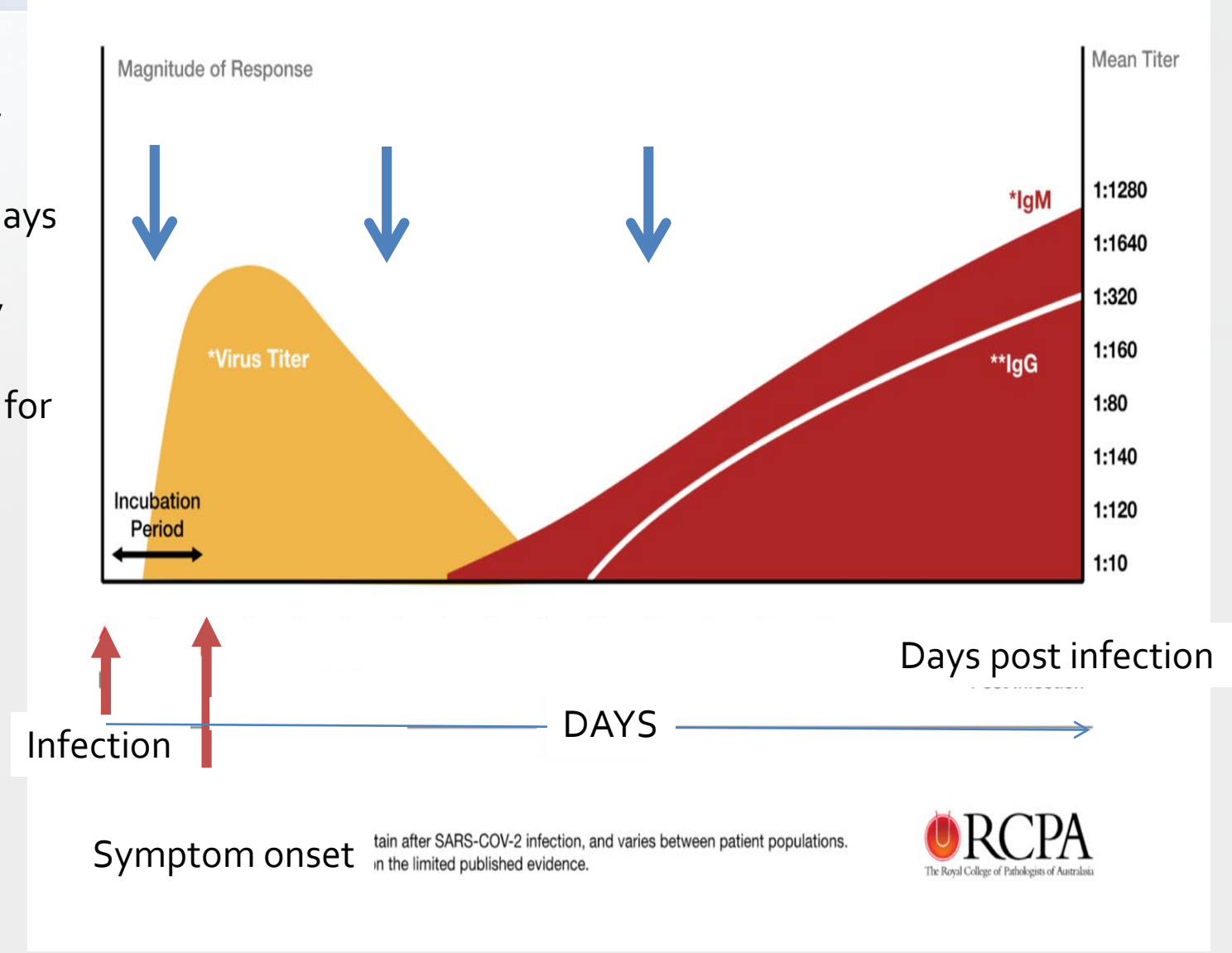
- Different definitions of airborne/aerosol /droplet
- Settings mostly laboratory
- RNA versus viable virus (presence of RNA doesn't confirm viability)
- Do not account for other important elements such as quantity and distribution of virus within the tiny droplet (infectious dose), ability to enter respiratory tract, ability to bind to specific host cell receptors, replication and infection competence etc.

What We've Learned So Far

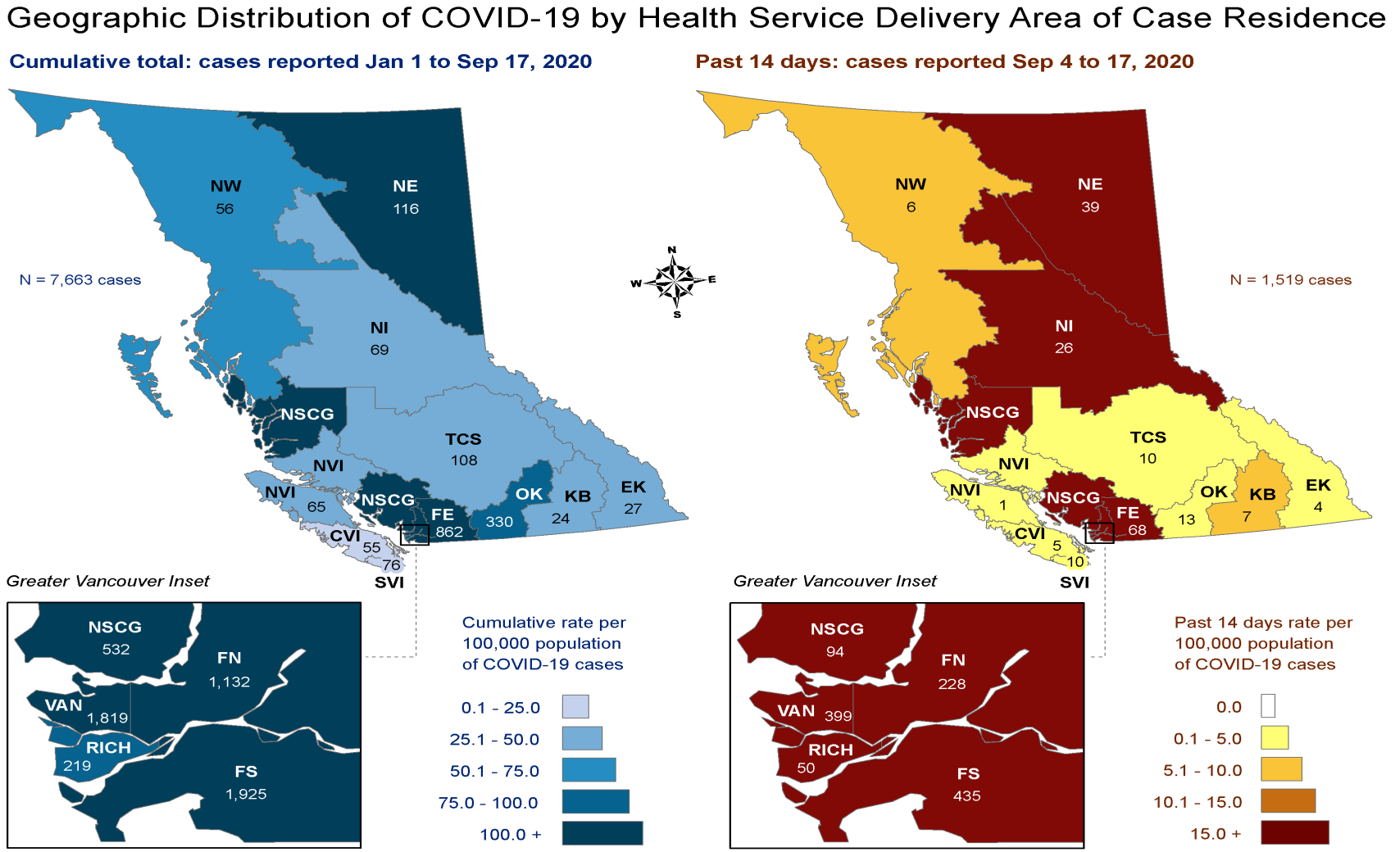
- Highest level of viable virus shed during the first week of symptoms
  - RNA load highest during the 1st week, then decreases
  - RNA shedding occurs ~3 weeks , can be longer
  - Viable viral shedding about 10 days but longer in severe cases or patients who are immunocompromised
- NP swabs more sensitive than throat swabs
- May be infectious pre-symptoms, but data regarding how that occurs is limited

What We've Learned So Far

- Upper respiratory tract viral load highest in first 5 days
- Lower respiratory tract likely starts later and extends for longer with lung involvement



BCCDC COVID-19 Data

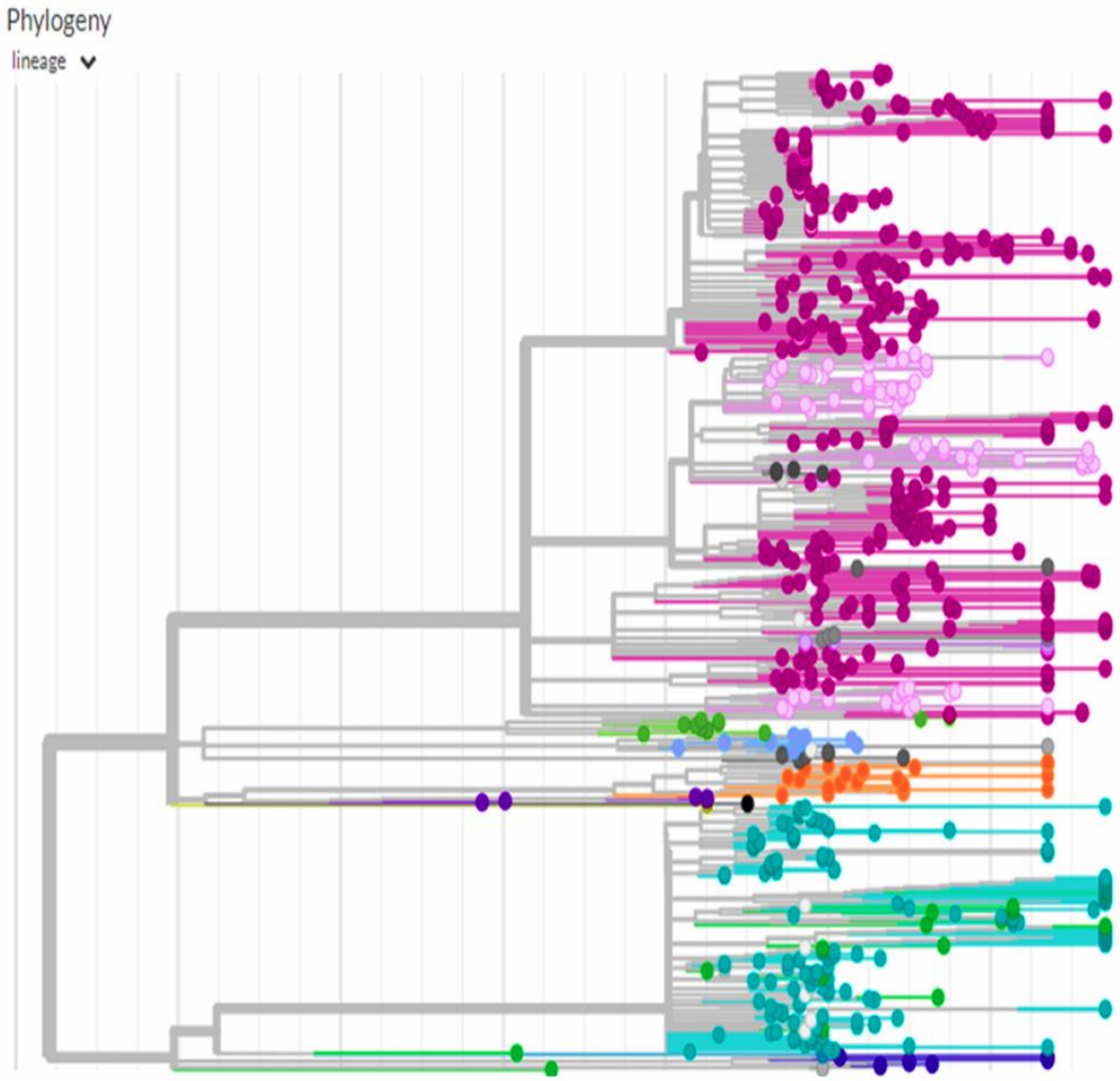


Notes: Cases are mapped by location of residence; cases with unknown residence and from out of province are not mapped. Data source: we operate in a live database environment; case information from the 5 regional health authorities of British Columbia are updated as it becomes available. How to interpret the maps: The map on the left (blue) illustrates the geographic distribution of all reported cases from January 1, 2020 onwards. The map on the right (brown) illustrates the reported cases during the past 14 days. Health Service Delivery Areas (HSDA) with higher rates are illustrated in darker colour shading. The number of reported cases appears under each HSDA label. Note that not all COVID-19 infected individuals are tested and reported; the virus may be circulating undetected in the community, including in areas where no cases have been identified by public health. Map created September 17, 2020 by BCCDC.

Number and percentage distribution of COVID-19 cases, hospitalizations, ICU admissions and deaths by age, compared to the general population of BC, January 1 – August 20, 2020 (N=4,775*)

Age group	+ COVID n, (%)	Hospitalized n, (%)	ICU n, (%)	Deaths n, (%)	General pop
<10	207 (3)	3 (<1)	0 (0)	0 (0)	468,280 (9)
10-19	398 (5)	2 (<1)	0 (0)	0 (0)	507,197 (10)
20-29	1744 (23)	22 (3)	7 (3)	0 (0)	684,681 (13)
30-39	1551 (21)	49 (7)	15(6)	0 (0)	730,523 (14)
40-49	1072 (14)	58 (9)	22 (9)	3 (1)	647,790 (13)
50-59	995 (13)	1001 (15)	40 (17)	5 (2)	721,355 (14)
60-69	633 (8)	137 (20)	57 (24)	20 (9)	675,632 (13)
70-79	412 (5)	163 (24)	70 (30)	39 (18)	436,179 (9)
80-89	308 (4)	103 (15)	19 (8)	90 (41)	188,010 (4)
90+	172 (2)	42 (6)	4 (2)	62 (28)	50,876 (1)
Total	7,497	680	234	219	5,110,523

Genomic Epidemiology: Virus Origin



European-like & Eastern Canada

Via Iran

Mainly China

Washington State-like

Mainly China

Prevalence in BC

- BCCDC lab tested 869 random specimens March 5-13 and another 885 specimens May 15-27
  - Labwork done for other reasons than COVID-19
- Results (2 from March and 4 from May) were extrapolated to the general population resulting in an estimated 8 cases for every one diagnosed.
- Swiss study results were 10/1,
- USA study results 6-24/1 (depending upon the county)

Clinical Illness Picture

- Majority of illness ~80% does not required hospitalization
  - Generally a similar presentation (fever, cough, dyspnea, sore throat, nasal congestion, fatigue, arthralgia, myalgia, headache, nausea/vomiting, diarrhea)
- Severe illness unique to individual immune systems (ARDS, acute kidney injury, stroke, COVID toes, multisystem inflammatory syndrome in children etc.)

Treatment

- Dexamethasone 6 mg IV/PO q24h for up to 10 days for patients requiring mechanical ventilation and for hospitalized patients requiring supplemental oxygen.
- Remdesivir has conditional approval by Health Canada for the treatment of COVID-19, however availability of Remdesivir in British Columbia remains limited to clinical trials.
- Antibiotics should be initiated if bacterial infection is suspected.

Treatment

- Enoxaparin 30 mg SC bid for VTE prophylaxis in critically ill patients and consider for VTE prophylaxis in ward-based patients with COVID-19.
  - higher doses of enoxaparin for hospitalized patients with weight above 100 kg or BMI above 40 kg/m 2
- Patients on ACE inhibitors and ARBs are recommended to continue these agents as indicated and not cease therapy solely on the basis of COVID-19

Testing for Antibodies

- About 95% sensitive at ~30 days post symptom onset and the specificity is approximately 99.5%.

- COVID-19 antibody testing is NOT available for routine clinical use NOR is it recommended for clinical diagnostic purposes in outpatient populations. Antibody testing is only recommended for :
  - a limited number of clinical scenarios, or
  - at the direction of medical health officers as part of public health investigations, or
  - epidemiologic and research studies

Antibody Testing

- Patients who present with atypical clinical manifestations such as inflammatory syndromes; ie. multisystem inflammatory syndrome in children (MIS-C).
- To help diagnose patients who are SARS-CoV-2 RNA negative, but present with a compatible syndrome, or who present later during their disease course.
  - note that serological testing becomes reliable after 14 or more days post-symptom onset. Testing at earlier may result in false negative results.
- Case-by-case testing after consultation with a clinical/medical microbiologist.

COVID and Immunizations
Challenges posed by COVID-19:

- Need for measures to avoid transmission of COVID-19 to staff
- Access to sufficient supplies of PPE for vaccinators and other staff
- Access to or suitability of usual venues for immunization administration
- Public fear of exposure to COVID-19 while accessing immunization services
- Potentially increased demand for influenza vaccine starting early in the campaign, as seen in the Southern hemisphere

Opportunities

- Immunization appointments provide an avenue to assess the needs of the client for education and advice on immunizations in general, influenza and COVID-19 in particular
- Develop and practice approaches that may be used for the anticipated COVID-19 massive immunization program
- Identify diverse needs of groups based on: access to services, vulnerability, ethnicity/culture and other socioeconomic factors

For 2020 Influenza Vaccination Season Consider:

- Extend immunization availability hours to avoid crowding
- Use an appointment system
- Designate a specific staff member(s) for immunizations to avoid disrupting the dispensing of medications
- Outdoor or drive through clinic if appropriate
- Mobile clinic that can visit a neighborhood or small remote community
- Funnel clients in a one way direction that also maintains physical distancing while waiting

Infection Prevention and Control Practices for Immunizers

- Staff:
  - Vaccinators should wear a medical mask and eye protection as should other staff who are not able to maintain a two-metre physical distance
  - wear gloves only, except when administering intranasal influenza vaccine or oral non-influenza vaccines (e.g., rotavirus) change between clients (and do hand hygiene)
- Screen clients for symptoms and do not proceed if they are ill
- Ask clients to wear a non-medical mask and do hand hygiene

COVID Resources

- List of links for quick access to COVID-19 literature

Document

Contact Us

- **General Inquiries:** picnet@phsa.ca

- **Joanne Archer**

  Education and Practice Coordinator
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College of Pharmacists of British Columbia

BOARD MEETING
September 18, 2020

7. Legislation Review Committee
a) Removal of Natural Health Products from the *Drug Schedules Regulation*

DECISION REQUIRED

Recommended Board Motion:

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.

Purpose

To seek Board approval to remove natural health products (NHPs) from the *Drug Schedules Regulation* under the *Pharmacy Operations and Drug Scheduling Act* to align with the removal of NHPs from the National Association of Pharmacy Regulatory Authorities' (NAPRA's) National Drug Schedules.

Background

Health Canada determines whether a drug must be sold by prescription only or can be sold over the counter (non-prescription status). Provincial regulatory authorities (PRAs) can further restrict the conditions of sale of "non-prescription" products; however, they cannot be less stringent than the federal requirements.

Typically, for those drugs determined by Health Canada to be non-prescription, most PRAs schedule by reference to recommendations made by NAPRA in the National Drug Schedules.

NAPRA created the National Drug Schedules Advisory Committee (NDSAC) to recommend appropriate placement of non-prescription drugs within a three schedule national model[1] in the National Drug Schedules. According to NAPRA, "NDSAC members are chosen for their knowledge and expertise in such areas as pharmacotherapy, drug utilization, drug interactions and toxicology, pharmacy practice, academic research, the drug industry and pharmaceutical regulatory affairs at federal and provincial levels".[2] Their recommendations include an examination of the scientific evidence to support their rationale, along with allowing for public input through a public posting period.

[1] The National Drug Schedules categorize drugs as Schedule I, II, or III.
[2] http://napra.ca/committee-membership

British Columbia is one of the few provinces in Canada that maintains its own list of scheduled drugs in the *Drug Schedules Regulation*.[3,4] Nevertheless, most amendments to BC's *Drug Schedules Regulation* are based on recommendations from NAPRA. The legislative authority for the Board to amend the *Drug Schedules Regulation* is outlined in section 22 of the *Pharmacy Operations and Drug Scheduling Act*:

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

Natural Health Products and the National Drug Schedules

Natural health products are naturally occurring substances that are "often made from plants, but can also be made from animals, microorganisms and marine sources."[5] NHPs are available in a variety of formulations, including creams, tablets, and capsules, and became subject to federal regulation in 2004 under the *Natural Health Products Regulation* (NHPR), under the *Food and Drugs Act*. As required by the NHPR, all NHPs must have a product license issued by Health Canada to be legally sold in Canada. Health Canada requires evidence of the efficacy and safety of an NHP prior to issuing a license, and there are different licensing pathways for NHPs that make modern health claims, and those that are used as traditional medicines.[6]

There were many products scheduled on NAPRA's National Drug Schedules that were reclassified as NHPs when the NHPR came into force in 2004.[7] This created a scheduling discrepancy, as only this subset of NHPs were scheduled on the National Drug Schedules. Products that had always been considered NHPs, and NHPs new to the market since 2004 have never been considered by NAPRA for scheduling on the National Drug Schedules. NAPRA determined that scheduling NHPs on the National Drug Schedules was beyond its scope but agreed to keep the reclassified NHPs on the National Drug Schedules on an interim basis.

In late 2019, NAPRA announced that it would begin removing NHPs from its National Drug Schedules in a step-wise manner. NAPRA stated that "given that the interim measure initiated many years ago only addresses the risk of a small subset of NHPs while others are available to consumers without directed conditions of sale, NAPRA has determined that this disparate

---

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

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

[4] The College has requested that the Ministry of Health consider amending the *Drug Schedules Regulation* to allow for automatic adoption of NAPRA recommendations, alongside with maintaining authority to make exceptions. At this time, the Ministry of Health has not indicated that it will amend the *Drug Schedules Regulation*.

[5] https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/regulation/about-products.html

[6] https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/regulation.html

[7] https://napra.ca/background-update-napra-nhp-policy

approach is no longer in the best interest of the public."[8] This was a broad policy decision, and the usual National Drug Schedules scheduling process was not followed (i.e. NDSAC did not assess the risk or benefit of removing each NHP from the National Drug Schedules). As of 2022, NAPRA will consider all products with a Natural Product Number (NPN) or Drug Identification Number-Homeopathic Medicine (DIN-HM) issued from Health Canada to be outside of its scope.

NHP removals from the National Drug Schedules will occur in two phases, with the first phase having already occurred:

1. Effective January 2, 2020: 34 unscheduled NHPs and 20 Schedule III NHPs were removed from the National Drug Schedules, except for Schedule III products containing ephedrine and pseudoephedrine.
2. Effective January 2, 2022: Schedule III NHPs containing ephedrine or pseudoephedrine, 33 Schedule II, and 5 Schedule I NHPs will be removed from the National Drug Schedules. An additional 22 Schedule I and Schedule II NHPs will have their listings changed (these primarily include NHPs in injectable form that will remain on the National Drug Schedules).

Appendix 1 contains a table of all the NHPs that have been, and that will be, removed from the National Drug Schedules.

Discussion

As the *Drug Schedules Regulation* in BC closely aligns with the National Drug Schedules, all the Schedule I, II and III NHPs that have been, and that will be, removed from the National Drug Schedules are currently scheduled on the *Drug Schedules Regulation*. The *Drug Schedules Regulation*, like the National Drug Schedules, only contains a subset of NHPs, and many other NHPs were never considered for scheduling on the *Drug Schedules Regulation*, but could have similar risks as those that are scheduled. The *Drug Schedules Regulation* lists only one NHP[9] that is not listed in the National Drug Schedules, indicating that it also does not provide a consistent scheduling approach for all NHPs licensed for sale in Canada. Consideration should be given to removing NHPs from the *Drug Schedules Regulation* in the same way they are being removed from the National Drug Schedules.

Jurisdictional Scan

While not the case in British Columbia, most other jurisdictions schedule drugs by reference to NAPRA's National Drug Schedules, and do not maintain their own provincial drug schedule (see Appendix 2). A subset of these jurisdictions schedule by reference, but have additional authority conferred in their legislation to make exceptions to the National Drug Schedules. Jurisdictions permitting exceptions include Alberta, Manitoba, Prince Edward Island, and Saskatchewan. So far, these four jurisdictions have not made any exceptions in response to the

[8] https://napra.ca/background-update-napra-nhp-policy

[9] The NHP listed in the *Drug Schedules Regulation* but not the National Drug Schedules is Lobelia and its alkaloids and preparations (except internal preparations containing not more than 2 mg lobeline sulphate, external preparations containing not more than the equivalent of 400 mg of crude lobelia or preparations containing 130 mg or less of lobelia inflata).

removal of the twenty Schedule III NHPs from the National Drug Schedules. This means that the twenty Schedule III NHPs removed from the NDS are no longer scheduled in most jurisdictions in Canada.

Newfoundland & Labrador is like BC in that they typically follow NAPRA's scheduling recommendations, but changes to the provincial drug schedule require Board approval. The Newfoundland & Labrador Pharmacy Board decided to align with NAPRA's policy decision, and removed the twenty Schedule III NHPs early in 2020.[10]

As the remaining forty Schedule I, II and III NHPs will not be removed from the National Drug Schedules until 2022, it is too early to know if jurisdictions that schedule by reference and also have the authority to make exceptions to the National Drug Schedules will make any exceptions for these products.

Scheduling Changes

In addition to the removal of forty Schedule I, II, and III NHPs, twenty-two Schedule I and II NHP listings on the National Drug Schedules will change in January 2022. The majority of these only involve changes to the listing comment (i.e., change "for parenteral use" to "in injectable form"). As per the NHPR, an NHP that is administered by puncturing the dermis does not meet the definition of an NHP.[11] As such, NHPs administered by injection will remain on the National Drug Schedules. See appendix 1 for the full list of planned National Drug Schedules NHP listing changes.

Considerations

In determining a path forward, the College considered assessing the benefits and risks of removing each NHP from the drug schedules. If the College were to take this approach, all other NHPs that have never been reviewed would need to be assessed for scheduling in the *Drug Schedules Regulation*, to ensure a consistent scheduling approach for all NHPs. This option may lead to misalignments in the scheduling of NHPs between BC and the rest of the country, as no other jurisdiction has pursued this option. Another barrier to this option is a potential lack of sufficient information, as information required for NHP licensing decisions is quite different than what is required for drug scheduling decisions.

The College will collaborate with other stakeholders, including NAPRA and other PRAs to determine how to best assess risk moving forward, focusing on the removal of Schedule II and I NHPs in 2022. NAPRA has been collaborating with Health Canada and other stakeholders to achieve an approach for the sale of NHPs in Canada that better protects Canadians from the risks of all NHPs, not only the current subset.

As only a subset of NHPs are scheduled on BC's *Drug Schedules Regulation*, and many others were never reviewed or assessed for scheduling, following the approach of NAPRA by removing NHPs from the *Drug Schedules Regulation* is recommended. This recommendation is consistent with the approaches of jurisdictions presented in appendix 2.

[10] https://nlpb.ca/provincial-drug-schedules-updated-to-reflect-napra-policy-changes/
[11] https://laws-lois.justice.gc.ca/eng/regulations/sor-2003-196/FullText.html

Guiding Questions

Key questions for the Board to consider are:

- Is the removal of natural health products from the *Drug Schedules Regulation* to align with NAPRA's National Drug Schedules in the best interest of the public?
- Are there any key considerations missing from the proposal to remove natural health products from the *Drug Schedules Regulation?*

Recommendation

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 NAPRA's National Drug Schedules.

Next Steps

If the removal of NHPs from the *Drug Schedules Regulation* is approved by the Board, the College will proceed with removing NHPs from the *Drug Schedules Regulation* to align with their removal from the National Drug Schedules. As the College moves forward with the step-wise process, the Board will be presented with recommended motions to remove or amend the NHP listings, accordingly.

Amendments to the *Drug Schedules Regulation* are currently subject to a temporary bylaw moratorium, as announced in December 2019 the Ministry of Health. The process to remove the first twenty NHPs from the *Drug Schedules Regulation* would begin as soon as the moratorium is lifted, as they have already been removed from the National Drug Schedules. College staff will present the Board with a proposed *Drug Schedules Regulation* amendment at an upcoming Board meeting for approval for filing with the Minister of Health. The filing period lasts for 60 days. Once the filing period is complete, the College will deposit the amendments with the Minister of Regulations. Once deposited, the amendments will be in effect.

The process would be repeated in 2021-2022 to remove the remaining forty Schedule I, II and III NHPs from the *Drug Schedules Regulation* to align with their removal from the National Drug Schedules in January 2022. The twenty-two Schedule I and II NHPs that require listing changes would also be amended in the *Drug Schedules Regulation* at this time.

Appendix	
1	CONFIDENTIAL (Do not circulate) – NHPs in NDS Confirmed Removals and Changes (by Date of Removal) – July 30, 2020
2	Jurisdictional Scan of Drug Scheduling Approaches and Responses

Appendix 2

Jurisdictional Scan of Drug Scheduling Approaches and Responses to NAPRA's Natural Health Product Policy Change[i]

Jurisdiction	Schedule by Reference to NAPRA'S NDS	Drug Scheduling requires Provincial Approval in addition to NDS	Jurisdiction may make exceptions to the NDS	Has the jurisdiction made an exception for a Schedule III NHP removed by NAPRA?
Alberta	✓		✓	No
Manitoba	✓		✓	No[ii]
New Brunswick	✓		No	(N/A)
Nova Scotia	✓		No	(N/A)
Ontario	✓		No	(N/A)
Prince Edward Island	✓		✓	No
Saskatchewan	✓		✓	No[iii]
British Columbia		✓	✓	Pending
Newfoundland and Labrador		✓	✓	No
Quebec	No	(N/A)	(N/A)	(N/A)

[i] Table adapted in part from https://napra.ca/implementation-national-drug-schedules

[ii] Note: Manitoba previously made scheduling exceptions for single entity pseudoephedrine products, which are Schedule II on the National Drug Schedules. The College of Pharmacists of Manitoba has indicated that the provincial conditions of sale of single entity pseudoephedrine will not be impacted by NAPRA's changes to the NDS.

[iii] Note: Saskatchewan includes ephedrine and pseudoephedrine in combination products as Saskatchewan College of Pharmacy Professionals (SCPP) Schedule III drugs; pseudoephedrine (single entity) as a SCPP Schedule II drug; and, epinephrine other than for emergency use for anaphylaxis as a SCPP Schedule I drug. It is not clear if the listings that include pseudoephedrine or ephedrine will change in 2022 to align with NAPRA or not.

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

APPENDIX 1

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

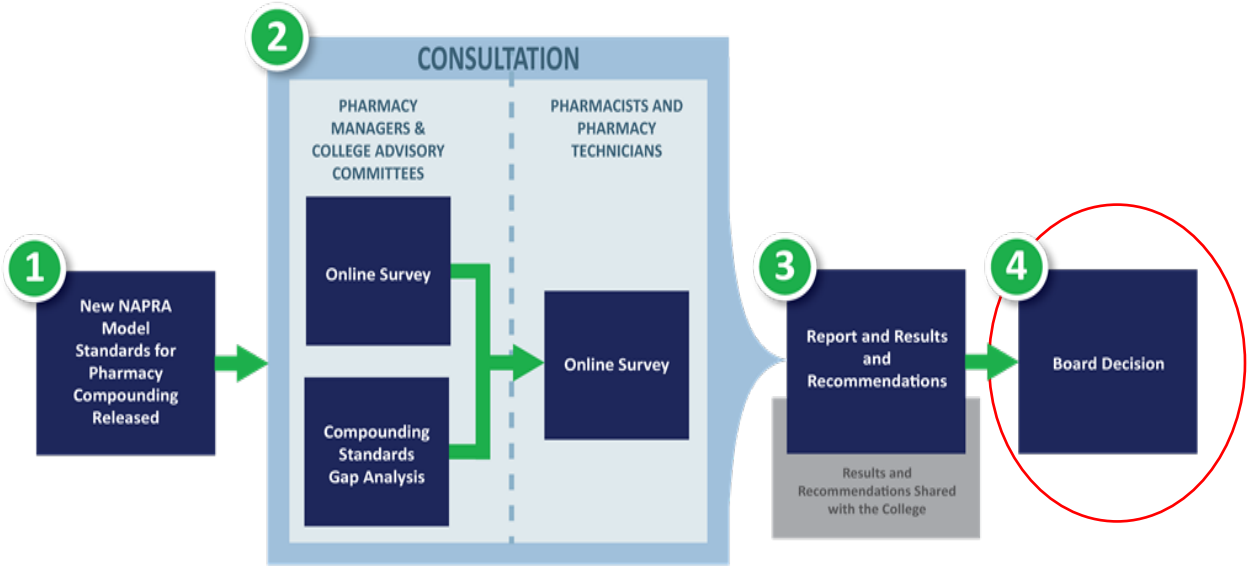
[3] http://napra.ca/Content_Files/Files/Mdl_Stnds_Pharmacy_Compounding_Hazardous_Sterile_Preparations_Nov2016_Revised.pdf

[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.

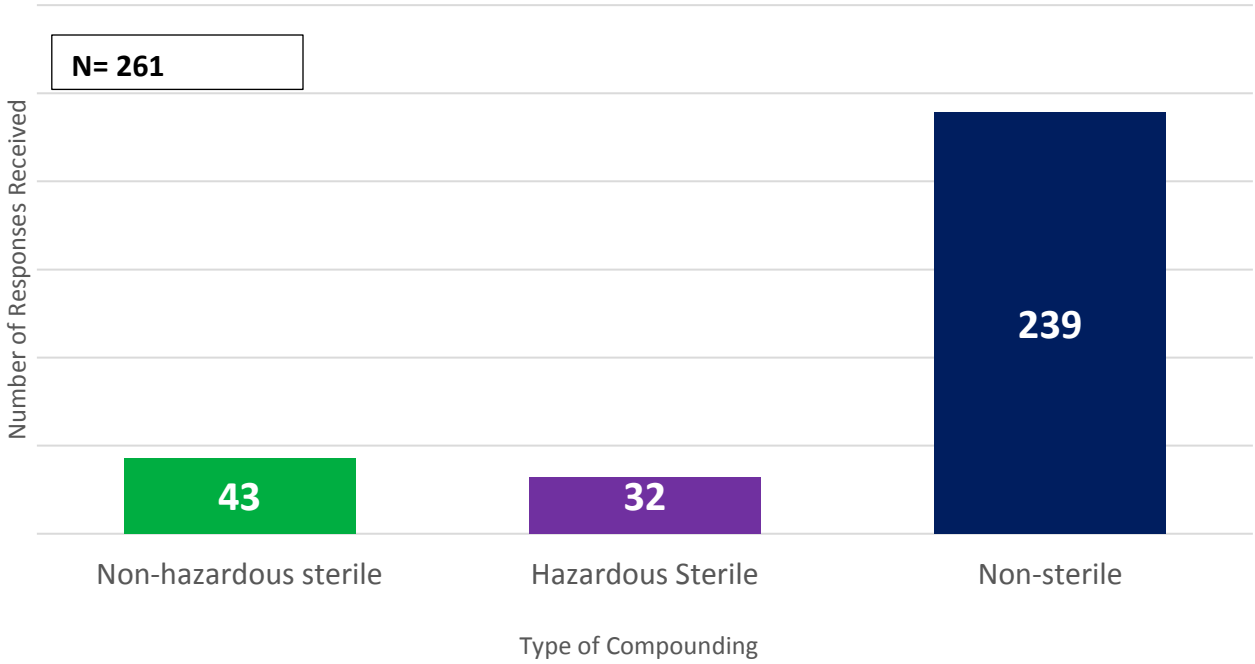
Consultation and Engagement
To inform the adoption and implementation of the two released Model Standards, a multi-step engagement process was developed (see below).



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

Existing College Minimum Standards for Pharmacy Compounding

Community

Existing Policy
PPP-64 Guidelines to Pharmacy Compounding. This policy states that the College of Pharmacists of BC adopts the NAPRA Guidelines to Pharmacy Compounding (2006) as the Standard of Practice for registrants.

Hospital

Existing Policies
PPP-61 Hospital Pharmacy Published Standards. This policy states that sterile products must be prepared in accordance with two CSHP Official publications – Guidelines for Preparation of Sterile Products in Pharmacies and Handling and Disposal of Hazardous Pharmaceuticals (including cytotoxic drugs).

PPP-57 Standards for Pharmacy Assistant Verification of Sterile Products in Hospital Pharmacy Practice. This policy outlines what can be delegated to pharmacy assistants regarding sterile compounding.

Existing Bylaws
Health Professions Act – Bylaws Schedule F (Part 2 – Hospital Pharmacy Standards of Practice) under the Drug Distribution section 3(3) is the following statement:

> **Sterile products must be prepared and distributed in an environment that is in accordance with:**
> 1. The CSHP Guidelines for Preparation of Sterile Products in Pharmacies.
> 2. The USP Pharmaceutical Compounding – Sterile Products Guidelines, and
> 3. Such other published standards approved by the Board from time to time

Health Professions Act – Bylaws Schedule F (Part 2 – Hospital Pharmacy Standards of Practice) under the Drug Distribution section 3(4) is the following statement:

> **Hazardous drugs** must be handled and prepared in accordance with the Requirements for the Safe Handling of Antineoplastic Agents in Health Care Facilities published by the Workers Compensation Board of British Columbia and such other published standards approved by the board from time to time.

Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations Engagement Summary and Recommendations

Consultation and Implementation Approach

Part 1 of 2

This report is part 1 of the consultation reports. Part 2 is a report for Hazardous Sterile Preparations.

Abstract

This report and the seven recommendations within was completed with the engagement and consultation of pharmacy registrants. This report (part 1), and part 2 together, are intended to inform and support implementation for all sterile compounding activities in the province of British Columbia.

Dana Lyons RPhT

September 2016

Table of Contents

Executive Summary

In light of the new NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations (NAPRA), and the historically ineffective nature of voluntary guidelines, it was likely that some form of enforceable sterile compounding standards similar to those in the United States would come into place in Canada. Despite a growing awareness of the importance of good sterile compounding practices, there remains a troubling disconnect between practice guidelines and actual practice. Developing an effective compounding strategy is critical to ensuring patients have access to properly compounded medications, but because each organization's needs differ, a one-size-fits-all solution cannot be applied to every hospital practice environment where compounding takes place. The responsibility to plan and become compliant involves facility infrastructure to changing historic personnel practices and cleaning routines.

Consultation with registrants including leaders and managers, frontline pharmacists and pharmacy technicians who compound in both hospital and community resulted in seven recommendations. Out of those seven recommendations is the proposed plan to adopt NAPRA Model Standards in four phases. Each phase has key NAPRA requirements attached to it with specific timelines.

To ensure we achieve compliance it is recommended that we measure compliance as we implement the four-phase model with completion of the phases targeted for May 2021.

Of a pharmacy professional's countless responsibilities, perhaps none is more critical to positive patient outcomes than ensuring patients receive safe medications, compounded according to established standards.

1.0 Scope

The scope of this initiative is to review what the current policies, standards and bylaws are that guide sterile compounding practices in hospital and community pharmacy in the province of British Columbia. This work includes a confirmation and review of what current state practice is and the potential gaps in practice. Pharmacy leaders have been engaged and consulted for recommendations on implementation timelines of the NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations. As well, sought input from these leaders on challenges and barriers to implementation balanced with potential ideas to overcome these challenges to fully understand the whole compounding picture. The data gathered was used to put forward recommendations, timelines and mitigation strategies for successful implementation of the NAPRA Model Standards in British Columbia.

2.0 Current Bylaws and Practice Guidelines

2.1 Community Pharmacy

The policy documents in place to guide sterile compounding practice in the Community Pharmacy setting include:

I. Professional Practice Policy – 64 (Guidelines to Pharmacy Compounding)

The following key statement is found within this policy: ***The Board of the College of Pharmacists of BC adopts the NAPRA Guidelines to Pharmacy Compounding as the Standard of Practice for registrants.***

The NAPRA document referenced in the Professional Practice Policy is based on eight performance indicators.

1. Knowledge and expertise to compound
2. Confirm the need to compound
3. Access to equipment
4. Quality ingredients
5. Labelling
6. Suitable containers
7. Storage
8. Documentation checking, duplicating and tracing.

Within this NAPRA 2006 document, there are three key points specific to sterile compounding practice and they are:

1. Pharmacists engaging in sterile compounding should be knowledgeable and obtain specialized technical training in this area.
2. Carefully established standards for the operation of cleanrooms and the preparation of sterile products should be documented in accordance with a recognized source. (E.g. Canadian Society of Hospital Pharmacists) (CSHP).
3. Sterility testing shall be done according to a clearly defined standard (E.g. United States Pharmacopeia) (USP) and the product assigned an estimated expiry date.

2.2 Hospital Pharmacy

The policy documents that currently guide the compounding practices in hospital pharmacy are:

I. Professional Practice Policy – 61 (Hospital Pharmacy Published Standards)
II. Professional Practice Policy – 57 (Standards for Pharmacy Assistant Verification of Sterile Products in Hospital Pharmacy Practice)

Within the professional practice policy documents, the following statement can be found: **Sterile Products must be prepared in accordance with the published standards noted below:**

1. CSHP Official Publications – Guidelines for Preparation of Sterile Products in Pharmacies
2. CSHP Official Publications – Handling and Disposal of Hazardous Pharmaceuticals (including cytotoxic drugs)

Bylaw documents for Hospital Pharmacy include:

I. Health Professions Act – Bylaws Schedule F (Part 2 – Hospital Pharmacy Standards of Practice)

Within the Health Professions Act – Bylaws Schedule F (Part 2 – Hospital Pharmacy Standards of Practice) under the Drug Distribution section 3 is the following statement:

> **Sterile products must be prepared and distributed in an environment that is in accordance with:**
>
> 1. The CSHP Guidelines for Preparation of Sterile Products in Pharmacies.
> 2. The USP Pharmaceutical Compounding – Sterile Products Guidelines, and
> 3. Such other published standards approved by the Board from time to time

CSHP Guidelines

The CSHP Guidelines for Preparation of Sterile Products in Pharmacies was published in 1996. The scope of this guideline was intended to be used in situations where pharmacies are involved in the preparation of sterile products for patients (e.g., hospitals, community pharmacies, nursing homes, home health care and others). This document was retired in 2014 after the CSHP guideline was published.

USP Chapter <797> Standards

The other choice for published guidelines referenced in the bylaws and currently the standard in British Columbia is USP Chapter <797> Pharmaceutical Compounding – Sterile Preparations. Chapter <797> was first published in 2004 and has specific requirements for the following areas:

- Design of the Facility
- Environmental and Engineering Controls
- Environmental Testing
- Personnel Training and Competency Testing
- Standard Operating Procedures and Documentation
- Quality Assurance
- Patient Monitoring and Adverse Events Reporting
- Storage and Dating

The aspects of compounding and the minimum requirements to perform this regulated task safely should be the same in all pharmacy practice settings. Therefore, the current bylaws and standards guiding sterile compounding in Community and Hospital practice must be the same.

Recommendation #1

The College creates Bylaws and Professional Practice Policies that guide the act of sterile compounding for any pharmacy registrant including the location where sterile compounding is taking place.

3.0 Current State of Compliance with Bylaws and Professional Practice Policies

The College protects public health by registering and regulating pharmacists and pharmacy technicians and the places where they practice. For hospital practice, College Inspectors review compliance approximately every three years and for community pharmacy inspections occur on a six-year cycle.

3.1 Community Pharmacy Compliance

Community pharmacy inspections do not currently include any sterile compounding-related practice or premise.

3.2 Hospital Compliance

Inspectors use a checklist for the many different practice areas they are reviewing in one visit. The criteria for sterile compounding compliance consists of twenty-three points.

Compliance with current standards appears to be lagging. One assumption may be that the inspection criteria is missing practice-related questions. Currently, the inspector's checklist is focused on the facility requirements and not the practice side of sterile compounding.

Other noted deficiencies with the inspector's checklist is the lack of quality assurance checks, in particular, beyond-use dates and environmental monitoring of all components required in the current USP <797> document. With the newly regulated status of pharmacy technicians, this might be an opportunity to review and improve the criteria for compliance.

Recommendation #2

Inspector checklists for sterile compounding should include a balance of the many components of sterile compounding including facility design, personnel metrics and quality assurance indicators.

4.0 Consultation and Engagement

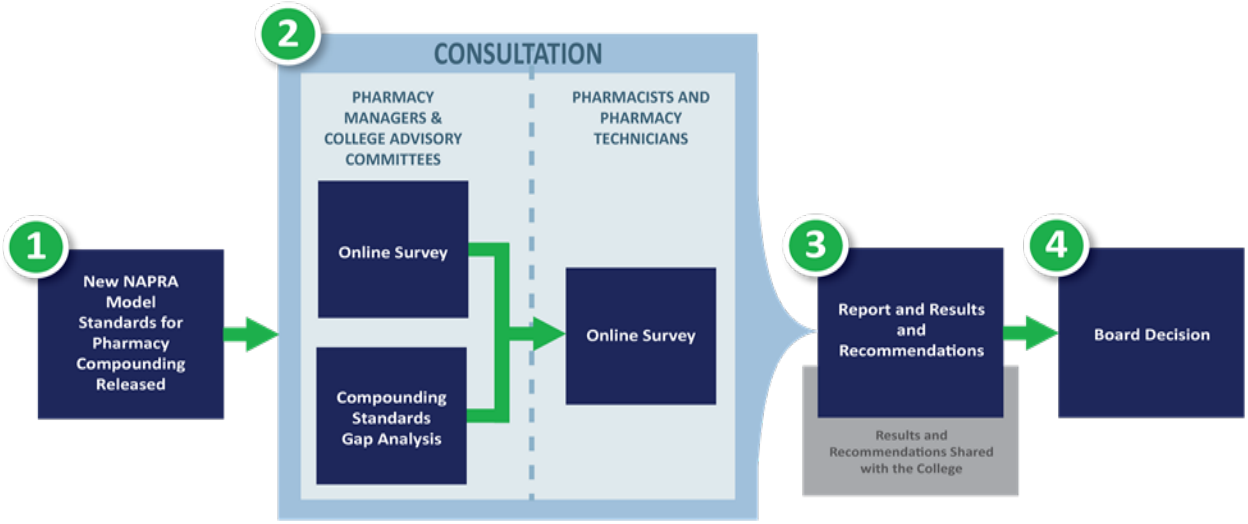
4.1 Method

A multi-step consultation process was designed to reach the many stakeholders including, leaders and pharmacy managers, as well as front-line pharmacists and pharmacy technicians all impacted by the change in sterile compounding standards.

The first step was to consult and engage with registrants who are leaders or managers and operate facilities or pharmacies where sterile compounding takes place. The registrants self-identified and chose to participate in the consultation session. Using “shall” statements from the NAPRA Model Standards, a 33-question survey on sterile compounding practices was sent to the pharmacy leaders and managers to complete. The second step of the consultation process involved a face-to-face engagement session for those that completed the gap survey. This step included a review of the gap survey results, following which the registrants participated in a workshop-style session where each person was placed in a small group and together worked through eight questions developed to understand where the barriers and challenges might exist. The third step was to engage all compounders who compound sterile preparations. To do this, a nine-question survey was developed. This survey was designed to understand what knowledge gaps front-line compounders might be facing and also to understand challenges and barriers from their perspective.

The results of the consultation session and surveys were used to make the recommendations in this report, understand barriers and identify risks. Mitigation strategies for a successful implementation are also an outcome of the consultation process.

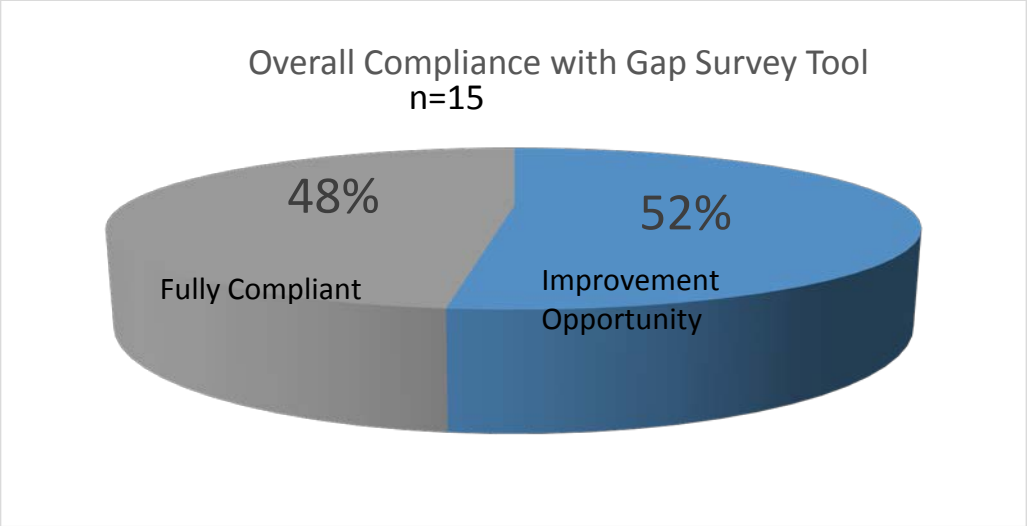
4.2 Consultation Process



5.0 Practice Gap

When looking at practice gaps, we needed to understand what gap we currently have with current standards, and then how does that gap widen with the introduction of new standards. Using the 33-question gap survey results (n=15), we can start to understand the gap in practice versus NAPRA.

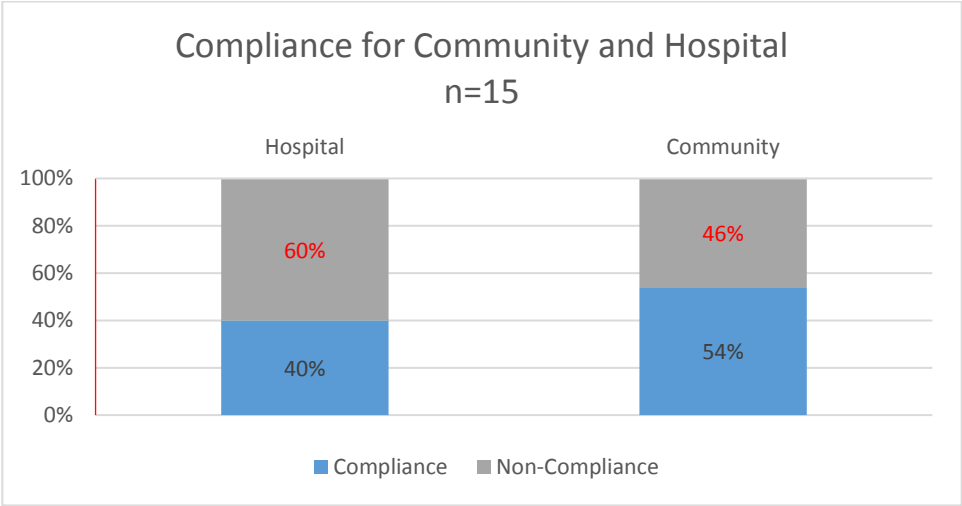
5.1 Overall compliance with the gap survey tool as self-reported from the participants is 48%.



5.2 Hospital versus Community Practice Gap

When comparing hospital versus community pharmacy compounding environments, we also wanted to know if there is a significant difference in compliance between the two practice environments. Out of the fifteen survey respondents six are hospital and **nine** are community practice-based.

The results from the self-reported gap survey data suggest a slightly higher reported compliance in Community pharmacy practice environments than hospital as shown in the graph below.



6.0 New Requirements NAPRA Introduces

6.1 Competency Assessment Program

There are a few notable additions that NAPRA introduces with the Model Standards that are not found in USP <797>. The first one being the introduction of the competency assessment programs for the

sterile compounding supervisor along with the third-party evaluation of the supervisor in the NAPRA Model Standards.

Taken from NAPRA:

5.1.2.3 Competency assessment program

- Sterile Compounding Supervisor shall be evaluated for knowledge and abilities, at the same frequency as compounding personnel by a third party.

5.1.2.4 Management of the competency assessment program

- Third Party Evaluator is defined as an evaluator with expertise in sterile compounding, at arm's length from the facility/pharmacy, and free of any real or perceived conflict with the individual being evaluated.

Feedback from the workshop participants indicated that this new addition in the NAPRA model standards would present very few new challenges. Similar responses came up in regards to cost and education/training.

6.2 Pharmacy Assistants and Compounding

A second difference with NAPRA and USP 797, is the mention of specific personnel involved in compounding including pharmacy assistants and pharmacy technicians.

Taken from NAPRA 5.1.1.3

"A pharmacy assistant with appropriate training, who prepares sterile preparations or performs other technical tasks related to sterile compounding only when assigned to do so by the sterile compounding supervisor and only after completion of a formal delegation of duties from a pharmacist to the pharmacy assistant, in compliance with the requirements of the provincial/territorial authority."

Feedback from survey respondents indicated that any change in the use of non-regulated personnel to compound may present some staffing challenges if not enough pharmacy technicians are graduating or available for employment.

Recommendation #3

The College bylaws should reinforce restricted activities as outlined in the Health Professions Act.

Note: NAPRA has language in the standards that at first read to some may indicate that pharmacy assistants can compound. In British Columbia, this would not apply as the HPA has listed compounding as a restricted activity to pharmacists and pharmacy technicians.

The NAPRA standards are more in-depth and provide clear must/shall statements and cover aspects such as final verification and cleaning protocols. The two standards (USP <797> and NAPRA) are very similar with the general concepts and intent being similar. USP <797> is currently in a revision cycle. With the updated chapter to be released January 2017, further gaps may be introduced as revisions

occur. The revision cycle for NAPRA updates has not officially been released, and this unknown may lead to concerns from registrants.

Recommendation #4

The College should seek formal update/revision cycle information from NAPRA to be shared with registrants.

7.0 Barriers Registrants Brought Forward to Implementing NAPRA

7.1 Knowledge of Standards

Education on current sterile compounding standards may possibly be a barrier for implementation and adoption of the NAPRA Model Standards. In the survey to frontline pharmacists and pharmacy technicians, we wanted to assess the general awareness of the NAPRA standards, so we asked the question: Are you aware that NAPRA published new Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations in November 2015? Out of 160 respondents 33.8% were not aware of the NAPRA Model Standards. Of the 66.2% of respondents that were aware of the NAPRA Model Standards we learned that respondents are *least likely* to have heard about these new standards from their employer and out of the 31 comments for "other" sources, 30% of the respondents in that category indicated that they learned of the NAPRA Model Standards through College communications.

7.2 Cost Constraints

Healthcare dollars are scarce and renovation budgets are planned years in advance. The full cost of implementing sterile compounding standards is not known, as the starting point is different for every facility. The cost of compliance is the top barrier to implementation as reported by 28% of survey respondents.

Mitigating strategy

The four-phase, four-year approach to NAPRA adoption and compliance should address most of the cost increases as they will be absorbed incrementally over time. The proposed implementation plan should also include the budget and infrastructure cycles heath authorities work within.

7.3 Beyond-Use Dates (BUD)

The BUD in NAPRA is based on the risk that a compounded sterile preparation (CSP) may have been contaminated. Traditionally, before newer standards were published, pharmacy practice was to use drug stability information to determine the expiry date of the CSPs. The introduction of USP <797> changed the way BUDs are applied using drug stability plus sterility to determine the safest BUD. In consultation with the leaders and managers, they revealed that the negative impact could include the following: increase in drug wastage, delivery costs and costs to patients, staffing time, and repetitive strain injuries.

Respondents from the survey indicated that **55.8%** are assigning CSPs a BUD of greater than the 14-day refrigerated maximum. One respondent had the following comment *"Patients will find it next to impossible to access their compounds and the price will be prohibitive."*

Mitigating strategy:
Continue to reinforce and inform registrants of the need to change practice when applying BUDs to CSPs.
Note: The requirement of shorter BUDs is not a new concept or a new standard for BC pharmacies. Best evidence is to apply a BUD to a compounded product that takes into consideration the stability and sterility. This is not a deviation from USP <797> and is a patient safety factor.

7.4 Change Management

7.4.1 Communication Strategy

Communications are a critical part of the change process. This plan articulates key messages that need to go to various impacted audiences. From the engagement workshop with leaders and feedback from the survey respondents, the change effort required to ensure the standards are adopted in a timely manner is a concern and many respondents cited this as a barrier to implementation.

This change requires multiple stakeholders within the industry to ensure they can meet any new demands, including from within the highest levels of Government and hospital executives to ensure funds are released when hospital pharmacy infrastructure requires updating.

Practice change and behaviour change, both of which are required to ensure our compounding practices are robust and safe, take resources and can be rate-limiting steps. A change effort of this magnitude requires proper planning, a solid methodical approach and leadership who believe this effort is of top importance and will move it forward. Leaders will be required to communicate this change to senior executives and to frontline staff. The College can play a role by developing a communication strategy that reaches stakeholders and frontline staff.

Recommendation #5
The College is to develop a communication plan to include messaging that hospital administrators and other leaders can use to help the change effort move forward.

7.4.2 Changing Behaviours

As the old cliché goes "what gets measured gets done". The message is clear: measuring something gives you the information you need in order to make sure you actually achieve what you set out to do. Asking our staff to show up prepared to compound, with no make-up, no nail extensions and in proper attire is one of the lowest cost changes we will be asked to comply with.

Simply asking compounding personnel to make these personal changes may not be robust enough. In fact, results from the gap survey taken revealed we have more work to do.

8.0 Risks

There are inherent risks in any change initiative, there are also risks if we decide not to remain status quo. In consulting with leaders and managers of compounding environments, we wanted to know what kinds of risks could surface if NAPRA Model Standards were adopted too quickly and, conversely, too slowly. The results from the participants are listed below.

8.1 Risk of Adopting NAPRA too Quickly

1. Facilities will fail
2. Confidence in the College will fall
3. Supply issues
4. Overwhelm frontline staff
5. Loss of economies of scale
6. Patient access to CSPs will be restricted
7. Compounding could be outsourced to less compliant provinces
8. Opportunity to train and gain knowledge may be lost

8.2 Risk of Adopting NAPRA too Slowly

1. Risk to public safety
2. Risk to staff
3. Loss of momentum
4. Loss of public respect
5. Standards will continue to change

There are challenges with adopting too fast or too slow. With adopting too quickly, the potential for errors of any kind are present, and this is risky for leadership. It is often less disruptive and less stressful if change occurs slowly; however, the real risk presents itself if adoption occurs too slowly and that is the risk to the public and public respect of the pharmacy profession to provide safe preparations.

9.0 Implementation Strategy

During the engagement workshop, participants were asked to provide their ideas on a phased in approach along with suggested timelines for achieving compliance with the phases. The participants were also asked to suggest an all-at-once implementation compliance date. Using the dot voting technique, participants were asked to place their dots on a phased in approach or an all-in-one approach that they believe represented the best option.

The phased in approached received the majority of the votes along with one particular design of a phased in approach where the main components of compliance were divided into four phases.

Based on the need to balance implementation and mitigate risks with an approach that is not too fast or too slow, the four-phase model for implementation is a good balanced approach. All of the various models suggested by participants for implementation are in appendix D and the most desirable model presented in table 1.

Table 1 Most Desirable Option for Compliance

Phase	Compliance Component	Date of Expected Phase Compliance
Phase 1	Hand Hygiene and Garbing	December 2016
Phase 2	Cleaning and Disinfecting,	December 2017
	Training and Assessment	
	Policies and Procedures	
Phase 3	Quality Assurance and Environmental Monitoring	December 2018
	Media Fill and Fingertip Sampling	
Phase 4	Facilities and BUD	December 2019 +++

Recommendation #6

Phased-in Approach

The implementation of NAPRA Model Standards requires a balanced approach, focused firstly on protection of the public and yet achievable for compounders and organizations. The four-phase approach should be undertaken with a timeline of four years plus a notification period to registrants.

10.0 Trends in Compliance

10.1 Canadian Compliance

Currently, there is no mechanism to trend compliance with compounding standards in Canada. A national compliance survey tool is not available or developed in Canada, although CSHP is working on a compliance tool that will be based on the newly released CSHP: Guidelines for Pharmacy Compounding (2014). The lack of a national gap tool using the NAPRA Model Standards must and shall statements, makes measuring overall compliance or even site-specific compliance trends nearly impossible.

10.2 Past Compounding Trends in Canada

A survey, sent to hospital pharmacies in 2009, was done to compare the extent of compounding compliance during the period from 1993 to 2009. During that time frame, the 1996 CSHP *Guidelines for Preparation of Sterile Products in Pharmacies* had been published for over a decade and USP <797> had been out for five years.

10.2 United States Compliance Trends

In the United States, a national compliance study is released each year and participants self-report compliance. This study is based on the shall and should statements found in USP Chapter <797> and results are published each year in their journal published on line on their website at this link: www.pppmag.com This survey may provide some insight into how compliance may look for Canada. While our governance is different, there still may be some insights we can learn from these results.

US Compliance Results 2015

www.pppmag.com

TABLE 3

Overall Compliance Trends in Domain Compliance Scores 2011 vs 2015

Subject Matter Domains Note: Not all domains or items in each domain pertain to all participants	2011	2015
Allergen Extracts as CSPs	87%	99%
Aseptic Technique	85%	90%
Bacterial Endotoxin Testing	47%	32%
Beyond Use Dating	87%	89%
Compounding Facility Management: Airflows and Pressure Differential Monitoring	50%	66%
Compounding Facility Management: Cleaning and Disinfecting	68%	78%
Compounding Facility Management: Equipment Calibration	73%	75%
Compounding Facility Management: Temperature and Humidity Monitoring	83%	86%
CSPs for Immediate Use	74%	79%
Depyrogenation by Dry Heat	80%	83%
Filter Integrity Test	16%	33%
Final Release Checks	88%	90%
General Facility Design	75%	76%
Gloved Fingertip Sampling	42%	62%
Handwashing and Garbing	75%	82%
Hazardous Drug Compounding	71%	81%
Initial and Ongoing Training and Competency Measurement	74%	76%
Inventory Storage and Handling/Delivery of CSPs	93%	94%
Low Risk Level CSPs with 12 Hour or Less BUD	68%	74%
Personnel Media-Fill Challenging Testing	81%	81%
Primary/Secondary Engineering Controls	77%	84%
Quality Management: Environmental Sampling Program	63%	72%
Quality Management: General	62%	67%
Quality Management: General Viable Air and Surface Sampling Considerations	56%	68%
Quality Management: Incubation	59%	73%
Quality Management: Non-Viable Particle Testing	90%	92%
Quality Management: Surface Sampling- A personnel metric	57%	68%
Quality Management: Viable Air Sampling- A facility metric	58%	75%
Radiopharmaceuticals as CSPs	52%	70%
Single- and Multiple-Dose Vials	92%	94%
Steam Sterilization	87%	88%
Sterility Testing	54%	58%
Sterilization by Dry Heat	80%	94%
Sterilization by Filtration	60%	68%
Sterilization Methods	88%	86%
Overall Compliance	**72%**	**80%**

Some noteworthy facts:

- The US has been enforcing compliance since 2008 in some states
- High-risk compounding practices, such as filter integrity, lag in improvements at only 33% compliance.

We have heard many news stories of improper compounding practices, most notably, the New England Compounding Center (NECC) tragedy of contamination in sterile compounds in the US. Yet, with enforceability and patient safety stories, the data indicates there may still be pockets of change resistance or lack of urgency to comply.

11.0 High-Risk Compounding

High-risk compounding as defined by NAPRA is when **any** of the three criteria are in play:

1. Non-sterile ingredients or equipment used before terminal sterilization
2. Non-sterile preparations, containing water, stored for more than 6 hours before terminal sterilization
3. Improper garbing or gloving by compounding personnel

Knowing the risk is inherently higher in high-risk compounding begs the question of whether high-risk compounding practices should be brought to the minimum standard in a speedier timeline. The following question was posed to the workshop participants:

High-Risk Compounding requires rigorous processes that are validated. For pharmacies that are compounding high-risk compounds or plan to continue, answer the following questions:

A. **Should these pharmacies be required to fully comply with NAPRA sooner than sites that are not engaged in high-risk compounding?**

B. **If" no" why, if" yes" suggest a date for full compliance for high-risk compounding facilities.**

The participants had limited feedback. The feedback was equally split, half of the comments suggested pharmacies should meet the minimum requirements sooner, and half felt that compliance for consistency not be expedited. One could assume a couple things. The participants are not engaged in high-risk compounding and, therefore, had less of an opinion. Or, perhaps, there is a knowledge gap on what high-risk compounding is. To further understand high-risk compounding and who is engaged in this activity we asked the front-line pharmacists and technicians if their site is engaged in high-risk compounding and **29.5%** of respondents indicated that high-risk compounding occurs in their pharmacy.

Does your pharmacy prepare high-risk compounding?

Response	Chart	Percentage	Count
Yes, we prepare high-risk products.		29.5%	46
No, we do not prepare high-risk products.		70.5%	110
	Total Responses		**156**

The potential for high-risk compounding to have adverse outcomes for our patients is greater due to the complexity and the additional requirement to ***sterilize*** the preparation, whereas the majority of

compounding is around ***maintaining asepsis***; this is the distinct fundamental difference between high-risk sterile compounding and low and medium-risk sterile compounding. Contamination is highly probable if our sterilization processes are inadequate or ineffective.

In my experience, the majority of high-risk preparations that require sterilization are sterilized using a 0.22 micron sterilizing grade filter. In order to confirm the filter performed as required, one must perform a simple *filter integrity test* sometimes known as a *bubble point test*. Looking at the US compliance report shared earlier, it notes only 33% compliance with the filter integrity test. This is alarming and we have to wonder, how are we doing with high-risk compounding in BC?

Recommendation # 7

The College should initiate a survey to all compounding facilities who perform high-risk compounding to get a sense of practice and risk and create a list of compounding sites engaged in this activity. A compliance tool for high risk compounding should also be developed.

12.0 Conclusion and Implementation Recommendations and Timelines

The adoption of the NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations will take time, money and considerable effort to implement properly and safely. My experience as a process specialist is if you take big initiatives or projects and break them down into attainable chunks of work which can be measured along the way, success of the larger goal will materialize. The phased in model for compliance with the NAPRA Model Standards, which the participants drafted and favored, has been adapted and presented below in the table. The three key sections (5, 6 and 7) in NAPRA have been divided according to the model with proposed timelines.

The adoption of the NAPRA Model Standards by the College of BC Pharmacists, would be in alignment with other provincial regulatory authorities (PRA) such as Alberta and Ontario. There is no reason to exclude any portion of the Model Standards or any reason to adopt partial segments of the chapter. The Model Standards will be in alignment with sterile hazardous and non-sterile compounding model standards which are being released in stages. The Model Standards have gone through extensive pharmacy stakeholder consultation from each PRA and many of the members within the PRA's. Therefore, the recommendation is for BC to adopt the NAPRA Model Standards for non-hazardous sterile compounding as the standard in BC.

13.0 Phased in Approach Recommendation and Timelines

Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations Implementation Plan			
NAPRA ID or page #	**NAPRA Compliance Area**	**Phase of compliance**	**Proposed compliance date**
Step 1	Define compounding risk level	Phase 1	November 2017
Step 1	Complete a gap analysis and prioritize a site plan	Phase 1	November 2017
6.3	Compounded sterile preparation log	Phase 1	November 2017
6.4	Patient file	Phase 1	November 2017
6.5	Conduct of personnel in areas reserved for the compounding of sterile preparations	Phase 1	November 2017
6.6	Aseptic compounding of non-hazardous sterile preparations	Phase 1	November 2017
6.7	Packaging	Phase 1	November 2017
6.8	storage	Phase 1	November 2017
6.9	Transport and delivery of compounded sterile preparations	Phase 1	November 2017
6.10	Recall of sterile products or final compounded sterile preparations	Phase 1	November 2017
5.1	Personnel	Phase 2	May 2019
5.2	Policies and procedures	Phase 2	May 2019

Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations Implementation Plan			
NAPRA ID or page #	**NAPRA Compliance Area**	**Phase of compliance**	**Proposed compliance date**
5.4	General maintenance log	Phase 2	May 2019
6.2	Compounded sterile preparation protocols	Phase 2	May 2019
6.11	Incident and accident management	Phase 3	May 2020
6.1	Beyond-use date and dating methods	Phase 3	May 2020
6.12	Waste management	Phase 3	May 2020
7.1	Program content	Phase 3	May 2020
7.2	Results and action levels	Phase 3	May 2020
7.3	Verification of equipment and facilities	Phase 3	May 2020
7.4	Quality assurance of personnel involved in aseptic compounding	Phase 3	May 2020
7.5	Quality assurance of compounded sterile preparations	Phase 3	May 2020
7.6	Documentation of quality control activities	Phase 3	May 2020
5.3	Facilities and equipment	Phase 4	May 2021

Appendices

A. Recommendations for the College

Recommendation ID	Recommendation(s)
1	The College should create Bylaws supported by Professional Practice Policies that guide the act of compounding for any pharmacy registrant including the location where sterile compounding is taking place.
2	Inspector checklists for sterile compounding should include a balance of the many components of sterile compounding including facility design, personnel metrics and quality assurance indicators.
3	The College bylaws should reinforce restricted activities as outlined in the Health Professions Act. Note: NAPRA has language in the standards that at first read to some may indicate that pharmacy assistants can compound. In British Columbia, this would not apply as the HPA has listed compounding as a **restricted activity to pharmacists and pharmacy technicians.**
4	The College to seek formal update/revision cycle from NAPRA to be shared with registrants.
5	The College to develop a communication plan to include messaging that hospital administrators and other leaders can use to help the change effort move forward.
6	Phased in Approach: The implementation of NAPRA Model Standards requires a balanced approach, focused firstly on protection of the public and yet achievable for compounders and organizations. The four-phase approach be undertaken with a timeline of four years plus a notification period to registrants.
7	The College should initiate a survey to all compounding facilities who perform high-risk compounding to get a sense of practice and risk and create a list of compounding sites engaged in this activity. A compliance tool for high risk compounding should also be developed.

B. Survey Questions and Results from Pharmacists and Pharmacy Technicians

Final Results

I am a...

TOTAL RESPONSES	COMPLETED RESPONSES	COMPLETION RATE	COMPLETION TIME
362	362	100%	22:54

Response	Chart	Percentage	Count
Pharmacist		76.8%	278
Pharmacy Technician		23.2%	84
		Total Responses	**362**

1. My pharmacy compounds non-hazardous sterile preparations.

Response	Chart	Percentage	Count
Yes		43.6%	158
No		56.4%	204
		Total Responses	**362**

2. Are you aware that NAPRA published new Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations in November 2015?

Response	Chart	Percentage	Count
Yes		66.2%	106
No		33.8%	54
		Total Responses	**160**

3. How did you hear about the new NAPRA Model Standards?

Response	Chart	Percentage	Count
Employer		29.5%	31
Colleague		34.3%	36
Other		36.2%	38
		Total Responses	**105**

How did you hear about the new NAPRA Model Standards? (Other)

#	Response

1.	PCCA
2.	PCCA
3.	College of pharmacists website
4.	College
5.	compounding companies
6.	email
7.	We are a certified compounding facility that is certified every 6 months. We also heard it from the company certifying us.
8.	PCCA
9.	email from College and Colleagues
10.	CPBC ECTF
11.	hood certification
12.	Reviewing regulatory proposals
13.	internet
14.	Provincial Safe Handling Committee
15.	By following NAPRA, USP regulations
16.	I was aware they were being released in late 2015
17.	I heard it in one compounding related CE
18.	email blasts
19.	Internet
20.	College committee
21.	PCCA
22.	PCCA compounding course
23.	PTSBC
24.	I work as an instructor
25.	College
26.	conferences
27.	College
28.	College of Pharmacists
29.	college of pharmacists BC

30.	Aware through activities of work
31.	from PCCA
32.	email from College of Pharmacists of BC
33.	Trade Journal & NAPRA news blast
34.	Colleague and College of Pharmacist committee members
35.	College
36.	College of Pharmacists of BC
37.	College Memo
38.	Representative

4. Have you read the new NAPRA Model Standards? Do you use them at your pharmacy?

Response	Chart	Percentage	Count
Yes; we use them at my pharmacy.		39.8%	41
Yes; we don't use them at my pharmacy.		31.1%	32
No; we use them at my pharmacy.		8.7%	9
No; we don't use them at my pharmacy.		20.4%	21
		Total Responses	**103**

5. Does your pharmacy follow the beyond-use-dates using the low, medium and high-risk method?

Response	Chart	Percentage	Count
Yes, products do not exceed 14 days' fridge dating.		44.2%	69
No, we do not currently follow beyond-use-dates as outlined.		55.8%	87
		Total Responses	**156**

6. Does your pharmacy prepare high-risk compounding?

Response	Chart	Percentage	Count
Yes, we prepare high-risk products.		29.5%	46
No, we do not prepare high-risk products.		70.5%	110

		Total Responses	**156**

7. Does your pharmacy provide yearly re-assessments of compounding staff?

Response	Chart	Percentage	Count
Yes, compounders are re-assessed at least yearly.		25.0%	39
No, we have not implemented re-assessments.		75.0%	117
		Total Responses	**156**

8. Does your pharmacy follow robust cleaning procedures?

Response	Chart	Percentage	Count
Yes, housekeeping follows this standard.		55.1%	86
No, housekeeping does not follow this standard.		44.9%	70
		Total Responses	**156**

What barriers, if any, do you anticipate by implementing the NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations? |

#	Response
1.	Does the College interpret these standards to mean that Pharmacy Assistants will no longer be permitted to mix? If so, when would the College enforce this requirement? We currently do chemo-certification for hazardous drugs. We do not have a process for non-hazardous drugs. Yearly is very difficult to maintain with a larger staff. Renovation would be required to meet the standards in this document. What timeframe for compliance would be given? Housekeeping standards will be difficult to meet. They do clean daily now, but the walls and ceilings are not done monthly, for example.
2.	Probably the amount of time. Since I work in a hospital we have standards that are set by our health authority.
3.	.
4.	None.
5.	1) PHARMACARE REIMBURSEMENT. I AM IN FULL AGREEMENT WITH THESE STANDARDS BUT UNLESS PHARMACARE REIMBURSES FOR THE COSTS ASSOCIATED WITH MAINTAINING THESE STANDARDS (IE, GLOVES, GOWNS, STERILITY AND POTENCY TESTING, ENDOTOXIN TESTING, ETC.), IT IS SIMPLY NOT FEASIBLE FOR PHARMACIES TO BILL PHARMACARE FOR REIMBURSEMENT OF THESE COMPOUNDS. 2) How is the College going to ensure that pharmacies compounding sterile preparations are compliant with the NAPRA guidelines? What sort of training or education programs will College Inspectors undergo so they are equipped with the right tools to inspect sterile compounding pharmacies? 3) Will the College be accrediting or certifying pharmacies who meet the NAPRA guidelines like in the USA where PCAB accredits compounding pharmacies?
6.	None
7.	Pharmacies with limited space and very little compounding may not follow implemented guidelines
8.	Higher budget required for higher turnover of sterile gloves, bootie-buddy machine, special sprays and wipes for the hood. Training for new employees, current employees will need re-orientation.
9.	No specific barriers have been identified
10.	Nothing to add at the moment
11.	none
12.	Standard training module that can be implemented.
13.	Extra cost for equipment maintenance.
14.	Cost. The margin and volume for sterile compounding in the small community setting does not support some of the major expenditures that are proposed. We offer this as a quick, efficient way for local residents to access treatment, without having to send the Rx to larger centers, and the delays in treatment that will be seen.
15.	cost for training, equipment time to implement

	is the system that broken that it needs to be fixed? e.g. has there been compounded medications that have proved hazardous to patients due to improper manufacturing techniques.
16.	Adequate staffing
17.	No barriers
18.	space, financial burdens on retail setting if more equipment needs upgrading, returns may not make it lucrative to compound.
19.	we will no longer sterile compound. Patients will find it next to impossible to access their compounds and the price will be prohibitive. imagine a 14-day expiry date on a product. How many times would we expect someone to pay for it?
20.	Buds are too restrictive. Most compounds are singles. Monitoring procedures are too onerous for a community setting
21.	Most store currently "compounding" will no longer be able to provide the service and the public will not understand why, and will go apeshit.
22.	No barriers. I think having more and better standards for non-hazardous compounding is a good thing
23.	None at my pharmacy. Other pharmacies - potentially cost.
24.	Extra work for staff, housekeeping & pharmacy.
25.	staff training, time for record keeping
26.	Not being able to keep up with demand for sterile products because of the requirements (our equipment and budget won't improve in time). I foresee patients missing out on valuable products due to regulations and either not receiving therapies entirely or needing to be transferred to higher level of care communities. (Which means increase costs to families and facilities). I'm curious to read the stats and data on what has actually harmed patients that we now have to adhere to these new standards. Nurses and doctors will continue to prepare sterile products in a non-sterile way, often in environments that are far less controlled and regularly cleaned compared to pharmacy.
27.	Not sure , will haven't review again
28.	I don't see any barriers but educating patient re: shorter beyond use dates raises concern: cost will be number 1. But on the other hand, like our pharmacy we have some of the formulas tested for longer expiry dates and have proper documentation for all BUD's. Hope these exceptions are outlined clearly in the new guidelines.
29.	Too onerous to implement.
30.	1. Any failure to educate and clearly communicate the new minimum NAPRA standards to ALL personnel involved in the preparation, delivery and administration of sterile products will lead to a deterioration of overall quality and safety: I have seen, first-hand, instances of medium risk sterile products being prepared on a lunch counter by nursing staff who had no patience to wait for pharmacy protocols. 2. Construction of compliant facilities will present physical and financial challenges in some cases. HVAC for large buildings cannot easily be changed to accommodate the very strict air management requirements in the NAPRA standards.

	3. Routine facility maintenance, ISO standard testing and training will probably be the most difficult areas to achieve compliance with the NAPRA standard. A significant annual budget is required which is seldom supported by traditional pharmacy budgets or revenue streams.
31.	None, as we are already doing >90% of what is required by NAPRA. With some more investment, we should be at 100% compliance. For the safety of patients in BC, the standards need to be implemented ASAP. We have seen too many "fly by night" compounders who think they know what they are doing and are sending out potentially unsafe preparations. As well, they are flouting current expiry and beyond use dates. Others are cutting corners, and undercutting prices to gain market share. This is not in the best interests of patients. As well, there are some pharmacies who send one or two staff members to a compounding course and then start compounding, without a clear understanding of what they are doing; as well as the fact that they have not made a proper investment in equipment required. This is not acceptable. It has also been brought to our attention that there are certain lower mainland hospital pharmacy departments that are compounding inappropriately, posing a risk to staff, and patients. Their facility/equipment is old, ventilation is inadequate, and proper NAPRA sanitation/cleaning is non-existent. A simple College Audit would identify these deficiencies. Thanks for taking on this initiative!
32.	I don't see any for our pharmacy. We are intending to improve our processes, environment until we meet the standards in full.
33.	Time and money
34.	None
35.	following BUD standards will increase workload and no additional funding is available for staffing
36.	None at this time
37.	space Time to clean Documentation (paperwork burden)
38.	just bringing everyone on board to understand the importance and need for things to be sterile. allot of staff say we have never had a problem before and it is a challenge to change their mind set. always the argument that it is too busy, short staffed so they NEED to cut corners. we are slowly making them understand the importance of proper cleaning of the environment, proper handwashing and garbing of the operator and why the BUD dates have to be shortened. we may have never had a problem before but we never tested our products or our staff
39.	Cost of implementing NAPRA standards, both cost in staffing and cost of drugs/shortened expiry Development, implementation and consistent adherence of facility/regional P and P to NAPRA standards (i.e.: follow up and/or oversight) Possible impact to patient care? Unknown? Impact to/on other Pharmacy procedures?
40.	None
41.	The time it will take to do yearly assessments of staff to ensure proper technique. We are professionals and do our jobs professionally. We don't need anyone to come once a year and make sure we are doing our jobs properly!

42.	n/a
43.	none
44.	workload
45.	Proper technique and formulations require membership with compounding companies. This will increase cost but also guarantee the product produced. There will also be significant expense incurred for compounding equipment and packaging options. The end payer, whether government, insurance companies, or patients must be educated to this fact.
46.	These will conflict with the established USP chapters that govern this type of practice (795, 797, 800). The document allegedly is "final" and yet makes reference to USP chapters that themselves have changed since this NAPRA document began its 4-version journey...only to arrive at something that is now referring to past versions of the USP in specific areas (e.g.: 3 risk categories which are now two per USP 797). The concept of "in-use times" has not been incorporated into the document. This is far larger a document than the proposed USP and is going to become confusing when one has to decide, where differences exist between this and USP, which one to follow. You can't call yourself "USP-compliant" in full if you have to compromise that compliance in order to comply with the NAPRA document. And the NAPRA document is not "user friendly" in that it's close to 100 pages long -- how do you find specific references you need in short order, when you already know the references "by heart" per the USP? This is re-invention of the wheel. It compromises patient safety, rather than bolsters it. And it contains specific American-type language that resembles the actions of the FDA in the USA to eliminate compounding from pharmacy practice, including "office-use" (by using "patient-specific"). If it isn't breaking, don't fix it. Require pharmacists to comply with USP requirements; don't invent additional confusing documents, just to have "your name" on them. I understand that Quebec has seen the document and has no intention of adopting something that is going to eliminate "office-use" prescriptions (based on the content of the document not being specifically permissive), as well as "patient-specific" being used which confuses the aspect of "office-use" which, at the time it is dispensed PER A LEGAL PRESCRIPTION, does not have a specific patient name at the pharmacy, but ultimately will be allocated to a patient of the prescriber. There ought to be an opportunity to comment as professionals on the CONTENT of the document, rather than have it forced upon us only for acceptance in terms of "time to implement." In deciding on that, one MUST consider the content/requirements in order to respond "yea" or "nay."
47.	We don't compound often. Usually outsourced from compounding pharmacy.
48.	x
49.	1) There is an increase in staffing resources required to adhere to procedures outlined. 2) There may be barriers in having non pharmacy staff comply with standards (i.e. housekeeping). 3) The infrastructure (the existing IV rooms), were not built for these standards. Adapting these standards in the existing environment is challenging.
50.	Unsure
51.	- Cost (supplies, environmental sampling, room renos) - Time/people to develop policy and procedures specific to site - Time/cost of developing or accessing comprehensive educational materials for staff, and finding good literature or information to base this on - Challenge of ensuring external contracted Housekeeping staff follow NAPRA guidelines

52.	Ensure that everyone is trained accordingly.
53.	1. Some of the information that is a 'must' is unclear- subject to interpretation 2. Pharmacy staff is responsible for training housekeeping staff and maintaining employee files- not reasonable 3. The standards talk about staff that fail a written or practical test, but no information on what/how to test- no standardization; who's to say someone couldn't work at another site and pass then take that pass to their primary site (where they failed) to grieve 4. Some definitions are missing; other definitions could be clearer 5. Some information in one section is contradicted in subsequent sections (e.g., 'musts' are contradicted later on in the document 6. Some of the information is incorrect 7. Sterile compounding supervisor must perform the final product checks (does not specify 'or delegate') ...not reasonable 8. Dictates that all received shipments must be stored immediately upon receipt- rarely happens (fridge items yes, not other items) 9. The sampling says agar plates are a must, but I understand you can use paddles as well...too restrictive in some of the 'how to' sections Note: I do NOT find the BUD's too restrictive
54.	The main barrier is coordination across hospital sites
55.	Staffing to accomidate changes to practice, roll out, etc. quality testing
56.	cost re-training/educating staff resistance to change waiting for management and higher-ups to direct/implement changes
57.	I have no idea. I haven't read them.
58.	Resistance from management and previously trained personnel. Number of re-certifications, updating and re-training and associated costs for taking these actions.
59.	Lack of motivation and time allowed for compounding pharmacy technicians to follow all the guidelines set in the standards. Not enough policing by the College to ensure standards are maintained
60.	ok
61.	Pharmacies that do not wish to expend the monies involved in setting up proper compounding facilities and following strict guidelines that had previously been set out. Unfortunately, we already see journals/magazines with pictures of pharmacists/technicians doing performing 'compounds' for a photo op and they are not donning proper PPE! What message does that send out? Even if it is a picture they should still be portraying that they are following guidelines. Saw a photo in a pharmacy journal where the pharmacist is in a lab in what appears to be an outside feather down red coat with a coffee mug beside him.
62.	Expiry dates of fridge items

63.	I look forward to the NAPRA standards becoming regulation. One of our areas with potential problems are the BUD when preparing admixtures in a hospital based CIVA hub, then transporting to the smaller sites that do not have sterile products facilities. Replacing stock based on a 14 day or lower BUD will have an impact on cost and workload. (I agree with the lower BUD though!) Once NAPRA becomes regulation, the pharmacy managers will need to staff this area adequately so that the NAPRA standards can be met.
64.	Not sure currently
65.	Space, old equipment, staffing
66.	My pharmacy must undergo a complete building renovation in order to comply with the regulations. We do so little sterile compounding that this will not be financially justifiable.
67.	Cost to implement. Increased workload.
68.	14 day expiry results in more wastage
69.	None
70.	Some of the physical requirements may propose problems.
71.	I don't disagree with implementing some standards for compounding, and notably sterile compounding. Not sure why we did not adopt USP 795 and 797 standards? Following NAPRA guidelines will change sterile compounding into manufacturing. Financial burden of equipment and ongoing quality assurance programs are significant barriers. I believe that most compounding pharmacies will cease to prepare sterile compounds, thus leaving sterile compounding to only a few - who will in turn become manufacturers for other pharmacies, clinics, etc. The benefits of compounding have always been to be able to customize a medication for a particular patient. The future of the NAPRA paradigm in a community compounding pharmacy setting will prove to be cost prohibitive for patients.
72.	To implement the current standards, our facility would have to undergo extensive renovations. At this moment we are considering the decision between making the necessary changes to meet the standards, or discontinue preparing sterile preparations.
73.	BUD dating too short
74.	BUD of 14 days is a bit strict for outpatient therapy. If we have data to show stability and sterility of a product is beyond 14 days from manufacturer and/or private sterility testing, then I believe this outweighs an overall 14 day stability that is suggested in this NAPRA model.
75.	Time constraints. Hopefully the NAPRA model standards will be clear and concise and applicable to real life situations at different facilities.
76.	Not enough staff or time.
77.	1. Spacing: We don't have a lot of spaces in the pharmacy for compounding. Sometimes we have to share our working area with front store staff. This can be very troublesome if we have to implement NAPRA standards. 2. Management: Generally, our pharmacy's business model relies on script counts. The management want you to pump out as many scripts as possible. When you're super busy with dispensing tablets, NAPRA safety standards can be easily ignored. 3. Staffing: on weekends, our pharmacy only has one pharmacist on duty with no assistant. Sometimes, the pharmacist has to compound while multitasking other pharmacy duties. If she is in a rush to pick up the phone without taking off her gloves which she was using to compounding an HRT cream in the fume hood, it can lead to contamination and safety hazard.

78.	Wasn't even aware of these standards. Will need to implement training in our pharmacy. So will be a staffing and time issue.
79.	Many: Physical barriers: No USP 797 standards. No properly designated compounding space, just crammed in a filthy corner near a leaky sink. Financial barriers: VGH doesn't have any money to spend on the Pharmacy. We are low priority for the higher-ups. They prefer to focus on pharmacist initiatives more than the day to day nitty gritty things like actually making and dispensing prescriptions to our patients.
80.	We will need more staff to allow for proper time management to implement all of the standards.
81.	None at the moment
82.	poor design of IV room non USP 797 standards not all staff updated on standards
83.	No
84.	Cost
85.	No we do not.
86.	Physical plant
87.	Manager will need to review and remind staff about the standards to make sure everyone is following the procedure. Manager may need a yearly reminder to communicate with staff.
88.	Costs to make preparations will be increased as more rigorous procedures need to be followed.
89.	1. Pharmacy/sterile room layout. Needs renovations to be closer to 797. 2. Money 3. Management of hospital 4. Lack of knowelagble staff to implement
90.	Costly, time consuming, training, lack of knowledge
91.	Not sure
92.	Consistent training of staff Consistent housekeeping standards for contracted services Capital expenditure for upgrading sterile suites Having adequate testing companies available to perform the required testing
93.	Non
94.	not enough time and not enough staff
95.	I'm not too sure as I have no read the new standards. Noth technicians proper training and I'm sure we will implement any changes that need to happen.
96.	Nor sure
97.	Not sure if our pharmacy would have adequate space to implement the NAPRA model.

98.	Lack of proper training
99.	does not apply to our pharmacy. We do no compound sterile preparation of any kind
100.	We do not have enough manpower to designate a 30-minute time frame to train or guide an assistant to ensure proper compound procedures and follow the NAPRA Compounding guidelines. In our pharmacy, only some pharmacists and one registered pharmacy tech know how to do the compound properly. The rest has no pharmacy proper training and only to quickly teach when possible which only happened once in a blue moon. This is not ensuring proper training and inefficient. When cutting costs, training time is very limited. It is very difficult to train when no manpower to be at the drop-off Rxs or Pick-up Rxs. Too many interruptions during a quick show on how to compound or a quick monitor if compounds were done according to NAPRA guidelines.
101.	Enough time of pharmacist and staffs
102.	Housekeeping staff is by non-pharmacy technicians and therefore different employer which means they will not invest any more of their time implementing this rule of how and when to clean the iv room. Pharmacy technicians must do their own extra housekeeping.
103.	Pharmacy manager compliance.
104.	not sure
105.	N/A
106.	2 sites: 1 site needs a room for the hood. Hood is in the pharmacy department with no barriers. 2 site is almost USP 797 fully compliant.
107.	Time needed to change all the formulas and SOP's. Extra time means extra costs to us and patient, hiring more staff.
108.	Unsure
109.	None at this time
110.	-Time to complete all housekeeping - Pharmacy staff and Housekeeping staff
111.	Staffing, organizational support in the hospital--it would be helpful to continue to get firm reports of what is needed to meet standards so that the room, supplies, staff are available to us to meet the requirements.
112.	$$ for housekeeping staff to clean (as per requirements) Time
113.	cost and time/staffing issues. Waste of drug that we currently have days + expiry now expiring sooner requiring us to compound more often and tighter control will be required from satellite pharmacy's (not very good at reporting)
114.	It appears that time and wages is the biggest barrier.
115.	Costs, space and time to train and implement
116.	time
117.	Require upgrading of existing facility to accommodate complete adherence to NAPRA.

118.	The only barrier that is foreseen is any colleague not aware of the updates.
119.	upgrade the iv room
120.	There could be possible time constraints in getting product out. Or there could be lack of properly trained staff to be trained in a timely manner.
121.	I see staff and compounding technicians being non-compliant in carrying out the daily cleaning procedures, weekly and monthly, unless it is enforced. I also see them complain about not having enough time allocated to perform all the tasks. There are no compliance regulations and guidelines from the College. Every compounding pharmacy does their own thing and are not accountable to any standards and inspections. It is imperative to have clear regulations, guidelines and expectations. Most of what is happening is what they learn from attending short training sessions from PCCA or Medisca. And most owners do not invest enough time and resources to achieve a high standard of practice.
122.	housekeeping staff being compliant development of procedures
123.	Current Sterile area is nowhere near standards. Yearly performance audits are difficult due to resources. Surface and finger testing are not currently supported due to cost. Robust sterile/ante room cleaning is not supported due to lack of human resources. There are many barriers but I would like to see the college adopt strict standards and force the addition of resources.
124.	None
125.	NA
126.	Like of time for training and implementation. Lack of time for proper cleaning
127.	Unknown
128.	Not really sure. We try to implement highest standards possible. I'm not really sure how much the NAPRA model will change that. I think mostly in procedure manuals and that sort of thing. I am not 100% sure of all the new standards.
129.	Awareness, recertification and training of staff. Costs!
130.	management will not implement all procedures
131.	Costly to implement with little return on investment. Will take a long time to recoup the cost of implementation
132.	The only issue that we would face is the holding of an emergency compounded product until the sterility testing results come back. We will be forced to disregard this particular waiting period in order to treat the patient right away.
133.	Nothing really at this time, we are still waiting for management at my workplace to let us know if assistants can still mix hazardous preparations which will probably be in the next model.
134.	not sure as I have not reviewed it yet
135.	Don't think there are any barriers for hospital just better guidelines
136.	narcotics - absence of narcotic safe fridges

137.	We have tried to implement these standards but many staff/management are unwilling to comply
138.	Allowing extra time for cleaning and upgrading SOPs
139.	Beyond use dating we use is based on formulas from Compounding companies. We also use best clinical judgment based on commercial products, experience, and research. And sterile products are expensive to make, and expensive for the patient. Patient non-compliance would skyrocket if we enforced these guidelines, people couldn't afford it. Most pharmacies wouldn't bother/couldn't afford to do it (most don't anyways) leading to poor access for patients.
140.	Having enough support staff to carry the workload during implementation and after it is adopted. Supervisors need to work the job themselves to see if it is feasible before expecting pharmacy technicians to cram more work into the day.
141.	consistency with cleanliness
142.	the need to renovate the clean room. financial investment required to meet the new standard resistance to change from compounding personnel patient & 3rd party unwillingness to reimburse for increased costs a standard implementation date for the standards right across Canada The document needs to clarify the wording to allow compounding for office use. Currently it requires a pharmacy-patient-physician relationship to exist which is not strictly possible for office use compounding. Office use compounds are important for naturopaths, veterinarians and physicians and patient need access to these types of meds. The College must take the initiative to educate government, patients and 3rd party insurers about the new standards, why they are important and why the cost of compounded injectable has increased. The College must advocate on the behalf of compounding pharmacies for adequate reimbursement of compounded injectable by government and insurance companies as it is the College that has set up these new standards
143.	Time restraints to implementation, lack of independent reviewer, lack of internal expertise, cost of new builds or upgrades, staff turnover resulting in lack of ability to maintain sterile preparation services in remote areas, shipping logistics for BUD to remote areas.
144.	Costs will increase for maintaining standards and staff will need to be trained and retrained to maintain standards. Additional equipment costs will also be needed
145.	I do not foresee any barriers at this time
146.	There are huge barriers, mostly related to time and money, but some of them are issues of practicality or even patient safety. I had not read the NAPRA Model Standards, but on a quick perusal of them (and I only got as far as section 6.9), I had the following concerns: - 5.3.2.3 - That the HVAC system must include air conditioning - that is a major facility upgrade, which would be expensive and take a fair bit of time to coordinate, not to mention issues with interruption of the HVAC system (and likely downtime in sterile compounding) while the process is completed. - 5.3.2.5 - Activities in the anteroom - it indicates that labeling would happen in the ante-room, but that is not the case in most facilities - there is a potential risk of cross-labeling or mis-labeling that most facilities avoid by labeling items as they are prepared. Not in the PEC LAFW hood, perhaps (and that

	might be worth spelling out in the guidelines), but definitely in the clean room. In addition, it appears to indicate that pass-throughs are strictly from the ante-room into the clean room. I believe this may be contradicted elsewhere, but if it is the case, then most facilities would need to build new pass-through, again, with risks to the cleanliness of the clean room and down time while the process is completed. - 5.3.3.2 – Other devices in the clean room – it is my understanding that the Baxa ExactaMix pump is the only one currently licensed for sterile compounding. It might be worth considering how the Baxa system works – in a practical sense – and make sure that the wording of this section (and there are some related sections elsewhere in the Standards) allows for the expected workflow and verification processes. In particular, the Baxa system requires a printer in the vicinity of the hood where the pump is located, because many items (particularly parenteral nutrition solutions) require the "manual additives" section of the Mix-Check report in order to complete the compounding process as well as for documentation of verification. And yet printing in a clean room would generally be inadvisable due to particulate production. 6.1.2.1 – BUD for single-use vials. The 6-hour expiry is *very* short and the requirement that the vial not leave the ISO 5 PEC means that it cannot be refrigerated (which could be an issue for stability of some drugs). I will leave that decision to the experts, assuming this is based on actual research and not the preferences of manufacturers (who had significant input into USP) for sales and legal protection reasons. However, if this is to be pursued, then this will have **MAJOR** impacts on the cost of health-care delivery in BC. And the government and the taxpayers both need to be made aware in the clearest and obvious ways possible that costs of sterile medication preparation are going to increase significantly. I don't know exact myself, but I hope that part of this process has involved a cost-impact analysis! 6.1.3 – Table 6 – This table seems to indicate that items prepared for a single patient are lower risk than those prepared for multiple patients. If the other criteria apply, I don't see why this would matter. 6.1.4 – BUDs for Immediate Use Preparation – this section primarily refers to the activities of *other* health care professionals (primarily nurses, but also many others). Since these guidelines are intended for pharmacists and pharmacies, I don't know how helpful it is to put this here. Will pharmacists be expected to ensure that these things are happening? Have the other health care professionals been consulted on these items? Also, some consideration should be given to how long these "immediate use" preparations are going to be given over. Many Intensive Care nurses, for example, prepare solutions for continuous infusion. While it might be started within an hour of starting compounding, there should probably be some sort of time limit placed on the administration time, because the potentially contaminated product is just sitting there at room temperature for 24 hours, and sometimes 48 hours, or even 72 hours, depending on the facility's policies. 6.2 – Compounded Sterile Preparation Protocols – This seems to indicate that a pharmacist's signature is required on every protocol. While this might make sense for one-time or custom protocols, and for the initial set-up of a protocol, it doesn't make sense for established protocols in most facilities where Tech-Check-Tech is the norm for sterile compounding. Perhaps this should be modified to include the possibility of having a registered technician's signature in cases where a pharmacist has previously created or verified the protocol. 6.3 – Lot for each individual patient – This will require significant changes to existing procedures and computer programs in most facilities. If this information could be obtained by cross-reference from other records (something I've done quite often), then is it still required to be part of the patient-specific log? Also, to have to include the "documentation of… any adverse reactions" – is this really the best place for this information? How would it be recorded? Is it feasible to do this? There are many occasions where pharmacies are never notified of such anyway.
147.	Costs, staffing, training
148.	Fiscal approval from organization to get us to standard

149.	all tools to be cleaned in a timely manner
150.	I feel as though the Air Sampling studies that need to be done every 6 months are excessive. We already get the hoods, equipment, and filters certified every 6 months. We also have an in house quality assurance program where we sample the surfaces in the clean rooms monthly, and look for growth after incubation of agar plates. Air sampling is very expensive, and any compounds we do that are covered by pharmacare (such as eye drops, IV bags, or injectables) do not even cover our labor costs to prepare these compounds. We already lose money on labor, it will be very difficult to fit increased testing into our budgets. There is also talk that compounding pharmacies may need to send out a percentage of sterile preparations for sterility testing. Sterility testing is very costly, and it would not be viable for our pharmacy. We already do Media Fill Tests for all different types of sterile compounds. Each employee regularly does a media fill test with the same procedure used when making eye preps, injections, IV bags, etc. If the media fill test shows our techniques are sterile, then I feel as though we do not need to send out for testing (as long as we are not creating large batches of medications). The above requirements may force us to stop doing sterile compounds entirely. This would be very unfortunate because we are one of the only facilities in the Interior that has the ability to provide patients with these medications. We have patients coming from all over the Okanagan Valley to have us compound sterile eye preps, fertility injections, palliative pain management IV medications, etc. If there is no change in the reimbursement model, and we stop making these medications, it will create an enormous void for the communities in this area. Our pharmacy provides IV bags for hospice patients. We do not have the hospice contract for these homes. We provide the bags as a service to the community. For each bag we are reimbursed the cost of drug, supplies and a 10-minute compounding fee. This fee does not even cover the cost to wash and gown up properly, let alone clean the hood, and prepare the medication. By calling for sterility testing, and extra air sampling, etc. - it will provide barriers which will force us to stop providing these services for the community.
151.	I am all for robust standards and feel there should be some standardization to compounding. My concern is the time and cost associated with the sterile regulations. For a location to put these in place is going to take some time, sufficient time to comply needs to be provided. My concern is more for non-sterile, the rules may be a bit much for some basic compounds. Space will be an issue for more pharmacies to renovate and put in a room. Renovations mean more ridiculous paperwork to the College for approval and diagrams to scale, etc. cleaning is important, the training and evaluation from a third party may be overkill and expensive and where are you going to find a non-biased third party to evaluate?
152.	Please find my comments with respect to NAPRA's Model Standard for Pharmacy Compounding of Non-hazardous Sterile Preparations: 1. First of all, any general comment about this guideline, especially compared to USP 797, which is the current standards referenced in the provincial legislation; The guideline is very straightforward which will make it easy to create or enhance current policies and procedures. It references USP 797 a lot, which is changing and will be modified periodically in the future. How often will the NAPRA guidelines be modified/amended in the future? What if NAPRA doesn't like the changes in 797? Why isn't the College just adopting 797? Why is NAPRA bothering to create their own document when it is essentially the same as 797? What if the pharmacy cannot comply with a certain part of the guideline (i.e. due to physical limitations), but has made an effort to provide an equivalent documented alternative with regard to safety, would the College make an exception? 2. How would the implementation of this standard impact your practice? We currently have the required equipment, maintain a comprehensive policy and procedure manual for compounding sterile products, follow the educational requirements, employee verification and have product quality assurance program. To be compliant with the NAPRA guidelines "to the letter," we

would have to make a few changes to our procedures and obtain surveillance equipment. We have already made considerable investment in the clean room facility, staff training and quality assurance equipment (i.e. incubator).

3. Any hurdles/issues that you can identified?

Sterile compounding pharmacies provides necessary, and in some cases lifesaving products for many British Columbians. It is essential that the requirements not make it impossible for some pharmacies to continue to provide this service. Our pharmacy has not even begun to recoup the costs of implementation and maintenance of our equipment. The reimbursement by Pharmacare for sterile prescriptions does not cover the true costs of maintaining a sterile program. For example, the reimbursement for CAD pump filling for a palliative patient is $20. I estimate it costs a minimum $40 just to have the sterile assistant prepare, gown up and compound the simplest of sterile compounds. That doesn't even take into account the costs to maintain the sterile room – Hydro, cleaning time and supplies, maintenance, filter replacement, certification etc.

Will the College inspectors be required to take a sterile training course in order to do an inspection of the facility? Will they observe the staff actually compounding? How will the College enforce the implemented guidelines? Will there be a specific "certification" given to a pharmacy that complies so prescribers and the public are aware of which pharmacies to choose?

Beyond Use Dates:

The BUDs in the NAPRA document are unrealistic in community practice. At 3 days, by the time the patient receives a high risk compound, it may be close to or past the BUD. USP 797 now has two categories of sterile preparations making the NAPRA guidelines out of date. It is already difficult to tell physicians that the BUD must be shorter than previously dispensed, because we are trying to follow the USP 797 guidelines for BUD. They question why it has changed and state that other pharmacies' products have a longer BUD. We have lost a considerable amount of business because our competitors offer longer BUDs than stated in USP 797.

Hazardous Drugs:

How does USP 800 play out in all of this? NAPRA already has created the hazardous guidelines so when is that going to be adopted by the College? Are hormones going to be included as hazardous drugs?

Office Use Medications:

The Guidelines as written exclude compounding for "office use".? It is stated on the OCPs website that it is not their intention to eliminate office use compounds. What is the College of Pharmacists of BCs position on this matter?

4. Any suggestions regarding the implementation timeline?

I think the implementation must be done ASAP as the public is at considerable risk with pharmacies providing sterile services without having the required equipment, procedures and quality assurance programs.

Thank you for the opportunity to submit my comments. Please feel free to contact me if you have any questions.

Below are additional comments from the Association of Compounding Pharmacies of Canada (ACPC) I was asked to submit with my comments:

The ACPC welcomes the opportunity to respond and comment on the implementation timeline for NAPRA'S Standards for Pharmacy Compounding of Hazardous (and Non-Hazardous) Sterile Preparations.

It is recognized that the implementation of compounding standards for sterile preparations is necessary to ensure the safe compounding of quality sterile products. Further, it is recognized that proper handling

	of hazardous drugs in the sterile room setting, as well as in any environment, is crucial not only for the protection of pharmacy staff but also to prevent cross-contamination and limit exposure of our patients and the environment. CONFLICTING GUIDELINES Pharmacy compounding is already held to a high standard for patient safety reasons, as well as for consistency of preparations, through pharmacists adhering to the requirements set out in the United States Pharmacopeia (USP 39-NF34). In particular, chapters (non-sterile compounding) and (sterile compounding) address compounding. A recent USP call for comments on proposed amendments to USP resulted in a revamping of that chapter, which will be published on November 1, 2016 and go into force on May 1, 2017 (assuming no further amendments are made). Similarly, a newly-proposed chapter to the USP has received substantial scrutiny (USP, Hazardous Drugs -- Handling in Healthcare Settings). This chapter will be relevant to all healthcare personnel who "handle HD preparations and all entities that store, prepare, transport, or administer HDs (e.g., pharmacies, hospitals and other healthcare institutions, patient treatment clinics, physicians' practice facilities, or veterinarians' offices)". In many instances, the NAPRA guidelines are either in conflict, incomplete or outdated when compared to USP standards. This will create confusion amongst compounders, many of whom are already in compliance with the universally-accepted USP standards and are therefore compounding sterile preparations in a safe, professional manner. The NAPRA guidelines may not be implemented by all provinces and territories. This will also add a bevy of issues around entrenching a national standard of practice for compounding sterile preparations. USP is already in place and could easily be adopted nationally. OFFICE-USE Dispensing for office-use is a vital pharmacy practice in which a pharmacist receives an order from a licensed prescriber for a specified medication, and then dispenses that medication to that prescriber for use in treating their patients. The key component of this practice is the prescriber-pharmacist relationship that exists at the time the order is being placed. Under no circumstances is the pharmacist dispensing medication without that relationship with the prescriber who is directly involved in treating patients. Dispensing for office-use is critical to effective patient care in many settings. While emergency-use preparations are most widely recognized, prescribers in many specialties rely on office-use to effectively treat their patients. These environments include: • Maternal Fetal Medicine • Urology • Ophthalmologists and retina specialists • Addiction medicine • Dermatology • Dentistry • Autism • General practice and pediatrics • Ear, nose and throat specialists • Pain management

	• Veterinary medicine Currently, office-use is allowed in Canada and by the provincial regulatory authorities. Significantly, the very terms "patient-specific" and “office-use” are not defined in the NAPRA documents. These critical terms are incorporated into both documents; which pharmacy PRAs are now considering adopting without further modifications. The terms must be defined in the documents in which they are used, as is done with other important terms found within the documents. One such definition suggested is: "patient-specific" shall include "office-use" prescription orders of a practitioner entitled to prescribe in a province/territory of Canada. TIMELINE Any pharmacy performing sterile compounding should already have SOPs in place (http://www.ocpinfo.com/regulations-standards/policies-guidelines/compounding) as required by the licensing body, along with an internal quality assurance program and follow USP. Until pharmacists are able to evaluate and resolve any conflicts between the NAPRA documents and current recognized standards, a timeline for implementation is impossible to calculate. As such, any comment on “timeline” must make reference to what is required to be put into place within that timeline (i.e., contents of proposed standards). It is the opinion of the ACPC that changes need to be made to the NAPRA documents to address the issues above and to bring them into compliance with current USP standards. The ACPC also believes that further stakeholder/public feedback is warranted on the content of the documents, given the discrepancies already identified between those documents and the reference documents to which they reference. It is premature at this time to simply look for a timeline to implement the proposed NAPRA standards and the ACPC suggests that input from the broad cross-section of practicing pharmacists with expertise in these areas regarding the content of the documents can only serve to better protect patient and employee safety. Erika Lucas, BScPhm Island Pharmacy #10 106-284 Helmcken Rd. Victoria, BC V9B 1T2 (250) 710-9531 cell erika@islandpharmacy.ca
153.	Funding to meet USP 797 standards..
154.	The cost of implementing the standards and staff resistance is a barrier. The document also needs to clarify the wording in the document, as it currently reflects that compounding for office use medications is not allowed.

C. Face-to-Face Engagement Workshop Presentation and Workshop Questions

125 years

Pharmacy Compounding (Non-hazardous Sterile Preparations) Consultation

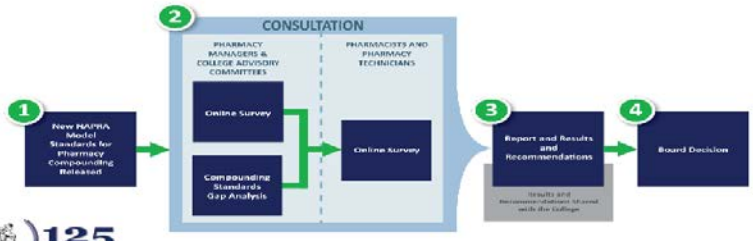
May 25, 2016

Purpose

With the newly released NAPRA Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations, the College is seeking input from pharmacies and registrants actively engaged with compounding in their practice to help inform the College's approach to implementing NAPRA's new compounding standards.

125 years

Engagement Process



125 years

College's Mandate

Our job is to protect public health by licensing and regulating pharmacists and pharmacy technicians and the pharmacies where they practice. We are responsible for making sure every pharmacist and pharmacy technician in BC is fully qualified and able to provide the public with safe and ethical pharmacy care.

125 years

Dana Lyons – Process Improvement Specialist

Licensed as a regulated pharmacy technician with the Alberta College of Pharmacists.

Expertise in implementation and management of sterile compounding processes and validation specific to USP 797 and CSHP Compounding Guidelines for Pharmacies (2014). Cleanroom management and microbial monitoring in accordance with current cleanroom standards.

Expertise in understanding and implementation of USP Chapter 797, Sterile Compounding with a particular interest in large hospital pharmacy distribution setting.

Certified Lean Six Sigma Black Belt
Certified in Prosci Change Management

125 years

Who Eats Here?

125 years

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Objectives

- Review project phase and outcomes
- Review gap identification data
- Workshop activities
- Wrap up and next steps in engagement process

Ground Rules

- Start and end promptly
- Everyone participates
- Technology

Introducing the NAPRA Model Standards into BC Practice

- NAPRA standards (November 2015)
- Consultation with registrants (May 2016)
- Recommendations and report to the Board

Introductions

1. **Your name**
2. **Workplace**
3. **One interesting thing about you**
4. **One reason you made a choice to be here**

Recent Misadventures

2012	California	9 patients develop fungal endophthalmitis after use of compounded Brilliant Blue-G (BBG) or receiving injections of triamcinolone products from the same compounding pharmacy
2012	Nationwide (USA)	More than 200 patients contracted fungal meningitis after receiving methylPREDNISolone acetate injection prepared by a compounding pharmacy contaminated with Exserohilum (brown-black mold) and Aspergillus
2013	Ontario, New Brunswick	1,202 patients under dosed (1,007 on cyclophosphamide, 191 on gemcitabine, 4 on both – all but 30 being treated for cancer) after contracted compounding pharmacy change

ISMP Alert

"When incidents like this occur, we are reminded of the need to remain vigilant to ensure quality throughout every step involved in providing health care services to patients."

Dr. Jake Thiessen April 9, 2013

Hppt://news.Ontario.ca/mohltc/en/2013/04/dr-jake-thiessen-to-lead-independent-review-of-cancer-drug-system.html Downloaded May 16, 2016

Part 2 - Workshop

Instructions:

1. Each table will pick a scribe and a speaker
2. You will have 14 minutes per question
3. Groups will move to clockwise around the room

Question 1

If a phased in approach to the NAPRA Model Standards was considered, brainstorm possible/achievable timelines, along with identifying key components from NAPRA Model Standards that would be attached to those timelines.

Groups may choose to build on previous groups work, or start a new timelines with key components.

Note: Be specific with your phases and timelines (for example: a 3 step phased in approach would need three dates and then key NAPRA components which would be attached to each phase)

Question 2

Considering the media attention sterile compounding has received over the last few years and the pressing need to ensure patient safety answer the following:

A. If the Model Standards were adopted too quickly what consequences might this present? Please list them.

B. Alternatively, if the Model Standards were adopted to slowly what consequences might this present?

C. Once your group has listed the consequences for each question, please suggest two dates for full compliance of the Model Standards and list reasons why these dates seem "reasonable"

Question 3

Beyond-Use-Dates (BUD) according to risk of microbial contamination outlined in the Model Standards (pg. 36, Table 6 & 7) may present some challenges especially if facility infrastructure is deficient.

A. Please list possible challenges with the immediate (with in 1 year), adoption of the BUD scheme.

B. Identify possible solutions or ideas to mitigate the challenges.

Questions 4

As part of a full competency assessment, you will be required to involve a third party evaluator for validating the knowledge and abilities of the compounding supervisor. (page 12&14)

Before answering this question take a few minutes to read the requirements for third party evaluator to fully understand the question.

A. What challenges does this present for your workplace – please list them

B. What ideas do you have to overcome this challenge? – please list them

Question 5

Quality assurance of personnel involved in aseptic compounding (page 60), includes fingertip sampling, and media fill tests as part of initial and ongoing qualification of personnel as mentioned in the following section in NAPRA 5.1.2.2.

Note: This is one of the survey questions in which 89% of respondents were non-compliant.

Prior to answering the question, please take a few minutes to fully read the sections in NAPRA, then as a group answer the follow questions?

A. What concerns or challenges exist with the implementation of this requirement?

B. Brainstorm ideas to overcome the challenges.

Question 6

Setting aside the financial impact of implementation of the Model Standards. NAPRA and USP 797 are not leaps and bounds apart, they are similar and we struggled to meet compliance with USP 797. In the inspection reports on average we are 50% compliant.

A. **What other barriers, to implementation and meeting the standards is occurring? What key components in NAPRA are these barriers related to? (besides money). (i.e. Is it knowledge, training, time etc.).**

Question 7

High-Risk Compounding requires rigorous processes that are validated. For pharmacies that are compounding high-risk compounds or plan to continue, answer the following questions:

A. **Should these pharmacies be required to fully comply with NAPRA sooner than sites that are not engaged in high-risk compounding?**

B. **If "no" why, If "yes" suggest a date for full compliance for high-risk compounding facilities.**

Note: High-risk compounding is when any non-sterile ingredient or container is used in the compounding process. (For example: cocaine eye gtts, alum for irrigation, many others). Discuss within your groups what dangers high risk compounding poses.

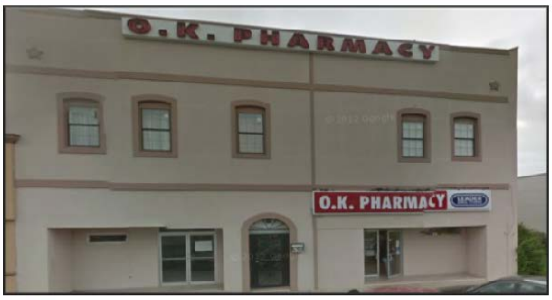
Question 8

Training and re-certification activities for compounding and cleaning personnel is rigorous. Review the training and validation requirements (pages 11 – 14) that are required. In your groups answer the following:

A. **What challenges do the training and assessment present?**

B. **Brainstorm ideas to overcome these challenges.**

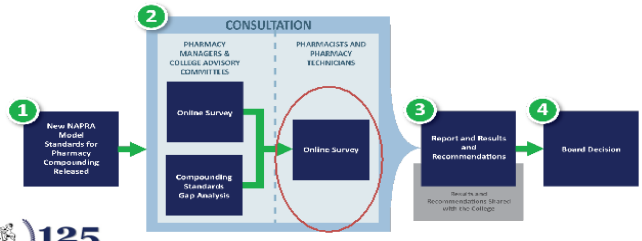
Who wants to be OK?



125 years

125 years

Engagement Process Next Steps



125 years

Thank You!

125 years

Q1 Phased in Approach Most desirable 26 votes

Phase 1	Hand hygiene and garbing (6.6,6.5)	Dec 2016
Phase 2	Cleaning and disinfecting Training and assessment Policies and Procedures	December 2017
Phase 3	Quality Assurance Environmental monitoring Media fill Fingertip Sampling	December 2018
Phase 4	Facilities BUD	December 2019 +++

14 votes

Phase 1	Facility design/layout compliance approved	18 month
Phase 2	Training/Education, SOP, P&P, Hygiene, Disinfection	12 – 18 months

Two votes

Phase 1	Training/education for supervisors, trainers and staff PPE, Hand hygiene, garbing, disinfection, training of housekeeping	Dec 2016
Phase 2	Fingertip testing, media fill testing, surface sampling Practical and theory exam	December 2017
Phase 3	Facility compliance (renos)	December 2018

Phase 1	Standards/Training in place	Dec 2017
Phase 2	QA processes, quality management program, antimicrobial testing etc.	24 months
Phase 2A	Data from testing supports the need for physical upgrades	

Question 2

Too Fast	Too Slow	Target Date
Facilities will fail	Risk to public	Dec 2018
Lose confidence in College	Risk to staff	Dec 2019
Feel picked on	Lose momentum or respect (process/credibility)	Dec 2020 (6 votes)
No opportunity for education/training	Standards could change	Dec 2026
Cost associated with renos/training/education/GFT/QA	5 years for complex IV products	
No time to break people habits/mindset	Prioritize topical vs IV i.e. prioritize based on risk to patients	
Supply issues		
Reverting to old practice		
Overwhelm staff		
Pharmacies will close		
Patient access restricted		
Lack of time to be compliant		
Outside BC will undermind local pharmacies selling for lower costs if timelines are different prov to prov.		
Lose economy of scale (share services/lab/QA), shared experiences/knowledge building		

Question 3 BUD

Challenges	Solutions	
Most sites at LMPS would only be able to provide 12 h BUD	Product sterility testing	
More frequent and smaller batches adding to scheduling challenges	Outsourcing	
More frequent replenishment	Centralized production at compliant facilities	
Repetitive strain	Renovate sterile rooms	
Increase staffing and set up time	Docking bags MB+	
Increase cost/budget	Robots (<$$ than reno)	
Increase delivery costs	Adequate reimbursement incentives for existing compounders to expand services	
Significant workflow redesign/optimization	Allow flexibility of BUD if evidence available to support	
Increase wastage	Consolidate central or hub processing in centres/sites that are compliant to do batch processes.	
Lack of testing facilities		
Delay getting Rx to patient		
Increased patient cots		
Doctor/Patient Expectations for long BUD		

Questions 4 Third Party Evaluator

Challenges	Solutions	
Who would qualify and where would you find them	Private experienced evaluator or College expert inspector	
Not in USP 797	Internal peer expert evaluator	
Cost, educating cost to administration	Contract to a service provider	

Questions 5 QA of Personnel

Challenges	Solutions	
Time factor – to perform as well as waiting for results	Increase funding	
Finding certified labs	Create an implementation plan	
Cost of materials	3rd party outsourcing	
Underlying processes need to up to date before starting	List of qualified labs	
Extra documentation involved	Group contract pricing	
Keeping track of 6 month period for each employee	In house testing (hospital micro labs)	
Need remediation plan if positive results	An opportunity for economy of scale and standardization if only a few vendors (labs) are in place	
Need for independent assessor or manager or internal fully trained	Education sessions to bring managers/owners up to speed on what the testing means	

Refrigeration and temperature storage of media	Having a defined standard (NAPRA) is already helpful for planning/targets	
Staff shortage while waiting for testing	Pass on testing costs to third party payers	
Staff intentionally failing so they don't have to work in IV room.		
Knowledge gaps		

Question 6 Other Challenges (other than $)

Wastage of drug (i.e. use of partials) after 6 hours	Solution	
BUD	Develop SOPS (massive effort)	
Complexity of quality control/sterility	Need time to do it thoroughly	
Education for senior hospital leadership	Change management support	
Various levels of regulation	Education	
Different standards to meet (worksafe BC, Food & Drug Act. Etc.)		
Renovated facilities not to standard		
Qualifications of auditors/decision makers		
Compounding for doctor office use		
Space restrictions		
Resources required		
Time		
Change aversion		
Continuous changes to practice environment		
Values – how to make people care		
Resistances to change		
Old school mindsets		
Change for staff, leadership, head office, Physicians, patients		
Continuously changing regulations		
A college defined standard/legislation will help for long term planning.		
Knowledge of standards is lacking		
Rural vs Urban access to resources (lab, training, expert teachers availability)		

Question 7 High-Risk Compounding

Comply sooner than other sites	If no Why	If Yes why
No all should comply at same time suggestion of 2 – 3 years. All provinces should implement at same time.	Confusion for public	More sever implications with high-risk compounding
Yes should comply sooner	No – should be all the same to add consistency	Suggestion of 1 year to meet minimum standard
		May be an opportunity to discontinue legacy an non-standard practices/products

Question 8 Training and Assessment

Challenges	Solutions	
Access to training and re-assessment	Realistic/adequate reimbursement by government an insurance companies.	
Financial costs	Flexibility to be allowed to adapt rules to fit practice	
Certification of staff	3rd party evaluated provided by College (qualified in sterile compounding)	
Time involved, frequency, documentation onerous, cost investment goes up.	Need CPBC support as requirement for licensure	
Need for pharmacists or regulated tech to perform certain tasks	Share or co-develop materials e.g. CSHP	
Shortage of regulated techs and training schools	FH – LMPS standardized training	
Multiple contracted housekeeping services	Centralized training facility	
Staff numbers <500 techs	Tech training programs to offer more in-depth sterile compounding as an option.	
Collective agreements/unions		
Hard to train staff if they compound infrequently. The cost to train everyone (and turn over training)		
Space to train		

College of Pharmacists
of British Columbia

GAP IDENTIFICATION TOOL

Adapted from NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations

2016

GAP Identification Tool Instructions

All information gathered through the use of this tool will be confidential. The information will be used for aggregate data collection purposes only.

The name and identification of your facility is not required to complete this gap identification tool.

Please refer to and read the Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations prior to completing this gap identification tool. The questions asked in the document are based on “shall or must” statements in the Model Standards.

Model Standards can be found here:
http://napra.ca/Content_Files/Files/Mdl_Stnds_for_Pharmacy_Compounding_NonHazardous_Sterile_Preparations_Dec2015_FINAL.pdf

Each question has a drop-down list; you must choose one of the available selections.

Please answer all questions in the identification tool.

Note: You may need to consult with your engineering and maintenance department to be able to answer some of the questions related to air changes per hour.

Email completed form to: Legislation at legislation@bcpharmacists.org

ID	Gap Identification Question(s)	Choose One Response that Accurately Represents Your Facility
1	What is the approximate number of beds of your compounding operation supports (for hospitals only)?	Please Select ONE Option
2	If you are a Community Pharmacy, how many sterile compounds does your operation prepare on average weekly?	Please Select ONE Option
3	Do **all** compounding personnel pass an initial gloved finger-tip sample before working in the compounding area?	Please Select ONE Option
4	Do **all** compounding personnel pass a initial media fill test before working in the compounding area for non-hazardous sterile products?	Please Select ONE Option
5	**All personnel** (pharmacists, pharmacy technicians and pharmacy assistants) assigned to the compounding of sterile preparations are assessed at least once a year for low or medium risk level; and at least twice a year for high risk level preparations?	Please Select ONE Option
6	The air supplied to areas used for compounding non-hazardous sterile preparations pass-through a terminally fitted **high-efficiency particulate air (HEPA) filter** to ensure a very high level of cleanliness?	Please Select ONE Option
7	Particle counts are performed by trained, qualified personnel at least **every 6 months** as	Please Select ONE Option

ID	Gap Identification Question(s)	Choose One Response that Accurately Represents Your Facility
	part of an internal quality control program **for facilities**? (see Appendices 5 and 6)	
8	Particle counts are performed by trained, qualified personnel at least **every 6 months** as part of an internal quality control program for the **primary engineering control (PEC)**? (see Appendices 5 and 6 in NAPRA)	Please Select ONE Option
9	Water sources, sinks and drains are **not** located in the clean room?	Please Select ONE Option
10	Compounding personnel and anyone else who accesses controlled areas wear appropriate protective clothing, as exactly described in **Table 5 (page 33) of the NAPRA Model Standards**?	Please Select ONE Option
11	**PPE is worn** for the compounding of sterile preparations includes the following: Shoe covers, hair cover, beard cover (if applicable), surgical mask, sterile non-powdered gloves, non-shedding gown (enclosed at neck and sleeves that fit snuggly at the wrist)?	Please Select ONE Option
12	Cleaning and disinfecting personnel (housekeeping staff) **fully comply** with hand hygiene and garbing procedures before entering sterile compounding areas and performing housekeeping duties?	Please Select ONE Option
13	**Daily cleaning and disinfecting** occurs for the following surfaces and areas and there is documented proof? (e.g. Counters, Carts, Floors)	Please Select ONE Option

ID	Gap Identification Question(s)	Choose One Response that Accurately Represents Your Facility
14	**Monthly cleaning and disinfecting** occurs for the following surfaces and areas and there is documented proof? (Walls, Ceilings, Shelves)	Please Select ONE Option
15	**Beyond-use dates** are assigned according to stability and the risk level associated with microbial contamination? (Low, Medium and High risk level BUDS)	Please Select ONE Option
16	**Before entering** the anteroom, personnel always remove personal outer garments (e.g., coat, hat, jacket scarf, sweater, vest, boots and outdoor shoes)?	Please Select ONE Option
17	**Before entering** the anteroom, personnel always remove jewelry, studs and other accessories from fingers, wrists, forearms, face, tongue, ears and neck (this includes personal electronic devices or accessories, such as cell phone, iPod and earbuds, which are not permitted in the anteroom or clean room)?	Please Select ONE Option
18	**Before entering** the anteroom, personnel always remove all cosmetics, including makeup, false eyelashes, perfume, hair products such as hairspray, henna tattoos and paper tattoos?	Please Select ONE Option
19	**Before entering** the anteroom, personnel always remove nail polish and other nail applications?	Please Select ONE Option
20	Where packaging allows, compounding equipment and products are **disinfected with sterile 70% isopropyl alcohol** just before being introduced into the clean room?	Please Select ONE Option

ID	Gap Identification Question(s)	Choose One Response that Accurately Represents Your Facility
21	A biomedical refrigerator or freezer **is used for storing products, ingredients and final compounded sterile preparations** that need to be refrigerated or frozen (see section 5.3.3.2).	Please Select ONE Option
22	Your pharmacy **has implemented** an environmental sampling plan that measures viable air and surface particles?	Please Select ONE Option
23	For **each** employee, GFS after the media fill test is completed annually for low- and medium-risk sterile compounding and every 6 months for high-risk sterile compounding and documented proof?	Please Select ONE Option
24	The cleanroom **meets** ISO 14644-1 for cleanroom particulate airborne cleanliness at the ISO 7 level and there is documentation to support this?	Please Select ONE Option
25	Sterile Isopropyl Alcohol is used to clean the PEC?	Please Select ONE Option
26	The anteroom has a **line of demarcation** clearly separating the clean and dirty side?	Please Select ONE Option
27	Does your pharmacy prepare **high-risk** compounds in batches greater than 25?	Please Select ONE Option
28	Cardboard **does not** enter the anteroom or cleanroom?	Please Select ONE Option
29	Alcohol based hand rub (AHBR) **with persistent activity** is used to perform hand antisepsis?	Please Select ONE Option

ID	Gap Identification Question(s)	Choose One Response that Accurately Represents Your Facility
30	Bins used to introduce supplies or products into the cleanroom are **always** disinfected prior to use?	Please Select ONE Option
31	The cleanroom is verified to have a **minimum of 30 air changes per hour** (ACPH)?	Please Select ONE Option
32	The anteroom is verified to have a **minimum of 20 air changes per hour** (ACPH)?	Please Select ONE Option
33	The PEC is cleaned and disinfected with clean wipes and germicidal disinfectant detergent, followed by sterile 70% isopropyl alcohol, at the **start and end of the day or shift (minimum twice per day)?**	Please Select ONE Option

F. Gap Identification Survey Tool "Collated Results"

Questionnaire #	Total	NO	Yes	Partially	N/A	no response	blank	Total
Q1	14	14%	29%	0%	0%	0%	57%	100%
Q2	14	29%	0%	14%	0%	0%	57%	100%
Q3	14	71%	14%	7%	0%	0%	7%	100%
Q4	14	71%	7%	14%	0%	0%	7%	100%
Q5	14	64%	14%	14%	0%	0%	7%	100%
Q6	14	29%	64%	0%	0%	0%	7%	100%
Q7	14	29%	50%	14%	0%	0%	7%	100%
Q8	14	14%	71%	7%	0%	0%	7%	100%
Q9	14	14%	79%	0%	0%	0%	7%	100%
Q10	14	7%	57%	29%	0%	0%	7%	100%
Q11	14	0%	93%	0%	0%	0%	7%	100%
Q12	14	14%	50%	29%	0%	0%	7%	100%
Q13	14	36%	36%	21%	0%	0%	7%	100%
Q14	14	29%	36%	29%	0%	0%	7%	100%
Q15	14	36%	21%	36%	0%	0%	7%	100%
Q16	14	0%	64%	21%	7%	0%	7%	100%
Q17	14	0%	50%	43%	0%	0%	7%	100%
Q18	14	7%	36%	50%	0%	0%	7%	100%
Q19	14	7%	71%	14%	0%	0%	7%	100%
Q20	14	43%	43%	7%	0%	0%	7%	100%
Q21	14	29%	43%	21%	0%	0%	7%	100%
Q22	14	57%	21%	14%	0%	0%	7%	100%
Q23	14	79%	7%	7%	0%	0%	7%	100%
Q24	14	29%	43%	14%	0%	7%	7%	100%
Q25	14	50%	36%	7%	0%	0%	7%	100%

Questionnaire #	Total	NO	Yes	Partially	N/A	no response	blank	Total
Q26	14	21%	43%	21%	7%	0%	7%	100%
Q27	14	50%	7%	7%	29%	0%	7%	100%
Q28	14	14%	71%	7%	0%	0%	7%	100%
Q29	14	43%	43%	0%	0%	7%	7%	100%
Q30	14	21%	64%	7%	0%	0%	7%	100%
Q31	14	29%	50%	14%	0%	0%	7%	100%
Q32	14	29%	43%	14%	7%	0%	7%	100%
Q33	14	21%	36%	36%	0%	0%	7%	100%

Report written by Dana Lyons RPhT

Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations Engagement Summary and Recommendations

Consultation and Implementation Approach

This report is part 2 of the consultation reports. Part 1 is a report for Non-Hazardous Sterile Preparations.

This report and recommendations builds on the prior engagement and consultative work done for the implementation of the non-hazardous NAPRA Model Standards. The two reports together, are intended to inform and support implementation for all sterile compounding activities in the province of British Columbia.

Dana Lyons RPhT
January 2017

Table of Contents

Executive Summary

In light of the newly released NAPRA Model Standards for Pharmacy Compounding Hazardous Sterile Preparations (NAPRA), and the historically ineffective nature of voluntary guidelines, it was likely that some form of enforceable national sterile compounding standards similar to those in the United States would come into place in Canada. Despite a growing awareness of the importance of good sterile compounding practices, there remains a troubling disconnect between practice guidelines and actual practice. Developing an effective compounding strategy is critical to ensuring patients have access to properly compounded medications, but because each organization's needs differ, a one-size-fits-all solution cannot be applied to every hospital and community practice environment where sterile compounding takes place. The responsibility to plan and become compliant involves facility infrastructure to changing historic personnel practices and cleaning routines.

Building on the prior consultation with registrants and the resulting **seven** recommendations is a proposed plan to adopt NAPRA Model Standards for Pharmacy Compounding of Hazardous Preparations in **four phases**. Each phase has key NAPRA requirements attached to it with specific timelines and aligns with the phased in approach for implementing the sterile non-hazardous NAPRA standards.

To ensure we achieve compliance it is recommended that we measure compliance as we implement the four-phase model with completion of the phases targeted over four years.

Of a pharmacy professional's countless responsibilities, perhaps none is more critical to positive patient outcomes than ensuring patients receive safe medications, compounded according to established standards and this report outlines key steps to achieving this responsibility.

1.0 Scope

The scope of this initiative is to review what the current policies, standards and bylaws are that guide hazardous sterile compounding practices in hospital and community pharmacy in the province of British Columbia. This work includes a confirmation of what current state practice is and the potential gaps in practice. This report and its findings builds on the work and engagement done with the non-hazardous NAPRA Model Standards.

2.0 Current Bylaws and Practice Guidelines

2.1 Community Pharmacy

The policy documents in place to guide sterile compounding practice in the Community Pharmacy setting include:

I. Professional Practice Policy – 64 (Guidelines to Pharmacy Compounding)

The following key statement is found within this policy: ***The Board of the College of Pharmacists of BC adopts the NAPRA Guidelines to Pharmacy Compounding as the Standard of Practice for registrants.***

The NAPRA document referenced in the Professional Practice Policy is based on eight performance indicators.

1. Knowledge and expertise to compound
2. Confirm the need to compound
3. Access to equipment
4. Quality ingredients
5. Labelling
6. Suitable containers
7. Storage
8. Documentation checking, duplicating and tracing.

Within this NAPRA 2006 document, there are three key points specific to sterile compounding practice and they are:

1. Pharmacists engaging in sterile compounding should be knowledgeable and obtain specialized technical training in this area.
2. Carefully established standards for the operation of cleanrooms and the preparation of sterile products should be documented in accordance with a recognized source. (E.g. Canadian Society of Hospital Pharmacists) (CSHP).
3. Sterility testing shall be done according to a clearly defined standard (E.g. United States Pharmacopeia) (USP) and the product assigned an estimated expiry date.

2.2 Hospital Pharmacy

The policy documents that currently guide the compounding practices in hospital pharmacy are:

I. Professional Practice Policy – 61 (Hospital Pharmacy Published Standards)

II. Professional Practice Policy – 57 (Standards for Pharmacy Assistant Verification of Sterile Products in Hospital Pharmacy Practice)

Within the professional practice policy documents, the following statement can be found: **Sterile Products must be prepared in accordance with the published standards noted below:**

1. CSHP Official Publications – Guidelines for Preparation of Sterile Products in Pharmacies
2. CSHP Official Publications – Handling and Disposal of Hazardous Pharmaceuticals (including cytotoxic drugs)

Bylaw documents for Hospital Pharmacy include:

I. Health Professions Act – Bylaws Schedule F (Part 2 – Hospital Pharmacy Standards of Practice)

Within the Health Professions Act – Bylaws Schedule F (Part 2 – Hospital Pharmacy Standards of Practice) under the Drug Distribution section 3 is the following statement:

> **Sterile products must be prepared and distributed in an environment that is in accordance with:**
>
> 1. The CSHP Guidelines for Preparation of Sterile Products in Pharmacies.
> 2. The USP Pharmaceutical Compounding – Sterile Products Guidelines, and
> 3. Such other published standards approved by the Board from time to time

II. WorkSafe BC – Bylaw 34

CSHP Guidelines

The CSHP Guidelines for Preparation of Sterile Products in Pharmacies was published in 1996. The scope of this guideline was intended to be used in situations where pharmacies are involved in the preparation of sterile products for patients (e.g., hospitals, community pharmacies, nursing homes, home health care and others). This document was retired in 2014 after the updated CSHP guidelines were published.

USP Chapter <797> Standards

The other choice for published guidelines referenced in the bylaws and currently the standard in British Columbia is USP Chapter <797> Pharmaceutical Compounding – Sterile Preparations. Chapter <797> was first published in 2004 and has specific requirements for the following areas:

- Design of the Facility
- Environmental and Engineering Controls
- Environmental Testing
- Personnel Training and Competency Testing
- Standard Operating Procedures and Documentation
- Quality Assurance
- Patient Monitoring and Adverse Events Reporting
- Storage and Dating

3.0 Consultation and Engagement

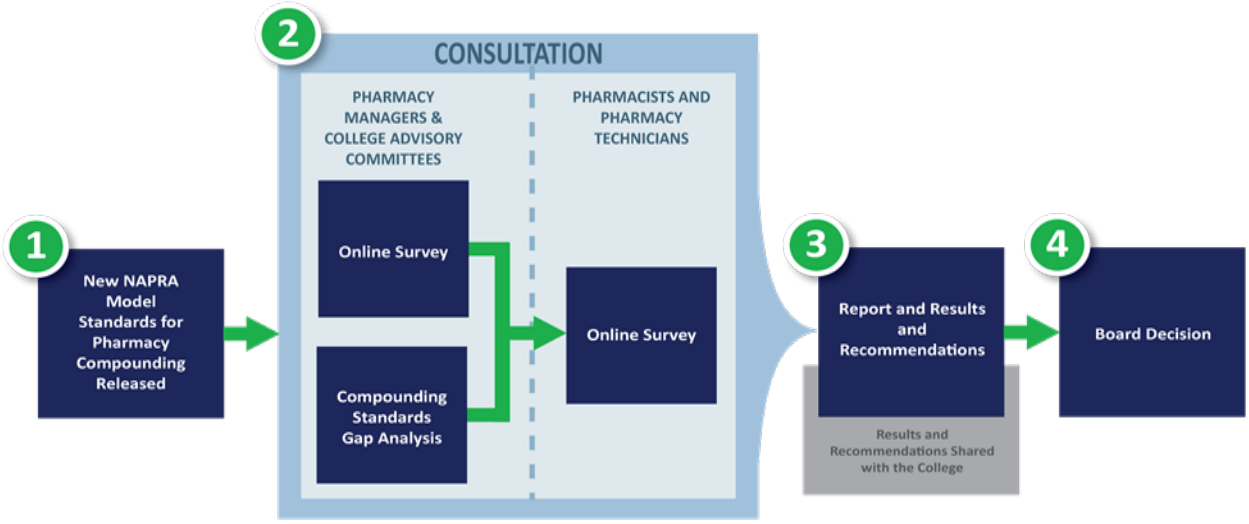
3.1 Method

A multi-step consultation process was designed to reach the many stakeholders including, leaders and pharmacy managers, as well as front-line pharmacists and pharmacy technicians all impacted by the changes in sterile compounding standards. Consultation on the hazardous NAPRA Model Standards, builds from the non-hazardous work.

A sixty-question gap tool was designed, and included some repeat questions from the non-hazardous gap tool where the requirement is the same for both hazardous and non-hazardous compliance and included hazardous specific questions as it relates to the "shall" or "must" statements in the NAPRA Model Standards. Participation in this gap tool survey was open to all pharmacists and pharmacy technician registrants in British Columbia.

The results of the survey were used to make recommendations in addition to the 7 recommendations found in the sterile non-hazardous report.

3.2 Consultation Process

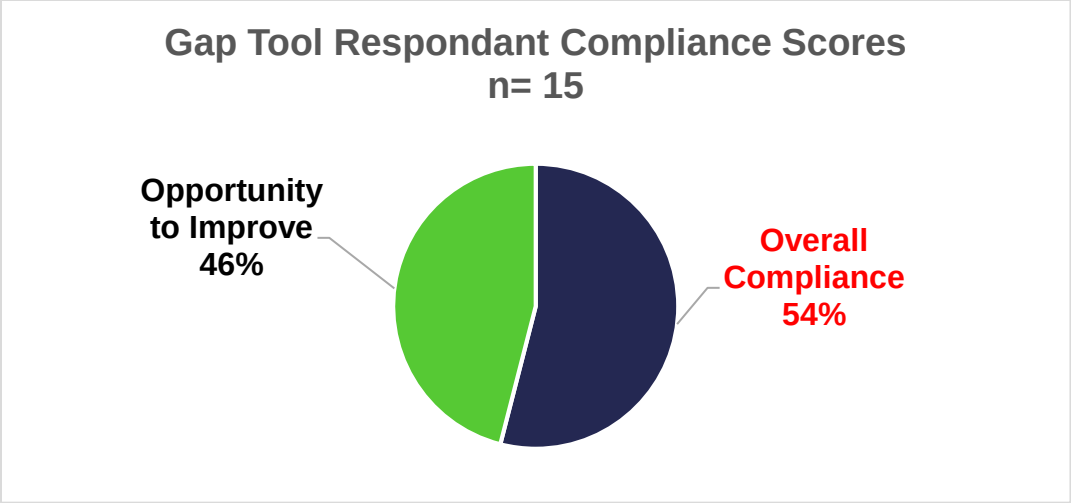


4.0 Practice Gap

When looking at practice gaps, we needed to understand what gap we currently have with current standards, and then how does that gap widen with the introduction of new standards. Using the 60-question gap survey results we can start to understand the gap in practice versus NAPRA.

4.1 Overall compliance with the gap survey tool as self-reported from the participants is 54%.

A total of 15 respondents submitted the survey which makes the sample size small and results should be interpreted keeping this in mind.



4.2 Hospital versus Community Practice Gap

When comparing hospital versus community pharmacy compounding environments, we also wanted to know if there is a significant difference in compliance between the two practice environments. Out of the fifteen survey respondents thirteen are hospital and two are community practice-based.

The low response rate from community practice sites might indicate that hazardous sterile compounding is mainly occurring in a hospital setting. The two community pharmacies self-reported an overall compliance score of 69% and 90%, which is encouraging as these compliance scores fall within the top 5 survey responses.

5.0 New Requirements NAPRA Introduces

There are numerous introductions of hazardous drug containment strategies that are over and above what was previously found in USP <797>. The newly published USP <800> chapter was not used for comparison as it was too new to be considered a standard in British Columbia.

6.0 Barriers Registrants Brought Forward to Implementing NAPRA

6.1 Knowledge of Standards

Education on current sterile compounding standards may possibly be a barrier for implementation and adoption of the NAPRA Model Standards. In the survey to frontline pharmacists and pharmacy technicians, we wanted to assess the general awareness of the NAPRA standards, so we asked the question: **Are you aware that NAPRA published new Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations in September 2016?** Out of 15 respondents 3 **were not** aware of the NAPRA Model Standards prior to the survey and 12 had known this standard was newly released. This is an indicator that pharmacists and pharmacy technicians are understanding that sterile compounding standards are changing in Canada.

The barriers sited from both the hazardous and non-hazardous gap tool surveys are very similar. A complete unedited list of barriers is provided in the appendices. No new barriers came forward and the top barrier remains cost mainly due to infrastructure changes.

6.2 Cost Constraints

Healthcare dollars are scarce and renovation budgets are planned years in advance. The full cost of implementing sterile compounding standards is not known, as the starting point is different for every facility and there will likely be additional costs for those facilities where compounding of non-hazardous and hazardous occur. The cost of compliance is a barrier to implementation as reported by survey respondents.

Mitigating Strategy

The four-phase, four-year approach to NAPRA adoption and compliance should address most of the cost increases as they will be absorbed incrementally over time. The proposed implementation plan should also include the budget and infrastructure cycles heath authorities work within. The College may need to assess as the implementation rolls out and adjust the compliance dates if availability of infrastructure dollars becomes the rate limiting step.

6.3 Beyond-Use Dates (BUD)

The BUD in NAPRA is based on the risk that a compounded sterile preparation (CSP) may have been contaminated. Traditionally, before newer standards were published, common practice was to use drug stability information to determine the expiry date of the CSPs. The introduction of USP <797> changed the way BUDs are applied using drug stability plus sterility to determine the safest BUD. In consultation with the leaders and managers, they revealed that the negative impact could include the following: increase in drug wastage, delivery costs and costs to patients, staffing time, and repetitive strain injuries. *The results from the hazardous gap survey indicates that **73%** of respondents are currently in compliance with BUDs as outlined in NAPRA.*

This is positive news, and the change arounds the BUDS for hazardous drug preparations won't be as onerous as non-hazardous.

6.4 Changing Behaviours

As the old cliché goes "what gets measured gets done". The message is clear: measuring something gives you the information you need in order to make sure you actually achieve what you set out to do. Asking our staff to show up prepared to compound, with no make-up, no nail extensions and in proper attire is one of the lowest cost changes we will be asked to comply with.

7.0 Implementation Strategy

Based on the need to balance implementation and mitigate risks with an approach that is not too fast or too slow, the four-phase model for implementation is a good balanced approach that can be used for both hazardous and non-hazardous sterile NAPRA Model implementation strategies. All of the various

models of implementation suggested by participants can be found in the *sterile non-hazardous report*, and the most desirable model presented in table 1 below.

Table 1 Most Desirable Option for Compliance

Phase	**Compliance Component**	**Date of Expected Phase Compliance**
Phase 1	Hand Hygiene and Garbing	Phase 1
Phase 2	Cleaning and Disinfecting, Training and Assessment Policies and Procedures	Phase 2
Phase 3	Quality Assurance and Environmental Monitoring Media Fill and Fingertip Sampling	Phase 3
Phase 4	Facilities and BUD	Phase 4

Recommendation #2

Phased-in Approach

The implementation of NAPRA Model Standards requires a balanced approach, focused firstly on protection of the public and personnel safety, yet achievable for compounders and organizations. The four-phase approach should be undertaken with a timeline of four years plus a notification period to registrants and should include non-hazardous and hazardous sterile compounding. Alternatively, the College could allow timeline extensions or a TBD for major infrastructure based on the need for further renovations when the non-sterile compounding Model Standards are released. (expected to be in 2017)

8.0 Conclusion and Implementation Recommendations and Timelines

The adoption of the NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations will take time, money and considerable effort to implement properly and safely. My experience as a process specialist is if you take big initiatives or projects and break them down into attainable chunks of work which can be measured along the way, success of the larger goal will materialize. Nonetheless, the effort required to implement the Model Standards and assess compliance is a large undertaking. The proposed phased in model for compliance with the NAPRA Model Standards, which the participants drafted and favored, has been adapted and presented below in the table. The

three key sections (5, 6 and 7) in NAPRA have been divided according to the model with proposed timelines.

The adoption of the NAPRA Model Standards by the College, would be in alignment with other provincial regulatory authorities (PRA) such as Alberta and Ontario. The Model Standards have gone through extensive pharmacy stakeholder consultation from each Provincial Regulatory Authority and many of the members within the PRA's. Therefore, the recommendation is for BC to adopt the NAPRA Model Standards for Hazardous Sterile Preparations as the standard in British Columbia.

9.0 Phased in Approach Recommendation and Timelines

Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations Implementation Plan			
NAPRA ID	**NAPRA Compliance Area**	**Phase of compliance**	**Proposed compliance date**
Step 1	**Define compounding risk level**	**Phase 1**	November 2017
Step 1	**Complete a gap analysis and prioritize a site plan**	**Phase 1**	November 2017
6.3	Compounded sterile preparation log	Phase 1	November 2017
6.4	Patient file	Phase 1	November 2017
6.5	Conduct of personnel in areas reserved for the compounding of hazardous sterile preparations	Phase 1	November 2017
6.6	Aseptic compounding of hazardous sterile preparations	Phase 1	November 2017
6.7	Packaging	Phase 1	November 2017
6.8	Receipt and storage of hazardous products	Phase 1	November 2017
6.9	Transport and delivery of hazardous compounded sterile preparations	Phase 1	November 2017
6.10	Recall of hazardous sterile products or final hazardous compounded sterile preparations	Phase 1	November 2017
5.1	Personnel	Phase 2	May 2019
5.2	Policies and procedures	Phase 2	May 2019
5.4	General maintenance log	Phase 2	May 2019
6.2	Compounded sterile preparation protocols	Phase 2	May 2019
6.11	Incident and accident management	Phase 3	May 2020
6.1	Beyond-use date and dating methods	Phase 3	May 2020

Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations Implementation Plan			
NAPRA ID	**NAPRA Compliance Area**	**Phase of compliance**	**Proposed compliance date**
6.12	Hazardous waste management	Phase 3	May 2020
7.1	Program content	Phase 3	May 2020
7.2	Results and action levels	Phase 3	May 2020
7.3	Verification of equipment and facilities	Phase 3	May 2020
7.4	Quality assurance of personnel involved in aseptic compounding	Phase 3	May 2020
7.5	Quality assurance of hazardous compounded sterile preparations	Phase 3	May 2020
7.6	Documentation of quality control activities	Phase 3	May 2020
5.3	Facilities and equipment	Phase 4	May 2021

Appendices

A. Recommendations for the College

Recommendation ID	Recommendation(s)
1	The College inspect community and hospital sterile compounding practices using the same tools for both settings. The frequency of sterile compounding facility and practice inspections should also be similar.
2	**Phased-in Approach** The implementation of NAPRA Model Standards requires a balanced approach, focused firstly on protection of the public and personnel safety, yet achievable for compounders and organizations. The four-phase approach should be undertaken with a timeline of **four years** plus a notification period to registrants and should include non-hazardous and hazardous sterile compounding as one joint effort. Alternatively, the College could allow timeline extensions or a TBD for major infrastructure based on the need for further renovations when the non-sterile compounding Model Standards are released. (expected to be in 2017)

College of Pharmacists
of British Columbia

GAP IDENTIFICATION TOOL

Adapted from NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations

2016

GAP Identification Tool Instructions

All information gathered through the use of this tool will be confidential. The information will be used for aggregate data collection purposes only.

The name and identification of your facility is not required to complete this gap identification tool.

Please refer to and read the Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations prior to completing this gap identification tool. The questions asked in the document are based on "shall or must" statements in the Model Standards.

Model Standards can be found here: http://napra.ca/Content_Files/Files/Mdl_Stnds_Pharmacy_Compounding_Hazardous_Sterile_Preparations_Nov2016_Revised.pdf

Each question has a drop-down list; you **must choose one** of the available selections.

Please answer **all** questions in the identification tool.

Note: You may need to consult with your engineering and maintenance department to be able to answer some of the questions related to the facility portion.

Email completed form by December 19th, 2016 to: Legislation at legislation@bcpharmacists.org

Thank you for participating in the survey.

ID	Gap Identification Question(s)	Choose One Response that Accurately Represents Your Facility
1	Please select if you are a **Community** licensed pharmacy or a **Hospital** licensed pharmacy and if neither apply choose “other”.	Please Select ONE Option
2	How many **sterile hazardous** compounds does your operation prepare on average weekly?	Please Select ONE Option
3	Are you aware of the newly released NAPRA Model Standards for Pharmacy Compounding of **Hazardous Sterile** Preparations published September 2016?	Please Select ONE Option
4	Are you a registered Technician or Pharmacist	Please Select ONE Option
5	**If you are aware of the new standards**, have you read the Model Standards for Hazardous Sterile Compounding and started implementing them?	Please Select ONE Option
6	How did you hear about the newly released NAPRA Hazardous Sterile Compounding Standards?	Please Select ONE Option
7	Do **all** compounding personnel pass an initial gloved finger-tip sample before working in the compounding area?	Please Select ONE Option
8	Do **all** compounding personnel pass an initial media fill test before working in the compounding area for hazardous sterile products?	Please Select ONE Option
9	**All personnel** (pharmacists, pharmacy technicians and pharmacy assistants) assigned to the compounding of hazardous sterile preparations are assessed at least once a year for low or medium risk level; and at least twice a year for high risk level preparations?	Please Select ONE Option

10	The air supplied to areas used for compounding hazardous sterile preparations pass-through a terminally fitted **high-efficiency particulate air (HEPA) filter** to ensure a very high level of cleanliness?	Please Select ONE Option
11	Particle counts (non-viable) are performed by trained, qualified personnel at least **every 6 months** as part of an internal quality control program **for facilities**? (see Appendices 5 and 6)	Please Select ONE Option
12	Particle counts are performed by trained, qualified personnel at least **every 6 months** as part of an internal quality control program for the **primary engineering control (PEC)**? (see Appendices 5 and 6 in NAPRA)	Please Select ONE Option
13	Water sources, sinks and drains are **not** located in the clean room?	Please Select ONE Option
14	The initial training and assessment program for compounding personnel includes reading and understanding P&Ps (see appendix 1), theoretical training with assessment (see appendix 3), assessment of aseptic techniques?	Please Select ONE Option
15	**PPE is worn** for the compounding of hazardous sterile preparations includes the following: Double Shoe covers, hair cover, beard cover (if applicable), N95 or N100 mask, sterile non-powdered gloves, non-shedding gown (enclosed at neck and sleeves that fit snuggly at the wrist, and moisture resistant)?	Please Select ONE Option
16	**Beyond-use dates** are assigned according to stability and the risk level associated with microbial contamination? (Low, Medium and High risk level BUDS)	Please Select ONE Option
17	**Before entering** the anteroom, personnel always remove personal outer garments (e.g., coat, hat,	Please Select ONE Option

	jacket scarf, sweater, vest, boots and outdoor shoes)?	
18	**Before entering** the anteroom, personnel always remove jewelry, studs and other accessories from fingers, wrists, forearms, face, tongue, ears and neck (this includes personal electronic devices or accessories, such as cell phone, iPod and earbuds, which are not permitted in the anteroom or clean room)?	Please Select ONE Option
19	**Before entering** the anteroom, personnel always remove all cosmetics, including makeup, false eyelashes, perfume, hair products such as hairspray, henna tattoos and paper tattoos?	Please Select ONE Option
20	**Before entering** the anteroom, personnel always remove nail polish and other nail applications?	Please Select ONE Option
21	Where packaging allows, compounding equipment and products are **disinfected with sterile 70% isopropyl alcohol** just before being introduced into the clean room?	Please Select ONE Option
22	Your pharmacy **has implemented** an environmental sampling plan that measures viable air and surface particles?	Please Select ONE Option
23	For **each** employee, a glove finger-tip sample is performed after the media fill test is completed annually for low-risk and medium-risk sterile compounding and every 6 months for high-risk sterile compounding?	Please Select ONE Option
24	The cleanroom **meets** ISO 14644-1 for cleanroom particulate airborne cleanliness at the ISO 7 level and there is documentation to support this?	Please Select ONE Option

25	**<u>Daily</u> cleaning, decontamination and disinfecting** occurs in the C-PEC, counters, carts, floors and frequently touches surfaces in the anteroom and the cleanroom where hazardous drugs are compounded? Note: review definitions of cleaning, decontamination and disinfection in NAPRA prior to answering this question.	Please Select ONE Option
26	Does your pharmacy prepare **high-risk** compounds? **Note:** High-risk is when non-sterile ingredients or supplies are used to create a sterile compound).	Please Select ONE Option
27	Cardboard **does not** enter the anteroom or cleanroom?	Please Select ONE Option
28	Alcohol based hand rub (AHBR) **with persistent activity** is used to perform hand antisepsis?	Please Select ONE Option
29	Bins used to introduce supplies or products into the cleanroom are **always** disinfected prior to use?	Please Select ONE Option
30	The cleanroom is verified to have a **minimum of 30 air changes per hour** (ACPH) with the air being completely exhausted to the exterior?	Please Select ONE Option
31	The cleanroom is verified to be kept under **negative** pressure relative to the anteroom. (-2.5 Pa)?	Please Select ONE Option
32	The anteroom is verified to have a **minimum of 30 air changes per hour** (ACPH)?	Please Select ONE Option
33	The pharmacy of the health care facility has established a committee comprised of representatives of the employer, representatives of compounding, administration personnel, and representatives of cleaning and disinfecting personnel for the compounding areas and within this team is a **pharmacist or pharmacy**	Please Select ONE Option

	technician to support hazardous product management?	
34	**Cleaning and disinfecting personnel** are provided theoretical training and assessment covering the issues and particularities of cleaning and disinfecting the premises and equipment used for compounding hazardous sterile preparations as outlined in appendix 3?	Please Select ONE Option
35	The pharmacy has a developed list of hazardous drugs that require special handling precautions. This list is available at the pharmacy and is reviewed at least every 12 months.	Please Select ONE Option
36	The compounding area consists of an anteroom and a cleanroom. These rooms are each controlled and physically separated by a walls, door and pass-throughs?	Please Select ONE Option
37	The compounding supervisor is evaluated at the same frequency as compounding personnel, by a third party evaluator?	Please Select ONE Option
38	The anteroom is separated into **two spaces by a visible demarcation line**. The first space is referred to as “dirty” but chemical free. The second space is referred to as “clean but chemically contaminated”.	Please Select ONE Option
39	Hazardous products are stored in a properly ventilated room with all air exhausted to the exterior and negative pressure relative to the adjacent rooms with at least **12 air changes per hour**?	Please Select ONE Option

40	Oncology adjunctive therapies can also be prepared in the BSC's or CACIs, if they are being compounded for the same patient as the hazardous sterile preparation. **These adjunctive therapies are handled and labeled to require hazardous drug precautions?**	Please Select ONE Option
41	All gloves (sterile and non-sterile) used in the unpacking, cleaning and disinfecting of the cleanroom, disinfecting the C-PEC, compounding, managing a spill and disposing of hazardous products are verified to be compliant with standards **D-6978-05 of ASTM International?**	Please Select ONE Option
42	When compounding hazardous drugs, both pairs of gloves are discarded and replaced at the earliest of the manufacture's limit for permeation of the gloves, every 30 minutes, or immediately if a tear, puncture or contamination has occurred or is suspected?	Please Select ONE Option
43	The gown is tested by the manufacturer to be resistant to permeability by hazardous drugs. It closes in the back, and has long sleeves with fitted cuffs at the wrist?	Please Select ONE Option
44	The gown is discarded and replaced at the earliest of the manufacturers time limit for permeation of the gown or after 2-3 hours of continuous compounding work or after each removal or after a contamination has occurred or is suspected?	Please Select ONE Option
45	A disposable hair cover is worn during compounding and it is discarded after each removal (not saved for re-use or worn outside of ante-room)?	Please Select ONE Option
46	**A chemical cartridge respirator with a pre-filter** is worn in the presence of vapours, gas and particles (e.g. dust) or if there has been a spill? (NAPRA page 36) ***Note:** In this case an N95 or	Please Select ONE Option

	N100 NIOSH-approved mask offers no protection from vapours, and gases and splashes.	
47	The mask worn during compounding is changed at the earliest of the following: after 3.5 hours of continuous compounding, after each removal or if contamination is suspected?	Please Select ONE Option
48	**Goggles and a face shield or full face-piece respirator** is worn when **deactivating, decontaminating and cleaning underneath the work surface of a C-PEC**, when cleaning up a spill, when there is risk of splashes to the face and eyes and when unpacking suspected damaged drugs? ***Note:** In this case an N95 or N100 NIOSH-approved mask offers no protection from vapours, and gases and splashes.	Please Select ONE Option
49	Compounding personnel wear clean room scrubs, not street clothes?	Please Select ONE Option
50	Cleaning equipment for cleaning areas used for the compounding of hazardous sterile preparation is specifically designated for this area?	Please Select ONE Option
51	Housekeeping personnel also don **two pairs of ASTM International gloves**, with the outer gloves being **sterile**?	Please Select ONE Option
52	**Daily cleaning, decontamination and disinfecting is** occurring for the following areas: C-PEC, counters, carts, floors, and surfaces that are touched frequently such as chairs) in hazardous drug compounding areas?	Please Select ONE Option

53	The minimum frequency of surface decontamination, deactivation, and disinfection inside the C-PEC are occurring? (see table 8, in NAPRA)	Please Select ONE Option
54	The maximum syringe fill limit is **75% or ¾** of the total syringe capacity when withdrawing hazardous drugs?	Please Select ONE Option
55	The verification of hazardous drug compounding is through direct observation or image capture?	Please Select ONE Option
56	**Two pairs of ASTM International approved gloves** are donned when **unpacking intact hazardous products** that have been received from the supplier sealed in impervious plastic?	Please Select ONE Option
57	All PPE worn for hazardous drug handling is discarded in a hazardous waste containor?	Please Select ONE Option
58	The level of hazardous drug contamination is measured at least every 6 months (wipe sampling program)?	Please Select ONE Option
59	Compounding personnel wear an N95 respirator when compounding hazardous drugs in a BSC?	Please Select ONE Option

60	The NAPRA Model Standards for Pharmacy Compounding of **Hazardous Sterile** Preparations is being adopted as a standard in BC. What barriers to implementation do you anticipate? Please also use the space provided to indicate any other concerns you might face with the NAPRA standards with the understanding that modifications to the standard are unlikely. **Please type your responses to this question in the grey text box.**

Save completed form and email to Legislation at legislation@bcpharmacists.org by December 19, 2016.

C. Gap Identification Survey Tool "Collated Results"

Question #	Survey question	% Compliant with each question
1	Please select if you are a **Community** licensed pharmacy or a **Hospital** licensed pharmacy and if neither apply choose "other".	2 Community 13 Hospital
2	How many **sterile hazardous** compounds does your operation prepare on average weekly?	1 – 10 preps = 2 respondents 11- 50 preps = 6 respondents 51 – 200 preps = 5 respondents 200> = 2 respondents
3	Are you aware of the newly released NAPRA Model Standards for Pharmacy Compounding of **Hazardous Sterile** Preparations published September 2016?	3 no, 11 yes
4	Are you a registered Technician or Pharmacist	8 techs & 7 pharmacists
5	**If you are aware of the new standards**, have you read the Model Standards for Hazardous Sterile Compounding and started implementing them?	3 – no, 9 yes, 3 planning on it
6	How did you hear about the newly released NAPRA Hazardous Sterile Compounding Standards?	3 employer, 5 colleagues, 6 other, 1 unaware
26	Does your pharmacy prepare **high-risk** compounds? **Note:** High-risk is when non-sterile ingredients or supplies are used to create a sterile compound).	9 out of 15 respondents prepare HR compounds
7	Do **all** compounding personnel pass an initial gloved finger-tip sample before working in the compounding area?	18%
8	Do **all** compounding personnel pass an initial media fill test before working in the compounding area for hazardous sterile products?	22%

Question #	Survey question	% Compliant with each question
9	**All personnel** (pharmacists, pharmacy technicians and pharmacy assistants) assigned to the compounding of hazardous sterile preparations are assessed at least once a year for low or medium risk level; and at least twice a year for high risk level preparations?	24%
10	The air supplied to areas used for compounding hazardous sterile preparations pass-through a terminally fitted **high-efficiency particulate air (HEPA) filter** to ensure a very high level of cleanliness?	78%
11	Particle counts (non-viable) are performed by trained, qualified personnel at least **every 6 months** as part of an internal quality control program **for facilities**? (see Appendices 5 and 6)	73%
12	Particle counts are performed by trained, qualified personnel at least **every 6 months** as part of an internal quality control program for the **primary engineering control (PEC)**? (see Appendices 5 and 6 in NAPRA)	76%
13	Water sources, sinks and drains are **not** located in the clean room?	60%
14	The initial training and assessment program for compounding personnel includes reading and understanding P&Ps (see appendix 1), theoretical training with assessment (see appendix 3), assessment of aseptic techniques?	71%

Question #	Survey question	% Compliant with each question
15	**PPE is worn** for the compounding of hazardous sterile preparations includes the following: Double Shoe covers, hair cover, beard cover (if applicable), N95 or N100 mask, sterile non-powdered gloves, non-shedding gown (enclosed at neck and sleeves that fit snuggly at the wrist, and moisture resistant)?	71%
16	**Beyond-use dates** are assigned according to stability and the risk level associated with microbial contamination? (Low, Medium and High risk level BUDS)	73%
17	**Before entering** the anteroom, personnel always remove personal outer garments (e.g., coat, hat, jacket scarf, sweater, vest, boots and outdoor shoes)?	73%
18	**Before entering** the anteroom, personnel always remove jewelry, studs and other accessories from fingers, wrists, forearms, face, tongue, ears and neck (this includes personal electronic devices or accessories, such as cell phone, iPod and earbuds, which are not permitted in the anteroom or clean room)?	64%
19	**Before entering** the anteroom, personnel always remove all cosmetics, including makeup, false eyelashes, perfume, hair products such as hairspray, henna tattoos and paper tattoos?	62%
20	**Before entering** the anteroom, personnel always remove nail polish and other nail applications?	76%
21	Where packaging allows, compounding equipment and products are **disinfected with sterile 70% isopropyl alcohol** just before being introduced into the clean room?	44%

Question #	Survey question	% Compliant with each question
22	Your pharmacy **has implemented** an environmental sampling plan that measures viable air and surface particles?	29%
23	For **each** employee, a glove finger-tip sample is performed after the media fill test is completed annually for low-risk and medium-risk sterile compounding and every 6 months for high-risk sterile compounding?	13%
24	The cleanroom **meets** ISO 14644-1 for cleanroom particulate airborne cleanliness at the ISO 7 level and there is documentation to support this?	60%
25	**Daily cleaning, decontamination and disinfecting** occurs in the C-PEC, counters, carts, floors and frequently touches surfaces in the anteroom and the cleanroom where hazardous drugs are compounded? Note: review definitions of cleaning, decontamination and disinfection in NAPRA prior to answering this question.	56%
27	Cardboard **does not** enter the anteroom or cleanroom?	64%
28	Alcohol based hand rub (AHBR) **with persistent activity** is used to perform hand antisepsis?	84%
29	Bins used to introduce supplies or products into the cleanroom are **always** disinfected prior to use?	42%
30	The cleanroom is verified to have a **minimum of 30 air changes per hour** (ACPH) with the air being completely exhausted to the exterior?	58%
31	The cleanroom is verified to be kept under **negative** pressure relative to the anteroom. (-2.5 Pa)?	60%

Question #	Survey question	% Compliant with each question
32	The anteroom is verified to have a **minimum of 30 air changes per hour** (ACPH)?	51%
33	The pharmacy of the health care facility has established a committee comprised of representatives of the employer, representatives of compounding, administration personnel, and representatives of cleaning and disinfecting personnel for the compounding areas and within this team is a **pharmacist or pharmacy technician** to support hazardous product management?	20%
34	**Cleaning and disinfecting personnel** are provided theoretical training and assessment covering the issues and particularities of cleaning and disinfecting the premises and equipment used for compounding hazardous sterile preparations as outlined in appendix 3?	44%
35	The pharmacy has a developed list of hazardous drugs that require special handling precautions. This list is available at the pharmacy and is reviewed at least every 12 months.	44%
36	The compounding area consists of an anteroom and a cleanroom. These rooms are each controlled and physically separated by a walls, door and pass-throughs?	71%
37	The compounding supervisor is evaluated at the same frequency as compounding personnel, by a third-party evaluator?	20%

Question #	Survey question	% Compliant with each question
38	The anteroom is separated into **two spaces by a visible demarcation line**. The first space is referred to as "dirty" but chemical free. The second space is referred to as "clean but chemically contaminated".	44%
39	Hazardous products are stored in a properly ventilated room with all air exhausted to the exterior and negative pressure relative to the adjacent rooms with at least **12 air changes per hour**?	47%
40	Oncology adjunctive therapies can also be prepared in the BSC's or CACIs, if they are being compounded for the same patient as the hazardous sterile preparation. **These adjunctive therapies are handled and labeled to require hazardous drug precautions?**	58%
41	All gloves (sterile and non-sterile) used in the unpacking, cleaning and disinfecting of the cleanroom, disinfecting the C-PEC, compounding, managing a spill and disposing of hazardous products are verified to be compliant with standards **D-6978-05 of ASTM International?**	67%
42	When compounding hazardous drugs, both pairs of gloves are discarded and replaced at the earliest of the manufacture's limit for permeation of the gloves, every 30 minutes, or immediately if a tear, puncture or contamination has occurred or is suspected?	62%
43	The gown is tested by the manufacturer to be resistant to permeability by hazardous drugs. It closes in the back, and has long sleeves with fitted cuffs at the wrist?	87%

Question #	Survey question	% Compliant with each question
44	The gown is discarded and replaced at the earliest of the manufacturers time limit for permeation of the gown or after 2-3 hours of continuous compounding work or after each removal or after a contamination has occurred or is suspected?	60%
45	A disposable hair cover is worn during compounding and it is discarded after each removal (not saved for re-use or worn outside of ante-room)?	93%
46	**A chemical cartridge respirator with a pre-filter** is worn in the presence of vapours, gas and particles (e.g. dust) or if there has been a spill? (NAPRA page 36) ***Note:** In this case an N95 or N100 NIOSH-approved mask offers no protection from vapours, and gases and splashes.	16%
47	The mask worn during compounding is changed at the earliest of the following: after 3.5 hours of continuous compounding, after each removal or if contamination is suspected?	69%
48	**Goggles and a face shield or full face-piece respirator** is worn when **deactivating, decontaminating and cleaning underneath the work surface of a C-PEC**, when cleaning up a spill, when there is risk of splashes to the face and eyes and when unpacking suspected damaged drugs? ***Note:** In this case an N95 or N100 NIOSH-approved mask offers no protection from vapours, and gases and splashes.	20%

Question #	Survey question	% Compliant with each question
49	Compounding personnel wear clean room scrubs, not street clothes?	80%
50	Cleaning equipment for cleaning areas used for the compounding of hazardous sterile preparation is specifically designated for this area?	80%
51	Housekeeping personnel also don **two pairs of ASTM International gloves**, with the outer gloves being **sterile**?	20%
52	**Daily cleaning, decontamination and disinfecting is** occurring for the following areas: C-PEC, counters, carts, floors, and surfaces that are touched frequently such as chairs) in hazardous drug compounding areas?	56%
53	The minimum frequency of surface decontamination, deactivation, and disinfection inside the C-PEC are occurring? (see table 8, in NAPRA)	76%
54	The maximum syringe fill limit is **75% or ¾** of the total syringe capacity when withdrawing hazardous drugs?	91%
55	The verification of hazardous drug compounding is through direct observation or image capture?	27%

Question #	Survey question	% Compliant with each question
56	**Two pairs of ASTM International approved gloves** are donned when **unpacking intact hazardous products** that have been received from the supplier sealed in impervious plastic?	27%
57	All PPE worn for hazardous drug handling is discarded in a hazardous waste container?	82%
58	The level of hazardous drug contamination is measured at least every 6 months (wipe sampling program)?	0%
59	Compounding personnel wear an N95 respirator when compounding hazardous drugs in a BSC?	47%

D. Barriers to Implementation (Raw data from respondents)

Survey question #60 responses

The NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations is being adopted as a standard in BC. What barriers to implementation do you anticipate? Please also use the space provided to indicate any other concerns you might face with the NAPRA standards with the understanding that modifications to the standard are unlikely.
We do not have a 797 compliant IV room No negative pressure, hazardous medication manufactured in the same room as regular CIVA and no anteroom No ventilated room for storing hazardous products. Currently stored in the compounding room with the BSC We do not have the respirator masks and staff have not been fitted to them BCCA has not been to certify staff since 2014 We do not do any fingertip or media fill testing
There are a number of concerns with adoption of NAPRA. The staffing level in our facilities are low and the requirement for auditing, training, sampling etc pulls these staff away from their operational duties.
Largest barrier would be financial and unless College mandates and provides a timeline for implementation, pharmacy sites will delay as long as possible which is not ideal or best practice. There are also limited training courses on the subject, so properly educating staff by qualified people will be a barrier.
Facility does not support implementation of NAPRA standards. New building is being built that will support standards. This will be available in September of 2017. My site has been without a site coordinator since September 2016. As such, there has not been a local supervisor to review the standards and implement changes. In fact, there has not been anyone supervising compounding other than the daily staff doing the work.

We will be challenged to implement the microbial testing of surfaces, media fill testing and gloved -fingertip testing to comply with NAPRA; We do not have the resources to verify HD compounding through direct observation or image capture-this will be a huge challenge to adhere to; The requirement to wear N95/100 NIOSH approved respirator masks when compounding HDs in a BSC (and using CSTD to prepare HDs)is unreasonable; annual HD wipe sampling should be acceptable - not sure why Q58 says every 6 months - NAPRA allows for the frequency of monitoring to be based on the results obtained on previous monitoring; In question 51- I think you mean housekeeping that is working in the cleanroom must wear 2 Pr of sterile chemotherapy approved gloves;
Physical and logistical barriers are going to be multitudinous. The fact is that most hospitals in the Lower Mainland simply do not have the space/building requirements to be USP 797 compatible, much less compatible with the new NAPRA Hazardous Compounding standards. Funding is a huge issue and it is the frequently cited excuse by VCH and FH upper management for why we do not have adequate Sterile Compounding areas.
At VGH Pharmacy, the hand wash sink is still directly next to the LFH's and BSC's, inside the 'sterile' room. We have no anteroom or buffer room. Management does not mandate Fingertip testing. The IV Supervisor has not been evaluated in many years, and regular check ins for Sterile Compounding staff are nonexistent.
Serious steps should be taken to impress the need for these standards to Upper Management in the Health Authorities, and throughout LMPS. Beyond self-driven standards for excellence, Technicians are having to work in very substandard compounding rooms that are not, by definition, sterile in any way.
We do not currently do GFS or Media-fill tests- although it is something I know we need to start doing sooner rather than later. I do not know what is involved in setting up this type of program and therefore do not know how long it would take to get going on it.
Because we outsource our housekeeping services, we do not have control over their training and competency assessments. I do not know that we will ever be able to annually assess our housekeeping staff (as they are not 'our' housekeeping staff)
I believe our center complies with the requirements of annual testing by an 'independent' person, however, this is not defined so I am not sure. Also, I do not know if it can be considered 'independent' when the pharmacy manager dictates what the staff are tested on. More clarity here would be helpful.
Our 'independent' evaluator currently does not comply with all the requirements mentioned in that section as they do not do annual competencies themselves.
In section 5.1.2.3 NAPRA talks about 'Failures' of compounding personnel, however, in Section 7.2, the Results and Action Levels do not talk about 'failures'. What is a 'failure'? More clarity here would be helpful.

The BUD of vials- wherein we can only reuse a vial that stays in an ISO Class 5 environment…I understand this requirement, however, ISMP would argue that having a cabinet full of vials is not safe. I don't know what to do with this one, however, as we use 'single-use' vials for up to 6 hours…and we remove them from out cabinet. This is another area we are NOT compliant
Implementing a camera checking system will take resources that my organization is currently looking at. We are not willing to have a person dedicated in the cleanroom to checking every preparation 'in real time' but we are willing to use a camera system. Hopefully we will be able to implement the camera checking by the time NAPRA is enforced. This checking process is WAY overdue for high-alert drugs.
We do not currently record the lot/expiry date of the IV solution bags and non-hazardous drugs used to compound patient-specific preparations…we do record the lot/expiry of each hazardous drug used.
Using a sporicidal to wipe items going into the cleanroom- I do not see the value in using a sporicidal for the sake of using a sporicidal. Because most (all?) sporicidal have an extended contact time to actually kill any spores, it would take an incredibly LONG time to introduce items into the cleanroom. I do not see us ever being compliant with this…we can use a sporicidal, but what is the point if we are not using it correctly?
Section 6.6.6.1- Role of personnel in verification- it is the supervisor's responsibility to verify all compounded hazardous drugs. This is not reasonable. We have alternate staff checking final products and therefore will not ever comply with this section of the standards.
Same section, it is the person that compounds the preparation's responsibility to store the final product where applicable- this also does not happen. For us, it is the person performing the final product check that ensures proper storage for products that are not immediately dispensed to nursing staff or the patient…it is not reasonable for the compounding staff to leave the cleanroom to store final products. We will never comply with this section of the standards.
When dispensing a final product for same-day use (e.g., within 1-2 hours' maximum), we do not put a BUD on the product UNLESS the product is time sensitive (e.g., must be adminstered within 30 minutes of first puncture of the vial stopper)
The layout of the existing pharmacy would need to be completely re-done including the ventilation system and temperature control and negative pressure. New fridges would need to be purchased. More staff would need to be hired.
1) Storage of hazardous products in a negative pressure room with at least 12 air exchange per hour - this will be especially difficult for any products that require refrigeration as our cleanroom and anteroom do not have enough space for a refrigerator. That means we have to construct a special room just to store the product, a challenge in an already built pharmacy.

2) Implementing a wipe sampling program every 6 months as that will add significant cost to send the samples for analysis.
It is unlikely that facility can be re-modeled to meet the standards in a short-time frame. If the standards were to be enforced by the College, then I foresee that many facilities will step away from compounding hazardous sterile products, resulting in lessened access for patients.
cost
dependent on upper management to implement
would require major renovations to anteroom/cleanroom
would increase preparation time = patients would need to wait longer for medication
A major concern that I have and one that will be a barrier for implementing NAPRA standards, is the physical layout and inadequate space of the area where the BSCs are located. Specifically, for my Kootenay Boundary Regional Hospital site [Trail, BC], the non-hazardous hood is located in a small room, with no anteroom, and no air exchange system. This "clean" room is accessed from the main pharmacy where there is heavy traffic. In addition, the staff are required to wash hands at the opposite end of the Pharmacy, prior to entering the clean room and donning PPE. Coupled to that is the very small and inadequate size of the overall Pharmacy Department. A sustainability plan for KBRH site has been drafted but is contingent on financial support from the Ministry. Based on competing priorities for very lean capital funding, the likelihood of this sustainability project moving forward is slim. Further to this issue our hazardous room, which does have an anteroom and an air exchange system, has one disadvantage of inappropriate access. The anteroom opens up to a public hallway. Due to major space constraints, we had no other options when planning the construction of this space and we tried to make due with limited opportunities. I do have a compounding facility in my Nelson Pharmacy that possible could meet the NAPRA standards, however it would be very impractical and result in significant time delays if I manufactured all sterile products at that facility and then had to transfer them to Trail. It takes over an hour to travel between sites and coupled with poor driving conditions, limited transportation options and poor stability of some manufactured products it would make this opportunity impossible.
aspects of NAPRA that are misaligned/"exceed" requirements of USP 800, NIOSH recommendations, provincial or health authority hazardous drugs handling policies
e.g. requirement for image capture or direct observation for compounding verification, requirement to wear N95 mask for hazardous compounding - cost of implementation - change saturation of staff e.g. layering on top of medication reconciliation, Clinical Systems Transformation project

Barriers: some barriers I anticipate include

1. BUD: this will change our practice and will need Pyxis/Omni cell capacity as well as time to manufacture more frequently

2. ceiling tiles used in my clean rooms are not sealed

We are having some air pressure issues in regards to the Pa of our ante room

4. We do not have fingertip sampling or media fill test set up

5. need to know if a fridge holding hazardous drugs is meant to be in the negative pressure clean room?

6. My site has difficulty maintaining regular/trained housekeeping staff to ensure proper procedures are known and followed

7. A working group for my health authority is working on a hazardous drug policy: having the knowledge from this group will help us move forward with proper receiving/storage and a complete list of hazardous drugs to follow

8. having someone verify that our products (egg. gown/gloves) are certified/tested for mixing/handling hazardous products

Other Jurisdictions that have Adopted the Released NAPRA Model Standards

Below is a summary of the regulatory authorities that have adopted the released NAPRA Model Standards and their implementation schedules, if applicable. Please note, that Alberta, Ontario and Manitoba have adopted the Model Standards through multi-year implementation phases.

Alberta

- Adopted Hazardous Sterile Model Standards: June 2016
- Adopted Non Hazardous Sterile Model Standards: December 2016
- Implementation (same for both):
    - Phase 1 by July 1, 2018
    - Phase 2 by January 1, 2019
    - Phase 3 has not yet been approved by Council
- Implementation phase details are below:

Phase 1 (July 1, 2018)	Phase 2 (January 1, 2019)	Phase 3 (timing not yet approved)
• Review NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations • Identify risk level (complexity, volume) of compounded sterile preparations • Perform a gap analysis by comparing the Model Standards with current pharmacy sterile compounding procedures and facilities • Prioritize the gap analysis and develop an action plan for compliance with the Model Standards • Initiate a quality assurance program • Verification of equipment, including PEC - Verification of controlled areas (clean room and anteroom) - Development of a written sampling plan for controlled areas according to specifications of a recognized standard, such as CETA	• Meet or exceed core requirements for a sterile compounding service - Personnel – both compounding personnel and cleaning personnel - Policies and procedures • Meet or exceed production preparation requirements - Compliance with beyond use dating and dating methods – including consideration of the requirements surrounding sterility and endotoxin testing - Compounded sterile preparation protocols - Compounded sterile preparation log - Patient file - Conduct of personnel in areas reserved for the compounding of sterile preparations - Aseptic compounding of non-hazardous sterile preparations – including but not limited to hand and forearm hygiene and garbing, cleaning and disinfection - Packaging - Storage	• Meet or exceed core requirements for a sterile compounding services - Facilities and equipment

applications guide CAG-002, CAG-003, or CAG-008	- Transport and delivery • Complete quality assurance program - Verification of equipment and facilities – certification and written sampling plan (Implementation Framework, step one) - Results and action levels - Quality assurance of personnel involved in aseptic compounding – Gloved fingertip sampling, media fill test - Quality assurance of compounded sterile preparations - Documentation of quality control activities	

Ontario

- Adopted Hazardous Sterile Model Standards: September 2016
- Adopted Non Hazardous Sterile Model Standards: September 2016
- Implementation (both): Everything by January 1, 2019

Nova Scotia

- Adopted both Hazardous Sterile and Non-Hazardous Sterile: November 2016
- No implementation schedule except for the following:
  - Standards 5.3 – Facilities and Equipment and 7.0 Quality Assurance Program: should a pharmacy identify that they are deficient in meeting this standard (either through a self-administered or external audit), the pharmacy should be provided with *6 months* [emphasis added] to address the deficiency because of the time to implement the changes.

Newfoundland and Labrador

- Adopted Hazardous Sterile Model Standards: February 2017
- Adopted Non Hazardous Sterile Model Standards: February 2016
- No implementation schedule.

Manitoba

- Adopted both Hazardous Sterile and Non-Hazardous Sterile: February 2017
- Implementation (both):
  - Phase 1 by June 1, 2018
  - Phase 2 by June 1, 2019
  - Phase 3 by January 1, 2021
- Implementation phase details are below:

Phase 1 (June 2018)	Phase 2 (June 2019)	Phase 3 (January 2021)
• 5.1 Develop and implement a training and assessment program for staff involved in non-hazardous sterile compounding. • 5.2 Develop and implement documented policies and procedures for non-hazardous sterile compounding • 6.2, 6.3, and 6.4 Develop and implement protocols and preparation logs for compounded sterile preparations. • 6.7, 6.8, 6.9, 6.12 Develop and implement protocols for non-hazardous medication packaging, storage, transport, waste management, and delivery procedures. • 6.10, 6.11 Develop recall procedures (traceability), and incident/accident management procedures. • 7. Develop and implement a quality assurance program for non-hazardous sterile compounding.	• 6.5, 6.6 Educate and validate all staff involved in non-hazardous sterile compounding (includes conduct of personnel in areas reserved for compounding, handwashing, garbing, aseptic compounding techniques, cleaning and disinfecting, verification, and labelling).	• 6.1 Establish documented beyond-use dates and dating methods. • 5.3 Facilities and Equipment

College of Pharmacists of British Columbia

Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

The College of Pharmacists of BC is interested in understanding the progress of pharmacy sites towards implementing the new Model Standards for sterile preparations (non-hazardous and hazardous).

For areas where you are not yet fully compliant, the College is hoping to learn what parts of the standards you are you are not yet compliant with. It will also be helpful for you to share any barriers you are facing in implementing the standards by May of 2021.

As a result, please use the comments field throughout the survey to provide this detail related to your progress in implementing the standards. If you do not have any comments to add, feel free to enter **"NA"**.

Learn more about the College's four-year implementation plan for pharmacies and pharmacy professionals to adopt the new Model Standards for pharmacy compounding.

Please complete the survey by August 3, 2020.

Saving Survey Responses

We encourage you to complete this survey in one session.

However, if you are unable to complete the survey your responses will be saved to your current computer or device. To access your saved responses you ***must use the original computer or device you started the survey with***.

Acknowledgement

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Learn more about our Privacy Policy at: https://www.bcpharmacists.org/privacy

College of Pharmacists
of British Columbia

Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

*** Pharmacy name:**

*** What Health Authority is your pharmacy within?**

College of Pharmacists
of British Columbia

Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

Does your pharmacy compound:

* non-hazardous sterile preparations?

- Yes
- No

* hazardous sterile preparations?

- Yes
- No

College of Pharmacists
of British Columbia

Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

Standards Under Phase 1 (Non-Hazardous Sterile Preparations)

Please indicate the current status of your pharmacy's compliance with the standards for compounding of non-hazardous sterile preparations through the questions below.

* **Standards under 6.3 (compounded sterile preparation log)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.4 (patient file)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.5 (personnel)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.6 (aseptic compounding of sterile preparations)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.7 (packaging)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.8 (storage)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.9 (transport and delivery of compounded sterile preparations)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.10 (recall of sterile products of final compounded sterile preparations)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

College of Pharmacists of British Columbia

Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

Standards Under Phase 2 (Non-Hazardous Sterile Preparations)

Please indicate the current status of your pharmacy's compliance with the standards for compounding of non-hazardous sterile preparations through the questions below.

* **Standards under 5.1 (personnel)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 5.2 (policies and procedures)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 5.4 (maintenance log)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.2 (compounded sterile preparations protocols)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

College of Pharmacists of British Columbia

Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

Standards Under Phase 3 (Non-Hazardous Sterile Preparations)

Please indicate the current status of your pharmacy's compliance with the standards for compounding of non-hazardous sterile preparations through the questions below.

* **Standards under 6.1 (beyond-use date)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.11 (incident and accident management)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.12 (waste management)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.1 (program content)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.2 (results and action levels)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.3 (verification of equipment and facilities)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.4 (quality assurance of personnel)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.5 (quality assurance of compounded sterile preparation)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.6 (documentation of quality control activities)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

College of Pharmacists of British Columbia

Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

Standards Under Phase 4 (Non-Hazardous Sterile Preparations)

Please indicate the current status of your pharmacy's compliance with the standards for compounding of non-hazardous sterile preparations through the questions below.

* **Standards under 5.3 (facilities and equipment)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

College of Pharmacists of British Columbia

Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

Non-Hazardous Sterile Preparations

Please answer the following questions for compounding of non-hazardous sterile preparations.

*** Are you expecting to be compliant with the NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations by May 2021?**

- ◯ Yes
- ◯ No. Please specify what your anticipated timeline for compliance is. (MM/DD/YYYY)

* Comments:

*** How many prescriptions for non-hazardous sterile preparations does your pharmacy typically compound in a month?**

Please enter an approximate number

Comments:

*** How frequently does your pharmacy compound non-hazardous sterile preparations?**

- ◯ Daily
- ◯ Weekly
- ◯ Monthly

Comments:

College of Pharmacists of British Columbia

Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

Standards Under Phase 1 (Hazardous Sterile Preparations)

Please indicate the current status of your pharmacy's compliance with the standards for compounding of hazardous sterile preparations through the questions below.

* **Standards under 6.3 (compounded sterile preparation log)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.4 (patient file)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.5 (personnel)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.6 (aseptic compounding of sterile preparations)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.7 (packaging)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.8 (storage)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.9 (transport and delivery of compounded sterile preparations)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.10 (recall of sterile products of final compounded sterile preparations)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

College of Pharmacists of British Columbia

Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

Standards Under Phase 2 (Hazardous Sterile Preparations)

Please indicate the current status of your pharmacy's compliance with the standards for compounding of hazardous sterile preparations through the questions below.

* **Standards under 5.1 (personnel)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 5.2 (policies and procedures)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 5.4 (maintenance log)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.2 (compounded sterile preparations protocols)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

College of Pharmacists of British Columbia

Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

Standards Under Phase 3 (Hazardous Sterile Preparations)

Please indicate the current status of your pharmacy's compliance with the standards for compounding of hazardous sterile preparations through the questions below.

* **Standards under 6.1 (beyond-use date)**

Percent complete

0% 50% 100%

* Please explain what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.11 (incident and accident management)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.12 (waste management)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.1 (program content)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.2 (results and action levels)**

Percent complete

0% 50% 100%

* Please explain what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.3 (verification of equipment and facilities)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.4 (quality assurance of personnel)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.5 (quality assurance of compounded sterile preparation)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.6 (documentation of quality control activities)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

College of Pharmacists of British Columbia

Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

Standards Under Phase 4 (Hazardous Sterile Preparations)

Please indicate the current status of your pharmacy's compliance with the standards for compounding of hazardous sterile preparations through the questions below.

* **Standards under 5.3 (facilities and equipment)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

College of Pharmacists of British Columbia

Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

Hazardous Sterile Preparations

Please answer the following questions for compounding of hazardous sterile preparations.

* **Are you expecting to be compliant with the NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations by May 2021?**

- ◯ Yes
- ◯ No. Please specify what your anticipated timeline for compliance is. (MM/DD/YYYY)

* Comments:

*** How many prescriptions for hazardous sterile preparations does your pharmacy typically compound in a month?**

Please enter an approximate number

Comments:

*** How frequently does your pharmacy compound hazardous sterile preparations?**

- Daily
- Weekly
- Monthly

Comments:

College of Pharmacists of British Columbia

Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

*** What percentage of your pharmacy's compounding is prepared by:**

Pharmacists	
Pharmacy technicians	
Non-regulated health professionals (e.g. pharmacy assistants)	

Are there any additional comments or considerations you would like to share about your pharmacy's implementation of the Model Standards?

College of Pharmacists of British Columbia

Community Pharmacies: Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

The College of Pharmacists of BC is interested in understanding the progress of pharmacy sites towards implementing the new Model Standards for sterile preparations (non-hazardous and hazardous).

For areas where you are not yet fully compliant, the College is hoping to learn what parts of the standards you are you are not yet compliant with. It will also be helpful for you to share any barriers you are facing in implementing the standards by May of 2021.

As a result, please use the comments field throughout the survey to provide this detail related to your progress in implementing the standards. If you do not have any comments to add, feel free to enter **"NA"**.

Learn more about the College's four-year implementation plan for pharmacies and pharmacy professionals to adopt the new Model Standards for pharmacy compounding.

Please complete the survey by August 11, 2020.

Saving Survey Responses

We encourage you to complete this survey in one session.

However, if you are unable to complete the survey your responses will be saved to your current computer or device. To access your saved responses you ***must use the original computer or device you started the survey with***.

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College of Pharmacists of British Columbia

Community Pharmacies: Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

* **Pharmacy name:**

* **Pharmacy licence number:**

* **City the Pharmacy is Located in:**

College of Pharmacists of British Columbia

Community Pharmacies: Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

Does your pharmacy compound:

* non-hazardous sterile preparations?

- ◯ Yes
- ◯ No

* hazardous sterile preparations?

- ◯ Yes
- ◯ No

College of Pharmacists of British Columbia

Community Pharmacies: Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

Standards Under Phase 1 (Non-Hazardous Sterile Preparations)

Please indicate the current status of your pharmacy's compliance with the standards for compounding of non-hazardous sterile preparations through the questions below.

* **Standards under 6.3 (compounded sterile preparation log)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.4 (patient file)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.5 (personnel)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.6 (aseptic compounding of sterile preparations)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.7 (packaging)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.8 (storage)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.9 (transport and delivery of compounded sterile preparations)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.10 (recall of sterile products of final compounded sterile preparations)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

College of Pharmacists of British Columbia

Community Pharmacies: Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

Standards Under Phase 2 (Non-Hazardous Sterile Preparations)

Please indicate the current status of your pharmacy's compliance with the standards for compounding of non-hazardous sterile preparations through the questions below.

* **Standards under 5.1 (personnel)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 5.2 (policies and procedures)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 5.4 (maintenance log)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.2 (compounded sterile preparations protocols)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

College of Pharmacists of British Columbia

Community Pharmacies: Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

Standards Under Phase 3 (Non-Hazardous Sterile Preparations)

Please indicate the current status of your pharmacy's compliance with the standards for compounding of non-hazardous sterile preparations through the questions below.

* **Standards under 6.1 (beyond-use date)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.11 (incident and accident management)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.12 (waste management)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.1 (program content)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.2 (results and action levels)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.3 (verification of equipment and facilities)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.4 (quality assurance of personnel)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.5 (quality assurance of compounded sterile preparation)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.6 (documentation of quality control activities)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

College of Pharmacists of British Columbia

Community Pharmacies:
Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

Standards Under Phase 4 (Non-Hazardous Sterile Preparations)

Please indicate the current status of your pharmacy's compliance with the standards for compounding of non-hazardous sterile preparations through the questions below.

* **Standards under 5.3 (facilities and equipment)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

College of Pharmacists of British Columbia

Community Pharmacies: Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

Non-Hazardous Sterile Preparations

Please answer the following questions for compounding of non-hazardous sterile preparations.

*** Are you expecting to be compliant with the NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations by May 2021?**

- ◯ Yes
- ◯ No. Please specify what your anticipated timeline for compliance is. (MM/DD/YYYY)

* Comments:

* **How many prescriptions for non-hazardous sterile preparations does your pharmacy typically compound in a month?**

Please enter an approximate number

Comments:

* **How frequently does your pharmacy compound non-hazardous sterile preparations?**

- ◯ Daily
- ◯ Weekly
- ◯ Monthly

Comments:

College of Pharmacists of British Columbia

Community Pharmacies: Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

Standards Under Phase 1 (Hazardous Sterile Preparations)

Please indicate the current status of your pharmacy's compliance with the standards for compounding of hazardous sterile preparations through the questions below.

* **Standards under 6.3 (compounded sterile preparation log)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.4 (patient file)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.5 (personnel)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.6 (aseptic compounding of sterile preparations)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.7 (packaging)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.8 (storage)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.9 (transport and delivery of compounded sterile preparations)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.10 (recall of sterile products of final compounded sterile preparations)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

College of Pharmacists of British Columbia

Community Pharmacies:
Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

Standards Under Phase 2 (Hazardous Sterile Preparations)

Please indicate the current status of your pharmacy's compliance with the standards for compounding of hazardous sterile preparations through the questions below.

* **Standards under 5.1 (personnel)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 5.2 (policies and procedures)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 5.4 (maintenance log)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.2 (compounded sterile preparations protocols)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

College of Pharmacists of British Columbia

Community Pharmacies:
Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

Standards Under Phase 3 (Hazardous Sterile Preparations)

Please indicate the current status of your pharmacy's compliance with the standards for compounding of hazardous sterile preparations through the questions below.

* **Standards under 6.1 (beyond-use date)**
Percent complete

0% 50% 100%

* Please explain what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.11 (incident and accident management)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 6.12 (waste management)**
Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.1 (program content)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.2 (results and action levels)**

Percent complete

0% 50% 100%

* Please explain what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.3 (verification of equipment and facilities)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.4 (quality assurance of personnel)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.5 (quality assurance of compounded sterile preparation)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

* **Standards under 7.6 (documentation of quality control activities)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

College of Pharmacists of British Columbia

Community Pharmacies: Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

Standards Under Phase 4 (Hazardous Sterile Preparations)

Please indicate the current status of your pharmacy's compliance with the standards for compounding of hazardous sterile preparations through the questions below.

* **Standards under 5.3 (facilities and equipment)**

Percent complete

0% 50% 100%

* Please indicate what requirements within this standard you are not compliant with, and any barriers you face in implementation.

College of Pharmacists of British Columbia

Community Pharmacies: Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

Hazardous Sterile Preparations

Please answer the following questions for compounding of hazardous sterile preparations.

*** Are you expecting to be compliant with the NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations by May 2021?**

- ◯ Yes
- ◯ No. Please specify what your anticipated timeline for compliance is. (MM/DD/YYYY)

* Comments:

*** How many prescriptions for hazardous sterile preparations does your pharmacy typically compound in a month?**

Please enter an approximate number

Comments:

*** How frequently does your pharmacy compound hazardous sterile preparations?**

- ◯ Daily
- ◯ Weekly
- ◯ Monthly

Comments:

College of Pharmacists of British Columbia

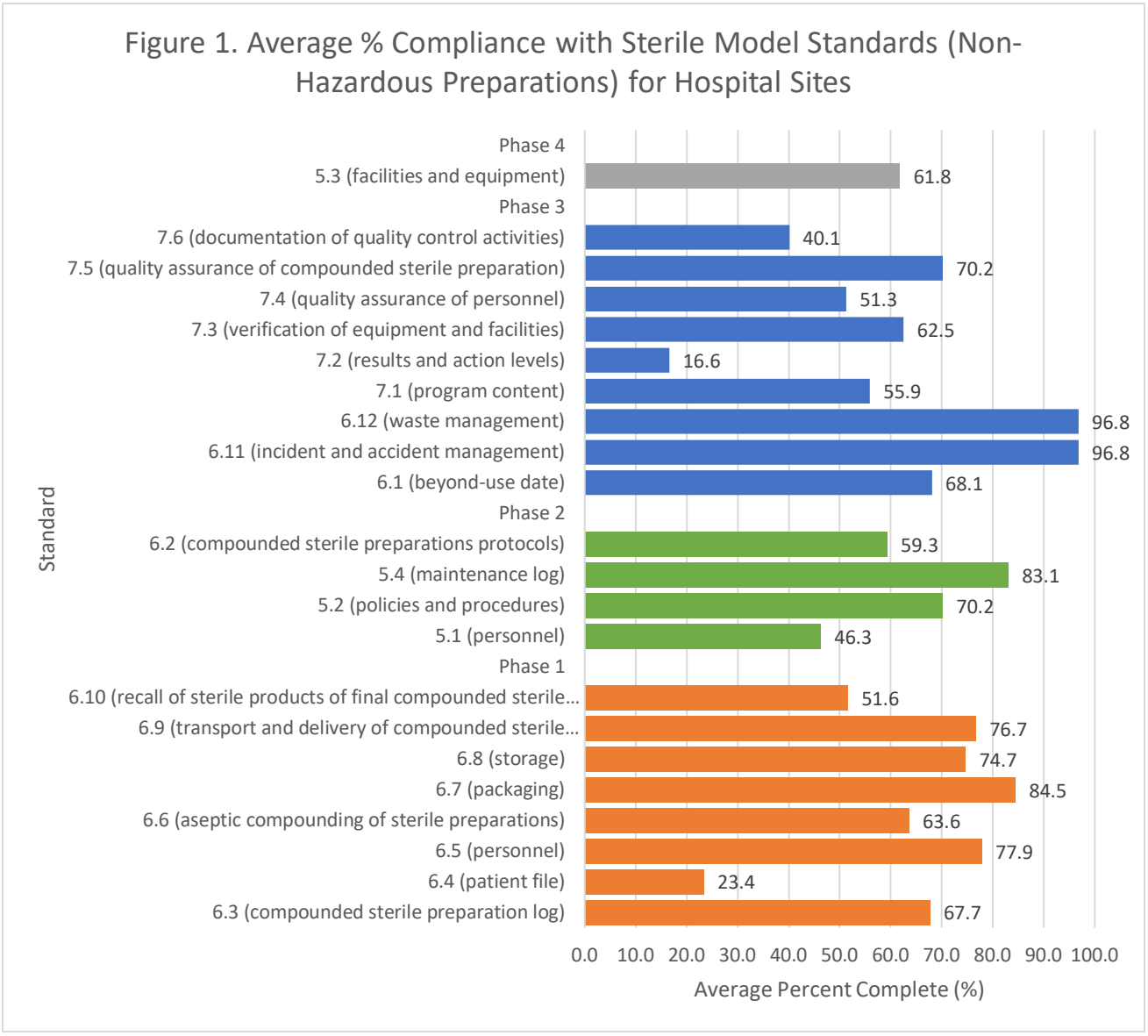
Community Pharmacies: Progress on Implementation of the NAPRA Model Standards for Sterile Preparations (Non-Hazardous and Hazardous)

*** What percentage of your pharmacy's compounding is prepared by:**

Pharmacists	
Pharmacy technicians	
Non-regulated health professionals (e.g. pharmacy assistants)	

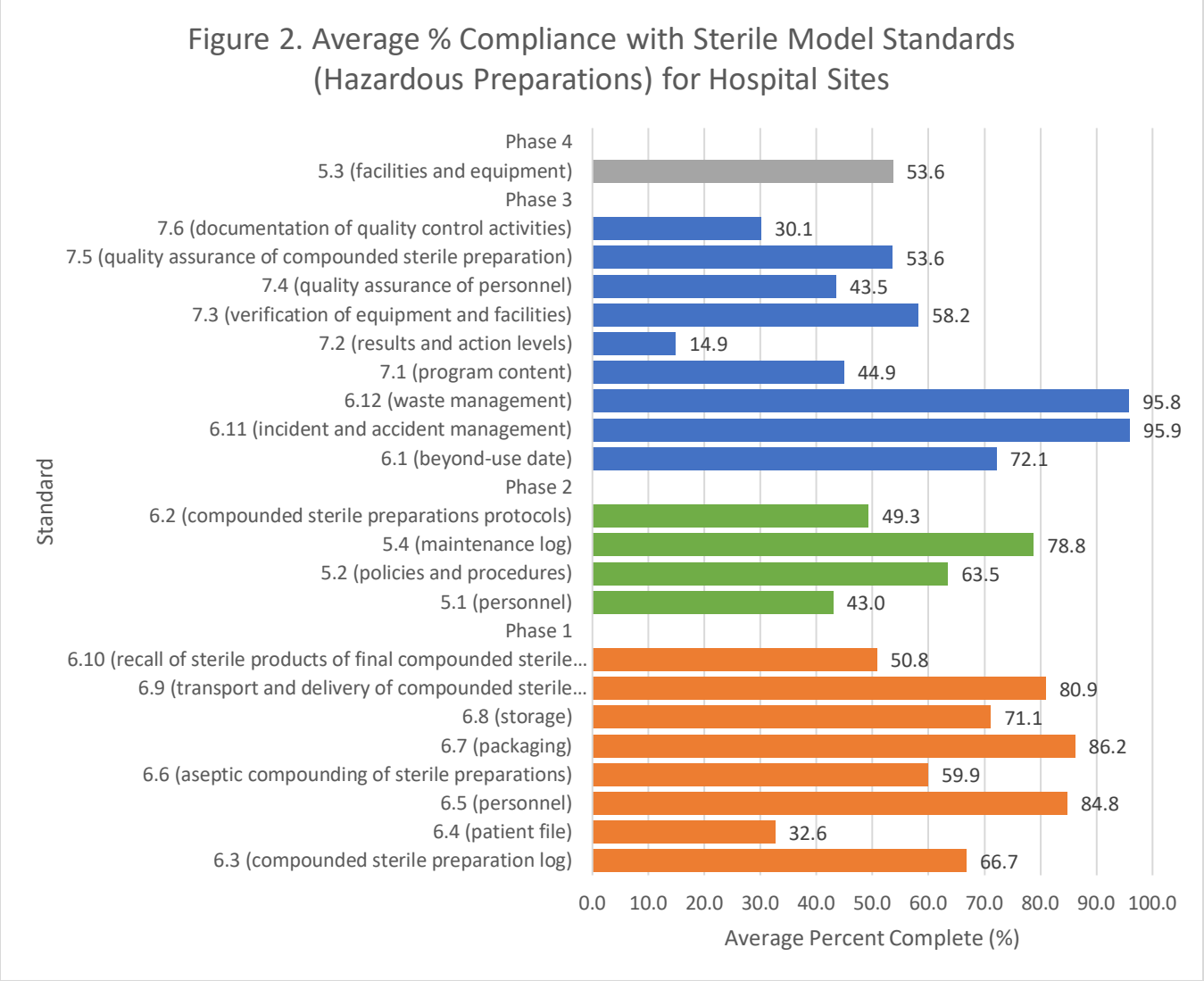
Are there any additional comments or considerations you would like to share about your pharmacy's implementation of the Model Standards?

Average % Compliance with Sterile Model Standards (Non-Hazardous Preparations) – Hospital Sites



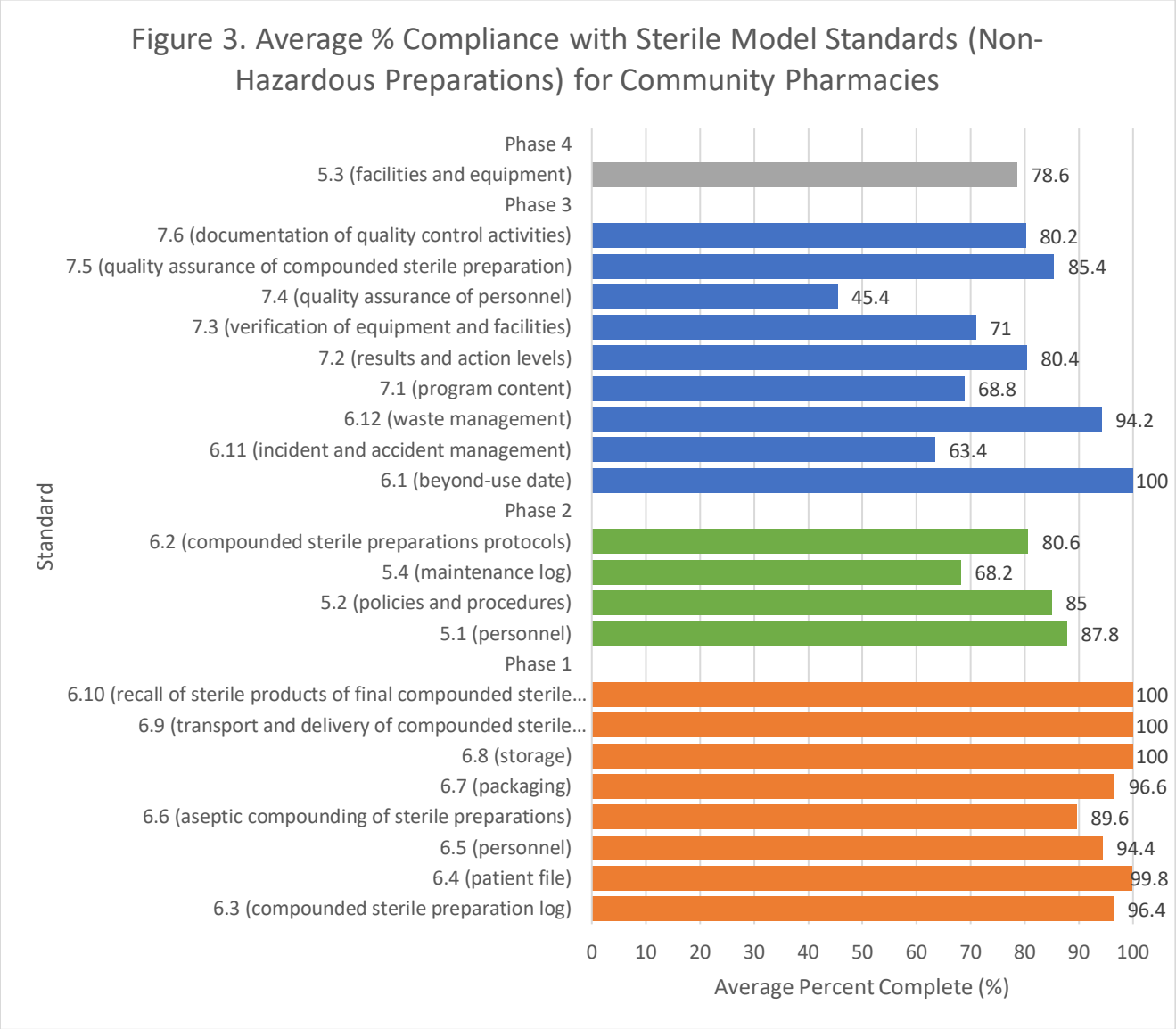
APPENDIX 4

Average % Compliance with Sterile Model Standards (Hazardous Preparations) – Hospital Sites



APPENDIX 4

Average % Compliance with Sterile Model Standards (Non-Hazardous Preparations) – Community Pharmacy



APPENDIX 5

August 12th 2020

Bob Nakagawa, Registrar
College of Pharmacists of B.C.

Dear Bob,

I am writing on behalf of hospitals within the consolidated Pharmacy Departments within the Health Authorities in the Lower Mainland (Fraser Health, Vancouver Coastal Health, Providence Health and the Provincial Health Services) to provide an update on our progress towards NAPRA compliance standards and to request an extension to the May 2021 deadline as outlined below.

Lower Mainland Pharmacy Services (LMPS) has made significant strides to ensure we have made every possible effort to meet the NAPRA standards as set out by the College of Pharmacists of BC (CPBC). We will also be working between now and the current May 2021 deadline to ensure we are as close as possible to meeting the majority of operational requirements to ensure compliance. We fully support the standards and believe the standards will ensure that the safety of the patient is maintained throughout the compounding process.

In terms of Facility compliance, the majority of our sites have undergone upgrades or in the process of being upgraded. One site, Powell River General Hospital has just undergone a feasibility study and is waiting for the final costing before moving forward with the renovations. Four sites within Fraser health are still waiting to be upgraded. Two of these sites, Burnaby and Royal Columbian have funding earmarked for a controlled clean room. These upgrades will come as part of the redevelopment of each of these facilities. As these redevelopment projects are not scheduled to be completed until at least 2025, these sites will not be compliant until this time. The remaining two sites, Eagle Ridge and Peace Arch Hospitals have not had the capital funding approved to proceed with the necessary upgrades. COVID – 19 has significantly increased the costs estimates to complete these projects and it is not known at this time, when the funding will be approved by the Fraser Health Capital Steering committee.

The challenge before us in becoming fully compliant with NAPRA is the increased requirements for more funding – either capital or human resource. With respect to capital, in addition to capital for facility upgrades, funding for equipment, verification software and camera systems is still required. We are currently evaluating which sites will require this equipment and which sites will utilize direct observation. For direct observation sites, this will require increased staffing dollars and a budget ask will go forward in the fall as part of the annual budget process.

The impact of COVID-19 cannot be underestimated. In addition to increasing construction costs, it has caused a delay in working toward meeting the NAPRA standards, especially in regards to direct observation/equipment requirements.

For the Lower Mainland, I would ask the College to consider the following:

- For facility compliance, the College considers a longer deadline to meet the necessary standards due to the ability to secure capital funding and redevelopment timelines.
- The College considers the impact COVID-19 has had on meeting the timelines for compliance, and considers pushing back the deadline into early 2022 to allow further work to be completed by the Health Authorities.

Thank you for considering this request and we would like to assure you that our goal will be to achieve compliance as soon as possible.

Sincerely,

Bruce Millin, BSc (Pharm), ACPR, FCSHP
Executive Director, Lower Mainland Pharmacy Services
supporting a consolidated Pharmacy Service in
Fraser Health | Providence Health Care | Provincial Health Services Authority | Vancouver Coastal Health

Interior Health
Every person matters

Aug. 11, 2020

Bob Nakagawa, Registrar
College of Pharmacists of BC

Dear Bob,

I am writing on behalf of Interior Health (IH) Pharmacy Services to provide an update on our progress towards NAPRA compliance standards and to request an extension to the May 2021 deadline as outlined below. Interior Health currently has 10 hospitals that compound hazardous and non-hazardous sterile products.

Since 2016 IH Pharmacy Services has taken steps to ensure we've made every possible effort to meet the NAPRA compliance deadline as set out by the College of Pharmacists of BC (CPBC). We have secured the necessary funding to upgrade the 9 IH hospital pharmacies that will continue to provide sterile compounding services for our patients moving forward. One of our hospital pharmacy sites (100 Mile House) will be ceasing sterile compounding activities and have product shipped from a nearby hospital. Two of our hospital pharmacies have their sterile compounding facilities tied in to major site building projects that we are certain will not meet the May 2021 deadline. Cariboo Memorial Hospital is building a new hospital that is expected to be completed in October, 2023. Royal Inland Hospital in building a new patient care tower and the HVAC system for the new pharmacy sterile compounding facility needs to be tied in to that tower. Expected completion for the pharmacy to be fully compliant is April 2022, but there is a chance the non-hazardous sterile compounding area may be ready as early as October 2021. 100 Mile House will be receiving sterile product from one or both of these two hospitals moving forward. The other 7 hospital pharmacy sterile compounding facilities are complete or expected to be complete by May 2021 assuming no construction delays. There is of course uncertainty of the impacts of COVID-19 through fall and winter of 2020-21.

With respect to equipment we have secured funding for the required verification software and camera system and do not anticipate any concerns with appropriate segregation of hazardous and non-hazardous products by having dedicated pharmacy grade fridges. We are expecting to have operational funding approved in the fall for staffing resources for the sterile compounding supervisors and pharmacy technicians, service fees for the verification system, and supplies such as sterile alcohol, sporicidal, and chemical cartridge respirators.

We do have some concerns about the implementation pieces of the operational components even once the funding is secured. The uncertainty about the impact of COVID-19 through the fall and winter of 2020-21, the fact that pharmacy technicians are difficult to fill positions and we are already sitting with staff vacancies.

For Interior Health our request is as follows:

- For facility compliance, we are requesting an extension to October 2023 for Cariboo Memorial Hospital, an extension to April 2022 for Royal Inland Hospital (and therefore 100 Mile House), and a 6 month extension to October 2021 if needed for all other sites.
- For operational compliance a 6 month extension to October 2021 for all sites if needed.

Thank you for considering our request and we would like to assure you that our goal will be to achieve compliance ahead of these requested extensions.

Sincerely,

Dawn Robb, BSc (Pharm), ACPR, MALH, RPh

Program Director, Pharmacy Services

Interior Health

3rd Floor, 505 Doyle Avenue

Kelowna, BC V1Y 0C5

Office (250) 469-7070 ext. 12255

Cell: 778-214-0624

northern health
the northern way of caring

Pharmacy Administration
#404-299 Victoria St
Prince George, BC V2L 5B8
Ph: 250.614-9530

August 11, 2020

Bob Nakagawa, Registrar
College of Pharmacists of BC

Dear Bob,

I am writing on behalf of Northern Health (NH) Pharmacy Services to provide an update on our progress towards NAPRA compliance standards and to request an extension to the May 2021 deadline as outlined below. Northern Health currently has 3 hospitals that compound hazardous sterile products only and 6 that compound both non-hazardous and hazardous sterile products as well.

NH Pharmacy Services has been moving forward to ensure we have made every possible effort to meet the NAPRA standards as set out by the College of Pharmacists of BC (CPBC). We have identified the capital renovation requirements and have secured the necessary funding to upgrade 7 of the 9 NH hospital pharmacies. Two of our hospital pharmacies have their sterile compounding facilities tied in to major site building projects that will not meet the May 2021 deadline. Mills Memorial Hospital (Terrace) is in an active design phase for a new facility set to open in August 2024, therefore a capital renovation to that facility has not been planned for this reason. Dawson Creek and District Hospital (Dawson Creek) is in the active planning for a new facility and so plans for renovation in that facility have been deferred. Planning is underway to provide compounded products from Fort St John if necessary, until the new build is complete.

As a result of COVID-19, there have been delays with capital projects, as health authority staff were diverted to emergency response issues, and contractors and designers experienced limitations in travel, etc. Of the 7 facilities planning a renovation, it is expected that GR Baker Hospital (Quesnel), St John Hospital (Vanderhoof), Fort St John Hospital and Haida Gwaii Hospital (Queen Charlotte) will meet the deadline of May 2021. Bulkley Valley District Hospital (Smithers) and Prince Rupert Regional Hospital (Prince Rupert) are planned to be complete by May 2021, but may experience delays and these projects are currently approximately 4-5 months behind target. The University Hospital of Northern BC (UHNBC) (Prince George) is still in active planning for a renovation due to significant space restrictions and the need to wait for renovations to complete at BC Cancer Centre for the North and other NH sites, and will not be complete by May 2021. We anticipate it would be winter of 2021 at the earliest before UHNBC renovation would be complete.

With respect to equipment, we are continuing to evaluate the available options for verification software and camera systems and do not yet have capital funding secured for this purchase. We are continuing to evaluate the budgetary impact of full compliance with the standards and will be bringing forward an operational funding proposal in the fall for staffing resources for the sterile compounding technicians, service fees for the verification system, and supplies such as sterile alcohol, sporicidal, and chemical cartridge respirators. Even with funding, we have significant concerns about the ability to implement all of the operational components, specifically technician staffing as recruitment continues to be a challenge at many of our facilities in NH. The uncertainty about the impact of COVID-19 through the fall and winter of 2020-21 will add to this.

For Northern Health our request is as follows:

- For facility compliance, we are requesting an extension to August 2024 for Mills Memorial Hospital, an extension to March 2022 for University Hospital of Northern British Columbia, and a 6 month extension to October 2021 if needed for all other sites.
- For operational compliance, a 6 month extension to October 2021 if needed.

Thank you for considering our request and we would like to assure you that our goal will be to achieve compliance ahead of these requested extensions.

Sincerely,

Dana Cole, BSc. Pharm, ACPR, PharmD
Regional Director, Pharmacy Services
Northern Health Authority

Cc:
Cathy Ulrich, CEO
Ronald Chapman, VP Medicine
Mark De Croos, VP, Finance/Chief Financial Officer

Cross-Jurisdictional Scan on the Adoption of the Sterile Model Standards

Below is a summary of the pharmacy regulatory authorities that have adopted the Sterile Model Standards and their implementation schedules, if applicable.

Alberta

- Adopted Hazardous Sterile Model Standards: June 2016
- Adopted Non Hazardous Sterile Model Standards: December 2016
- Implementation (same for both):
  - Phase 1 by July 1, 2018
  - Phase 2 by January 1, 2019
  - Phase 3 ~~July 1, 2020~~, extended to July 1, 2021 in light of the COVID-19 pandemic.
- Implementation phase details are below:

Phase 1 **(July 1, 2018)**	**Phase 2** **(January 1, 2019)**	**Phase 3** **~~(July 1, 2020)~~** extended to July 1, 2021 in light of the COVID-19 pandemic
• Review NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations • Identify risk level (complexity, volume) of compounded sterile preparations • Perform a gap analysis by comparing the Model Standards with current pharmacy sterile compounding procedures and facilities • Prioritize the gap analysis and develop an action plan for compliance with the Model Standards • Initiate a quality assurance program • Verification of equipment, including PEC – Verification of controlled areas (clean room and anteroom) – Development of a written sampling plan for controlled areas according to specifications of a recognized standard, such as CETA	• Meet or exceed core requirements for a sterile compounding service – Personnel – both compounding personnel and cleaning personnel – Policies and procedures • Meet or exceed production preparation requirements – Compliance with beyond use dating and dating methods – including consideration of the requirements surrounding sterility and endotoxin testing – Compounded sterile preparation protocols – Compounded sterile preparation log – Patient file – Conduct of personnel in areas reserved for the compounding of sterile preparations – Aseptic compounding of non-hazardous sterile preparations – including but not limited to hand and forearm hygiene and garbing, cleaning and disinfection – Packaging	• Meet or exceed core requirements for a sterile compounding services – Facilities and equipment

applications guide CAG-002, CAG-003, or CAG-008	– Storage – Transport and delivery • Complete quality assurance program – Verification of equipment and facilities – certification and written sampling plan (Implementation Framework, step one) – Results and action levels – Quality assurance of personnel involved in aseptic compounding – Gloved fingertip sampling, media fill test – Quality assurance of compounded sterile preparations – Documentation of quality control activities	

Ontario

- Adopted Hazardous Sterile Model Standards: September 2016
- Adopted Non Hazardous Sterile Model Standards: September 2016
- Implementation (both): Everything by January 1, 2019

Nova Scotia

- Adopted both Hazardous Sterile and Non-Hazardous Sterile: November 2016
- No implementation schedule.

Newfoundland and Labrador

- Adopted Hazardous Sterile Model Standards: February 2017
- Adopted Non Hazardous Sterile Model Standards: February 2016
- No implementation schedule.

Manitoba

- Adopted both Hazardous Sterile and Non-Hazardous Sterile: February 2017
- Implementation (both):
  - Phase 1 by June 1, 2018
  - Phase 2 by June 1, 2019
  - Phase 3 by January 1, 2021
- Implementation phase details are below:

Phase 1 (June 2018)	Phase 2 (June 2019)	Phase 3 (January 2021)
• 5.1 Develop and implement a training and assessment program for staff involved in non-hazardous sterile compounding. • 5.2 Develop and implement documented policies and procedures for non-hazardous sterile compounding • 6.2, 6.3, and 6.4 Develop and implement protocols and preparation logs for compounded sterile preparations. • 6.7, 6.8, 6.9, 6.12 Develop and implement protocols for non-hazardous medication packaging, storage, transport, waste management, and delivery procedures. • 6.10, 6.11 Develop recall procedures (traceability), and incident/accident management procedures. • 7. Develop and implement a quality assurance program for non-hazardous sterile compounding.	• 6.5, 6.6 Educate and validate all staff involved in non-hazardous sterile compounding (includes conduct of personnel in areas reserved for compounding, handwashing, garbing, aseptic compounding techniques, cleaning and disinfecting, verification, and labelling).	• 6.1 Establish documented beyond-use dates and dating methods. • 5.3 Facilities and Equipment

Saskatchewan

- Adopted both Hazardous Sterile and Non-Hazardous Sterile: February 2019
- Implementation (both):
  - Phase 1 by September, 2020
  - Phase 2 by March 2021
  - Phase 3 by July 2021
  - Phase 4 by December 2021
- Implementation phase details are below:

Phase 1 (September 2020)	Phase 2 (March 2021)	Phase 3 (July 2021)	Phase 4 (December 2021)
• Facility and equipment compliance plan to be submitted to SCPP by Phase 1 deadline. Full compliance required by December 31, 2021. • 5.3 – Identify facility and equipment related gaps and develop a plan for compliance with the NAPRA Model Standards for Pharmacy Compounding of Hazardous/Non-hazardous Sterile Preparations • 6.1 – Begin reviewing existing beyond-use dates and dating methods. • 6.2, 6.3, 6.4 – Begin reviewing and revising existing compounding procedures and compounding records for all hazardous/non-hazardous sterile compounds to ensure compliance with NAPRA Model Standards for	• 5.2 – Develop and implement documented policies and procedures for all activities related to hazardous/non-hazardous sterile compounding • 5.4 – Develop and implement the use of a general maintenance log for recording certification and maintenance of the facility and all equipment • 6.7, 6.8, 6.9, 6.12 – Develop and implement policies and procedures for packaging, storage, transport, and waste management of hazardous/non-hazardous sterile preparations • 6.10, 6.11 – Develop and implement incident/accident management procedures • Completion of gap analysis SCPP audits to assess compliance	• 6.1 – Establish documented beyond-use dates and dating methods • 6.2, 6.3, 6.4 – Develop and implement procedures and compounding records for all hazardous/non-hazardous sterile compounds • Completion of gap analysis SCPP audits to assess compliance	• 5.3 – Facilities and equipment compliance with the NAPRA Model Standards for Hazardous and Non-Hazardous Sterile Compounding Standards • SCPP Site Audits to assess compliance with facilities and equipment requirements. *Ongoing audits to assess

Pharmacy Compounding of Hazardous and Non-hazardous Sterile Preparations • 5.1 – Develop and implement a training and assessment program for staff involved in sterile hazardous /non-hazardous compounding • 6.5,6.6 – Educate and validate all staff involved in hazardous/non-hazardous sterile compounding (includes conduct of personnel in areas reserved for compounding, handwashing, garbing, aseptic compounding techniques, cleaning and disinfecting, verification, and labelling) • 7 – Develop and implement a quality assurance program for hazardous/non-hazardous sterile compounding • Completion of gap analysis SCPP audits to assess compliance			

College of Pharmacists of British Columbia

BOARD MEETING
September 18, 2020

7. Legislation Review Committee
c) *Health Professions Act* Fee Amendments

DECISION REQUIRED

Recommended Board Motion:

Approve the following resolution:

RESOLVED THAT, in accordance with the authority established in section 19(1) of the Health Professions Act, and subject to filing with the Minister as required by section 19(3) of the Health Professions Act, the Board amend the bylaws of the College of Pharmacists of British Columbia to amend the Fee Schedule to operationalize the College's 2020/2021 budget, as set out in the schedule attached to this resolution.

Purpose

To approve amendments to the *Health Professions Act* ("HPA") Bylaws Schedule D – Fee Schedule in accordance with the College's 2020/2021 budget, as set out in the attached schedule to the resolution (Appendix 1).

Background

The Board may make bylaws as per section 19(1)(p) of the HPA to establish fees payable to the College by registrants. These fees must be consistent with the duties and objectives of the College.

Section 19(6.2) of the HPA exempts the establishment of HPA fees (amongst other bylaw making authorities) from the 90 day public posting period. Accordingly, if approved by the Board, these bylaws will be sent to the Ministry of Health for filing.

This package includes proposed bylaw amendments to actualize HPA fee increases previously approved as part of the College's 2020/2021 budget. At their February 2020 meeting, the Board approved the 2020/2021 budget, which included fee increases in order to meet the needs of the College.

In addition to the amended fee schedule (Appendix 2), corresponding revised forms have also been approved by the Registrar and do not require Board approval. These forms will also be sent to the Ministry of Health for filing.

Discussion

Originally, this package was on the agenda for the Board's consideration at their April meeting. However, at that April meeting, the Board directed the Registrar to review the impact of COVID-19 on the finances of the College before proceeding with operationalizing the fee increases approved in the 2020/21 budget.

As such, on August 20, 2020, the Audit and Finance Committee met to review the impact of the COVID-19 health pandemic on the 2020/21 budget. That Committee is recommending a fee increase, and this briefing package operationalizes that recommendation (see briefing materials for item five on today's agenda).

Guiding Question

A key question for the Board to consider is:

- Does the HPA fee amendment proposal effectively operationalize the Audit and Finance Committee's recommendation?

Recommendation

The Legislation Review Committee recommends that the Board approve the HPA Bylaws Schedule D – Fee Schedule for filing with the Ministry of Health, by approving the schedule to the resolution in Appendix 1.

Next Steps

Upon approval by the Board, the amended fee schedule will be submitted for filing with the Ministry of Health.

Appendix	
1	Schedule to the Resolution
2	Amended Fee Schedule (track changes)

SCHEDULE

The bylaws of the College of Pharmacists of British Columbia made under the authority of the *Health Professions Act* are amended by repealing and replacing Schedule D- Fee Schedule.

College of Pharmacists of B.C.		
FEE SCHEDULE		
HPA Bylaw "Schedule D"		
REGISTRATION FEES		
Pharmacist		
Application for Pre-registration	Valid for up to three years.	$ 428.00
Application for Reinstatement	Valid for up to three years.	$ 428.00
Full Pharmacist - registration	For a term of one year.	$ 778.00
Full Pharmacist - registration renewal	For a term of one year.	$ 778.00
Non-practising Pharmacist - registration	For a term of one year.	$ 778.00
Non-practising Pharmacist - registration renewal	For a term of one year.	$ 778.00
Limited Pharmacist - registration	For a term of one year. Maximum three one-year terms.	$ 778.00
Limited Pharmacist - renewal	Maximum two one-year renewal terms	$ 778.00
Temporary Pharmacist	Valid until cancelled by the registration committee or registrar.	$ 0.00
Temporary Limited Pharmacist	Valid until cancelled by the registration committee or registrar.	$ 0.00
Late registration renewal fee (≤90 days from renewal date).		$ 137.00
Student Pharmacist		
New Student Pharmacist (UBC)	Valid for one year.	$ 107.00
New Student Pharmacist (Non UBC)	Valid for one year.	$ 107.00
Registration Renewal (UBC)	Valid for one year.	$ 0.00
Temporary Student Pharmacist	Valid until cancelled by the registration committee or registrar.	$ 0.00
Pharmacy Technician		
Application for Pre-registration	Valid for up to three years.	$ 285.00
Application for Reinstatement	Valid for up to three years.	$ 285.00
Pharmacy Technician - registration	For a term of one year.	$ 518.00
Pharmacy Technician - registration renewal	For a term of one year.	$ 518.00
Non-practising Pharmacy Technician - registration	For a term of one year.	$ 518.00
Non-practising Pharmacy Technician - registration renewal	For a term of one year.	$ 518.00
Temporary Pharmacy Technician	Valid until cancelled by the registration committee or registrar.	$ 0.00
Late registration renewal fee (≤90 days from renewal date).		$ 137.00
Structured Practical Training Program	Valid for 6 months from application date.	$ 403.00
CERTIFICATION FOR INJECTION DRUG ADMINISTRATION		
Application for certification		$ 111.00
ADMINISTRATION FEES		
Replacement of registration certificate		$ 135.00
Certificate of standing		$ 135.00
Processing of non-sufficient funds (NSF) cheque		$ 135.00
Criminal Record Check (CRC)	See Criminal Record Check Fee Regulation BCReg238/2002 as amended	-
Jurisprudence Examination (JE)		$ 267.00

NOTES:

1) Fees are non-refundable nor transferable.

2) All fees except Criminal Record Check are subject to GST.

3) Annual registration renewal notices are sent at least thirty (30) days prior to expiry date.

4) Completion of registration forms may be required for items with $0.00 fee amounts.

SCHEDULE

The bylaws of the College of Pharmacists of British Columbia made under the authority of the *Health Professions Act* are amended by repealing and replacing the following Forms:

4A, 4B, 4C-1, 4C-2, 4C-3, 4C-4, 4C-5, 4-C6, 6A, 6B, 7A, 7B-2, 7B-3, 7B4, 7B-5, 8A, 8B, 10A, 10B, 10C, 10E, 10F, 11A, 11B, 11C, 11F, 11G, 13.

College of Pharmacists of B.C.
FEE SCHEDULE
HPA Bylaw "Schedule D"

REGISTRATION FEES

Pharmacist			
Application for Pre-registration	Valid for up to three years.	~~$ 407.00~~	$ 428.00
Application for Reinstatement	Valid for up to three years.	~~$ 407.00~~	$ 428.00
Full Pharmacist - registration	For a term of one year.	~~$ 739.00~~	$ 778.00
Full Pharmacist - registration renewal	For a term of one year.	~~$ 739.00~~	$ 778.00
Non-practising Pharmacist - registration	For a term of one year.	~~$ 739.00~~	$ 778.00
Non-practising Pharmacist - registration renewal	For a term of one year.	~~$ 739.00~~	$ 778.00
Limited Pharmacist - registration	For a term of one year. Maximum three one-year terms.	~~$ 739.00~~	$ 778.00
Limited Pharmacist - renewal	Maximum two one-year renewal terms	~~$ 739.00~~	$ 778.00
Temporary Pharmacist	~~Valid for up to 90 days; during an emergency situation only.~~ Valid until cancelled by the registration committee or registrar.	$ 0.00	$ 0.00
Temporary Limited Pharmacist	Valid until cancelled by the registration committee or registrar.	$ 0.00	$ 0.00
Late registration renewal fee (≤90 days from renewal date).		~~$ 130.00~~	$ 137.00
Student Pharmacist			
New Student Pharmacist (UBC)	Valid for one year.	~~$ 102.00~~	$ 107.00
New Student Pharmacist (Non UBC)	Valid for one year.	~~$ 102.00~~	$ 107.00
Registration Renewal (UBC)	Valid for one year.	$ 0.00	$ 0.00
~~Application for Reinstatement (UBC)~~	~~For reinstatement after 90 days of registration expiry; valid for one year.~~	~~$ 0.00~~	~~$ 0.00~~
Temporary Student Pharmacist	Valid until cancelled by the registration committee or registrar.	$ 0.00	$ 0.00
Pharmacy Technician			
Application for Pre-registration	Valid for up to three years.	~~$ 271.00~~	$ 285.00
Application for Reinstatement	Valid for up to three years.	~~$ 271.00~~	$ 285.00
Pharmacy Technician - registration	For a term of one year.	~~$ 492.00~~	$ 518.00
Pharmacy Technician - registration renewal	For a term of one year.	~~$ 492.00~~	$ 518.00
Non-practising Pharmacy Technician - registration	For a term of one year.	~~$ 492.00~~	$ 518.00
Non-practising Pharmacy Technician - registration renewal	For a term of one year.	~~$ 492.00~~	$ 518.00
Temporary Pharmacy Technician	~~Valid for up to 90 days; during an emergency situation only.~~ Valid until cancelled by the registration committee or registrar.	$ 0.00	$ 0.00
Late registration renewal fee (≤90 days from renewal date).		~~$ 130.00~~	$ 137.00
Structured Practical Training Program	Valid for 6 months from application date.	~~$ 383.00~~	$ 403.00

CERTIFICATION FOR INJECTION DRUG ADMINISTRATION

Application for certification		~~$ 105.00~~	$ 111.00

ADMINISTRATION FEES

Replacement of registration certificate		~~$ 128.00~~	$ 135.00
Certificate of standing		~~$ 128.00~~	$ 135.00
Processing of non-sufficient funds (NSF) cheque		~~$ 128.00~~	$ 135.00
Criminal Record Check (CRC)	See Criminal Record Check Fee Regulation BCReg238/2002 as amended	-	-
Jurisprudence Examination (JE)		~~$ 254.00~~	$ 267.00
~~Pharmacy Practice Manual (available free on website)~~		~~$ 281.00~~	-

NOTES:

1) Fees are non-refundable nor transferable.
2) All fees except Criminal Record Check are subject to GST.
3) Annual registration renewal notices are sent at least thirty (30) days prior to expiry date.
4) Completion of registration forms may be required for items with $0.00 fee amounts.

College of Pharmacists of British Columbia

BOARD MEETING
September 18, 2020

7. Legislation Review Committee
d) *Pharmacy Operations and Drug Scheduling Act* Fee Amendments

DECISION REQUIRED

Recommended Board Motion:

Approve the following resolution:

RESOLVED THAT, in accordance with the authority established in section 21(8) of the Pharmacy Operations and Drug Scheduling Act, the Board approve the proposed draft bylaws of the College of Pharmacists of British Columbia to amend the Fee Schedule to operationalize the College's 2020/2021 budget, for public posting, as circulated.

Purpose

To approve amendments to the *Pharmacy Operations and Drug Scheduling Act* ("PODSA") Bylaws Schedule A – Fee Schedule in accordance with the College's 2020/2021 budget.

Background

The Board may make bylaws as per section 21(1)(c.1) of PODSA regarding the information and fees that must be provided for the purpose of making an application to issue, renew or reinstate a pharmacy licence. Unlike the *Health Professions Act* ("HPA"), PODSA does not exempt particular bylaws (e.g. fee schedules) from the 90 day public posting period requirement.

The proposed PODSA fee schedule amendments needed to actualize the fee increases previously approved as part of the College's 2020/2021 budget are outlined in Appendix 1. At their February 2020 meeting, the Board approved the 2020/2021 budget which included fee increases in order to meet the needs of the College.

In addition to the amended fee schedule (Appendix 1), corresponding revised forms have also been approved by the Registrar. These forms do not require Board approval or filing with the Ministry of Health.

Discussion

Originally, this package was on the agenda for the Board's consideration at their April meeting. However, at their April meeting, the Board directed the Registrar to review the impact of COVID-19 on the finances of the College before proceeding with operationalizing the fee increases approved in the 2020/21 budget.

As such, on August 20, 2020, the Audit and Finance Committee met to review the impact of the COVID-19 health pandemic on the 2020/21 budget. That Committee is recommending a fee increase, and this briefing package operationalizes that recommendation (see briefing materials for item five on today's agenda).

Guiding Question

A key question for the Board to consider is:

- Does the PODSA fee amendment proposal effectively operationalize the Audit and Finance Committee's recommendation?

Recommendation

The Legislation Review Committee recommends that the Board approve the PODSA Bylaws Schedule A – Fee Schedule for public posting, as circulated.

Next Steps

Once the 90 public posting period is completed, pending review of any feedback received, the PODSA fee schedule will be brought to the Board at a future meeting for filing approval. It is anticipated that an extraordinary meeting will be established to seek filing approval.

Appendix	
1	Amended Fee Schedule (track changes)

College of Pharmacists of B.C.
FEE SCHEDULE
PODSA Bylaw "Schedule A"

~~PHARMACY~~ LICENSURE FEES

~~LICENSURE FEES~~ PHARMACY APPLICATIONS

Community Pharmacy Licence	Annual licence fee.	~~$ 2,345.00~~	$ 2,474.00
Hospital Pharmacy Licence	Annual licence fee.	~~$ 2,345.00~~	$ 2,474.00
Pharmacy Education Site Licence	Annual licence fee.	~~$ 750.00~~	$ 791.00
Telepharmacy	Annual licence fee.	~~$ 2,345.00~~	$ 2,474.00
Hospital Pharmacy Satellite	Annual fee for each satellite site, to be charged to Hospital Pharmacy.	~~$ 750.00~~	$ 791.00
Application for New Pharmacy Licence (Community, Hospital and Telepharmacy)	Application valid for up to three years. Includes change of ownership.	~~$ 750.00~~	$ 791.00
Reinstatement of Pharmacy Licence	For reinstatement of a pharmacy licence that has been expired for 90 days or less.	~~$ 750.00~~	$ 791.00
Change of direct owner	Annual licence fee + application for new pharmacy	~~$ 3,095.00~~	$ 3,265.00
Change of indirect owner		$ 0.00	$ 0.00
Change of manager		$ 0.00	$ 0.00
Change in corporation name		$ 0.00	$ 0.00
Change in operating name of the pharmacy		$ 0.00	$ 0.00
Change in location of the pharmacy		~~$ 750.00~~	$ 791.00
Change in layout of the pharmacy		$ 0.00	$ 0.00
Criminal Record History (CRH)	*Fee charged by Sterling ~~Talent Solutions (formerly known as~~ BackCheck)	$ -	$ -

OTHER FEES

~~INSPECTION FEE~~

Inspection Fee: Follow-up site review(s)	Where 3 or more site reviews are required to address deficiencies. From visit 3 onwards, this fee applies for each additional visit.	~~$ 1,020.00~~	$ 1,076.00
Administrative Fee			$ 137.00

NOTES:

1) Fees are non-refundable.

2) Fees are subject to GST.

3) Annual renewal notices of pharmacy licensure are sent at leas t sixty (60) days prior to the expiry date.

College of Pharmacists of British Columbia

7. Legislation Review Committee

Justin Thind

Chair, Legislation Review Committee

College of Pharmacists of British Columbia

7 a) Removal of Natural Health Products from the *Drug Schedules Regulation*

College of Pharmacists of British Columbia

Purpose of Presentation

- To seek approval to remove natural health products (NHPs) from the *Drug Schedules Regulation* under the *Pharmacy Operations and Drug Scheduling Act* (PODSA) to align with the National Drug Schedules.

College of Pharmacists of British Columbia

Background – Drug Scheduling in Canada

- Health Canada determines whether a drug must be sold by prescription or may be sold over the counter.
- Provincial regulatory authorities (PRAs) can further restrict the conditions of sale of “non-prescription” products.
- For non-prescription products, PRAs typically follow the National Association of Pharmacy Regulatory Authorities’ (NAPRA’s) National Drug Schedules.
- Many PRAs schedule by reference to the National Drug Schedules.

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Background – National Drug Schedules

- The National Drug Schedules Advisory Committee recommends appropriate placement of non-prescription products in the National Drug Schedules.
- The National Drug Schedules follows a three schedule national model:
  - Schedule I – prescription required for sale
  - Schedule II – non-prescription, not available for self-selection (i.e. behind the counter)
  - Schedule III – non-prescription, available for self-selection when a pharmacist is available to assist

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Background – BC's *Drug Schedule Regulation*

- The Board has the legislative authority to amend the *Drug Schedules Regulation* as per section 22 of PODSA:

  Regulations of the board

  22 (1) Subject to the Food and Drugs Act (Canada), the board, by regulation, may make drug schedules specifying the terms and conditions of sale for drugs and devices.

  (2) A regulation under subsection (1) must be filed with the minister.

- BC is one of the few provinces in Canada that maintains its own list of schedules drugs and does not schedule by reference to the National Drug Schedules.
- However, most amendments to the *Drug Schedules Regulation* are based on recommendations from NAPRA.

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Background – BC's *Drug Schedule Regulation*

- BC's scheduling model is similar to the National Drug Schedules:
  - Schedule I – prescription required for sale
  - Schedule IA – prescription required for sale (controlled prescription program)
  - Schedule II – non-prescription, not available for self-selection (i.e. behind the counter)
  - Schedule III – non-prescription, available for self-selection when a pharmacist is available to assist
  - Schedule IV – drugs which may be prescribed by a pharmacist

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NHPs

- NHPs are naturally occurring substances that are "often made from plants, but can also be made from animals, microorganisms and marine sources,"[1] and are available in a variety of formulations.
- Before 2004, NHPs were sold as either drugs or food under the *Food and Drugs Act* because there was no other category under which to classify them.[2]
- In 2004, NHPs became subject to federal regulation under the *Natural Health Products Regulation* (NHPR).
- The NHPR requires all NHPs sold in Canada to be licensed by Health Canada.

1. https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/regulation/about-products.html
2. https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/frequently-asked-questions/general-questions-regulation.html

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NHPs and the National Drug Schedules

- NAPRA does not typically schedule NHPs on the National Drug Schedules.
- Some products listed on the National Drug Schedules became *reclassified* as NHPs after the NHPR came into effect.
- NAPRA agreed to keep this subset of NHPs on the National Drug Schedules on an interim basis.

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NHPs and the National Drug Schedules, continued

- In 2019, NAPRA announced it would begin the process of removing this subset of NHPs from the National Drug Schedules. It stated:

> *"given that the interim measure initiated many years ago only addresses the risk of a small subset of NHPs while others are available to consumers without directed conditions of sale, NAPRA has determined that this disparate approach is no longer in the best interest of the public."*[3]

3. https://napra.ca/background-update-napra-nhp-policy

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NHPs and the National Drug Schedules, continued

NHP removals from the National Drug Schedules is occurring in two phases:

1. Effective January 2, 2020, the following were removed:
    - 34 unscheduled NHPs
    - 20 Schedule III NHPs
2. Effective January 2, 2022, the following are planned to be removed:
    - Schedule III NHPs containing ephedrine or pseudoephedrine
    - 33 Schedule II NHPs
    - 5 Schedule I NHPs

Also, 22 Schedule I and Schedule II NHPs will have their listings changed.

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NHPs and the *Drug Schedules Regulation*

- BC's *Drug Schedules Regulation* closely aligns with the National Drug Schedules. Both only contain a subset of NHPs.
- All Schedule I, II, and III NHPs that have been removed or will be removed from the National Drug Schedules, are listed on BC's *Drug Schedules Regulation.*
- Consideration should be given to removing NHPs from the *Drug Schedules Regulation*.

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Jurisdictional Scan

- Most other Canadian jurisdictions schedule by reference to the National Drug Schedules.[4]
- Some jurisdictions make exceptions to the National Drug Schedules, though none have deviated from NAPRA's approach.
- Newfoundland & Labrador has their own provincial drug schedule, and has not deviated from NAPRA's approach.

4. https://napra.ca/implementation-national-drug-schedules

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Considerations

- The College considered independently assessing the benefits and risks of removing each NHP from the *Drug Schedules Regulation.*
- This could lead to a misalignment with many other Canadian jurisdictions, as none have pursued this option.
- There is also a potential lack of information: the information required for NHP licensing is quite different than what is required for drug scheduling decisions.

College of Pharmacists of British Columbia

Considerations, continued

- The College will collaborate with stakeholders, including NAPRA and other pharmacy regulators to determine how to best assess risk moving forward.
- NAPRA is collaborating with Health Canada and other stakeholders to achieve an approach for the sale of NHPs in Canada, from a public safety perspective.

College of Pharmacists of British Columbia

Recommendation

- Direct the Registrar to remove NHPs from the *Drug Schedules Regulation* in a step-wise manner to align with the removal of NHPs from the National Drug Schedules.
- This recommendation is consistent with NAPRA's policy decision, and consistent with the approaches of other Canadian jurisdictions.

College of Pharmacists of British Columbia

Next Steps

- At the present time, amendments to the *Drug Schedules Regulation* are subject to a temporary bylaw moratorium, as announced in December 2019 by the Ministry of Health.
- If approved by the Board, the College will proceed with removing NHPs from the *Drug Schedules Regulation* to align with their removal from the National Drug Schedules, as soon as the moratorium is lifted.
- As the College moves forward with the step-wise process, the Board will be presented with recommended motions to remove or amend the NHP listings, accordingly.

College of Pharmacists of British Columbia

7 a) Removal of Natural Health Products from the *Drug Schedules Regulation*

MOTION:

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.

College of Pharmacists of British Columbia

Questions

College of Pharmacists of British Columbia

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

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What is Compounding?

- Compounding in respect to a drug, is defined as mixing together 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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Compounding Incidents

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 cocktails came in were overfilled, diluting the concentration of the cancer-fighting drugs by as much as 20 per cent.

New England Compounding Centre

- 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.
- In 2019, the former supervising pharmacist of the New England Compounding Centre was sentenced in this case. An appeal in relation to this case was not granted by a United States federal court.

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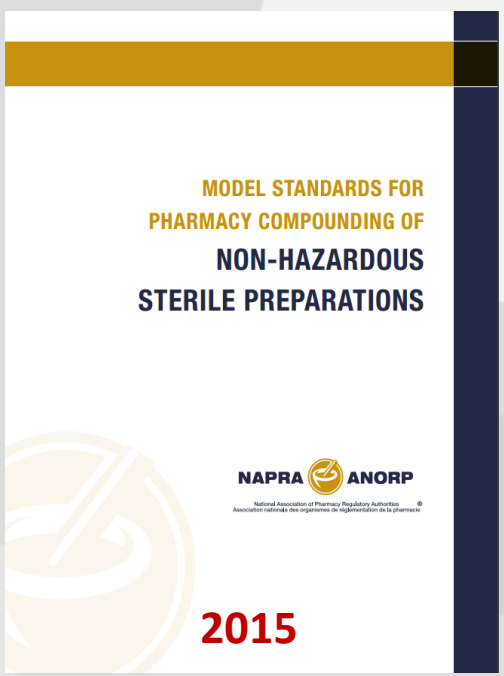
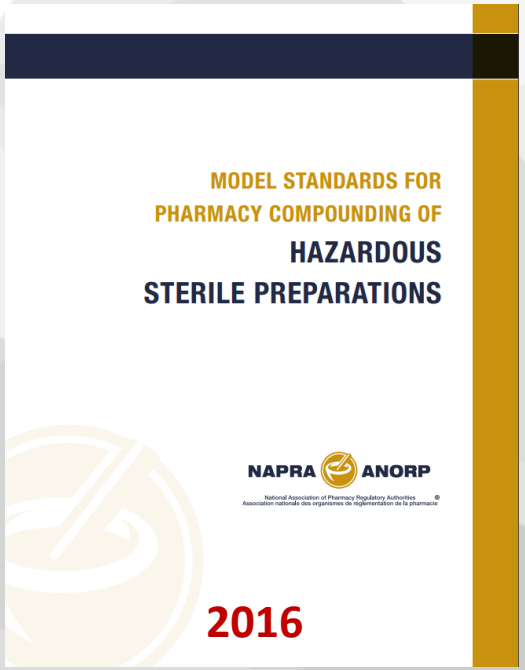
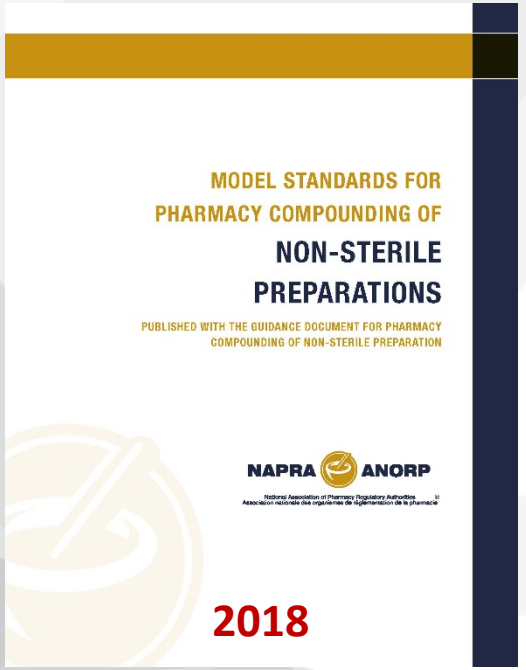
New NAPRA Model Standards for Compounding







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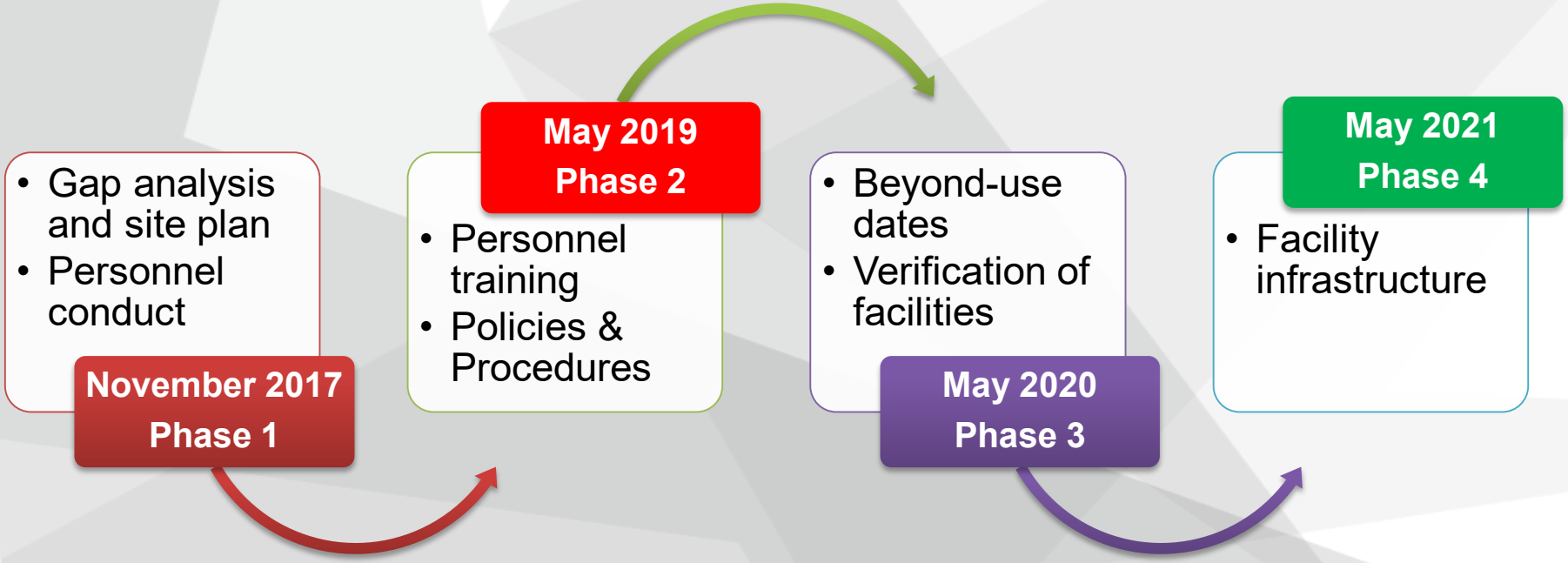
CPBC Implementation of the Sterile Model Standards



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Recent Consultation on Pharmacy Implementation of the Sterile Model Standards

- Consultation with pharmacies to assess their readiness in implementing the Sterile Model Standards was initially planned for April 2020.
- As a result of the COVID-19 pandemic, policy and legislation changes that were not related to address COVID-19 were temporarily paused.

College of Pharmacists of British Columbia

Survey

- In June 2020, pharmacies were surveyed to understand their compliance with the Sterile Model Standards.
- The survey was sent to 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 was sent to those identified community pharmacies.

College of Pharmacists of British Columbia

Survey Questions

The survey included questions on:

- Compliance with each standard under the four-phases in the implementation plan.
- Barriers being faced in complying with the Sterile Model Standards.
- If compliance will be achieved by May 2021. And if not, the date that compliance will be achieved.
- 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).

College of Pharmacists of British Columbia

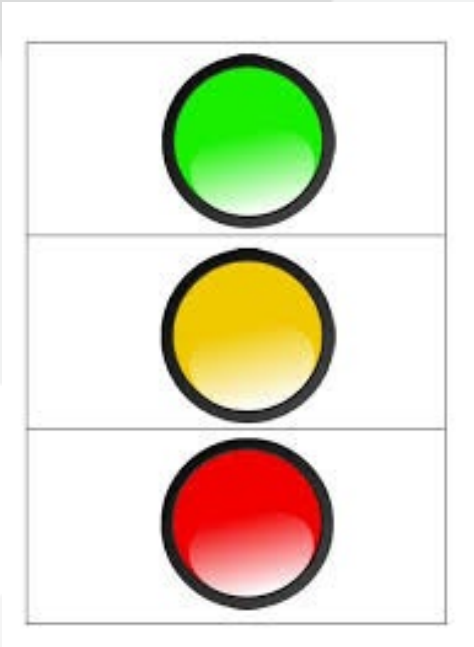
Survey Results

- Each health authority submitted survey results:
  - 57 hospital sites submitted responses.
- The survey was completed by 7 community pharmacies. This is almost half (about 47%) of the community pharmacies identified as preparing sterile non-hazardous compounds and/or hazardous compounds.
- The results indicate that both hospital sites and community pharmacies are progressing towards compliance with the Sterile Model Standards.

College of Pharmacists of British Columbia

Summary of Survey Results for Hospital Sites

- Of the 57 surveys received from hospital sites, 84% of sites *will not* be compliant with the Sterile Model Standards by May 2021.



- 8 sites expect to be fully compliant by May 2021.

- 32 sites expect to be fully compliant by July 2022.
- 14 sites have an interim plan (i.e., source from another site or operate with a segregated compounding area), until they can be fully compliant.

- 3 sites are planning for pharmacy sites, and do not expect to be fully compliant until 2024-2025.

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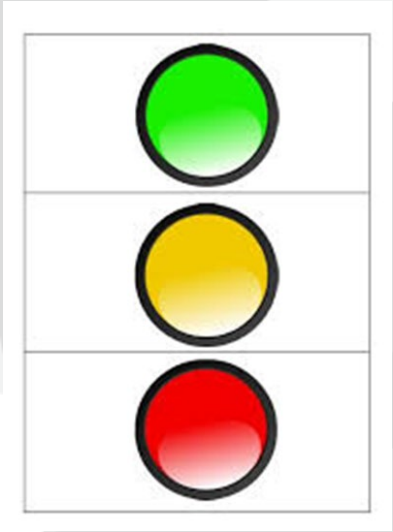
Summary of Survey Results for Community Pharmacies

- Of the 7 surveys received from community pharmacies, only 1 site will not be compliant by May 2021.



- 4 sites expect to be compliant by May 2021
- 1 site expects to be compliant by July 2022
- 2 sites will no longer compound sterile preparations.

College of Pharmacists of British Columbia

Barriers Identified in Implementing Sterile Model Standards by May 2021

- A range of barriers were identified; however, hospital sites typically cited COVID-19 as a key reason why they cannot meet the May 2021 deadline. For instance:
  - Responding to COVID-19 has created delays in working toward meeting the Sterile Model Standards, especially in regard to staffing, construction costs and equipment requirements.
  - Uncertainty about the impact of COVID-19 through the fall and winter of 2020-21 may further delay the implementation of operational components (i.e., staffing).

College of Pharmacists of British Columbia

Adoption of NAPRA Model Standards Across Canada

- To date, three provincial pharmacy regulatory authorities have already adopted the Sterile Model Standards:
  - Ontario
  - Nova Scotia and,
  - Newfoundland and Labrador
- Alberta, Manitoba and Saskatchewan still have active implementation plans, set to end in 2021.
- Alberta extended its implementation timeline by one year, due to COVID-19. This extension will end in July 2021.

College of Pharmacists of British Columbia

Options for the Board's Consideration

- **Option 1:** Extend the May 2021 Deadline to July 1, 2022.

- **Option 2:** Continue with the May 2021 Deadline (previously approved).

College of Pharmacists of British Columbia

Recommendation

- The Legislation Review Committee recommends that the Board proceed with Option 1: Extend the May 2021 deadline to July 1, 2022.
- This option recognizes the compliance date identified by the majority of hospital sites.
- There 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.

College of Pharmacists of British Columbia

Next Steps

- If Option 1 is approved, College staff will:
  - Draft bylaws to adopt the Model Standards, effective for July 1, 2022.
  - Communicate the one-time extension to registrants, health authorities and the public.
  - Update the dedicated webpage on the College's website.
  - Continue to work with pharmacy sites, to further encourage and clarify their level of compliance.

College of Pharmacists of British Columbia

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

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.

College of Pharmacists of British Columbia

Questions

College of Pharmacists of British Columbia

7 c) *Health Professions Act* Fee Amendments

College of Pharmacists of British Columbia

Previous Board Decision

February 2020 Board Meeting

- The Board approved the 2020/21 budget, which included fee increases in order to meet the needs of the College.

April 2020 Board Meeting

- The proposed HPA fee schedule changes, were deferred by the Board as a result of the COVID-19 public health emergency.
- The Board directed the Registrar to review the impact of COVID-19 on the finances of the College before proceeding with the fee increases.

College of Pharmacists of British Columbia

HPA Fee Changes

- On August 20, 2020, the Audit and Finance Committee reviewed the impact of COVID-19 on the 2020/21 budget, and recommend fee increases (presented in item 5 on today's agenda).
- Amendments to the HPA Bylaws Fee Schedule are required, to implement those fee increases.
- HPA fee changes are not required to be publicly posted.
- If approved by the Board, the bylaws will be sent to the Ministry of Health for filing (60 day period).
- After the filing period, the HPA fee changes will take effect. This will occur in November 2020.

College of Pharmacists of British Columbia

7 c) *Health Professions Act* Fee Amendments

MOTION :

Approve the following resolution:

RESOLVED THAT, in accordance with the authority established in section 19(1) of the Health Professions Act, and subject to filing with the Minister as required by section 19(3) of the Health Professions Act, the Board amend the bylaws of the College of Pharmacists of British Columbia to amend the Fee Schedule to operationalize the College's 2020/2021 budget, as set out in the schedule attached to this resolution.

College of Pharmacists of British Columbia

Questions

College of Pharmacists of British Columbia

7 d) *Pharmacy Operations and Drug Scheduling Act* Fee Amendments

College of Pharmacists of British Columbia

Previous Board Decision

February 2020 Board Meeting

- The Board approved the 2020/21 budget, which included fee increases in order to meet the needs of the College.

April 2020 Board Meeting

- The proposed PODSA fee schedule changes, were deferred by the Board as a result of the COVID-19 public health emergency.
- The Board directed the Registrar to review the impact of COVID-19 on the finances of the College before proceeding with the fee increases.

College of Pharmacists of British Columbia

PODSA Fee Changes

- On August 20, 2020, the Audit and Finance Committee reviewed the impact of COVID-19 on the 2020/21 budget, and recommend fee increases (presented in item 4 on today's agenda).
- Amendments to the PODSA Bylaws Fee Schedule are required, to implement the fee increases.
- PODSA fee changes are required to be publicly posted (90 day period).

College of Pharmacists of British Columbia

PODSA Fee Changes

- If approved by the Board, the PODSA fee changes:
  - Will be publicly posted (90 day period). Any comments received will be reviewed.
  - Will be brought forward to the Board for approval for filing with the Ministry of Health, at a future meeting.
- Once the filing period (60 days) is completed, the PODSA fee changes will take effect (tentatively, April 2021).

College of Pharmacists of British Columbia

7 d) *Pharmacy Operations and Drug Scheduling Act* Fee Amendments

MOTION :

Approve the following resolution:

RESOLVED THAT, in accordance with the authority established in section 21(8) of the Pharmacy Operations and Drug Scheduling Act, the Board approve the proposed draft bylaws of the College of Pharmacists of British Columbia to amend the Fee Schedule to operationalize the College's 2020/2021 budget, for public posting, as circulated.

College of Pharmacists of British Columbia

Questions

College of Pharmacists of British Columbia

BOARD MEETING
September 18, 2020

8. Practice Review Committee: Practice Review Program Annual Report

INFORMATION ONLY

Purpose

To present the Board with the Practice Review Program ("PRP") Annual Report for the 2019-2020 Fiscal Year (March 1, 2019 to February 29, 2020).

Background

The PRP is a comprehensive cyclical review of pharmacies and pharmacy professionals completed to ensure the standards of the College of Pharmacists of British Columbia ("CPBC") are met. The PRP was launched in 2015 based on the direction of the CPBC Board to replace previous pharmacy inspections and assessment programs for pharmacy professionals. The goal of this change was to develop an in-person, comprehensive and holistic review program that enhanced patient safety through collaboration between pharmacies, pharmacy professionals, and the CPBC while focusing on compliance with current standards of practice.

The Practice Review Program is split into two components; the Pharmacy Review and the Pharmacy Professionals Review. The Pharmacy Review focuses on the legislated physical requirements of a pharmacy and the responsibilities of a pharmacy manager. The Pharmacy Professionals Review focuses on areas identified and approved by the Board as having the greatest impact on patient safety including patient identification verification, profile check, counselling, documentation, product distribution and collaboration.

A Practice Review is a 3-step process completed over a 2-3-month period which includes an online pre-review questionnaire, an on-site review, and post visit follow-up documentation. Throughout the process, Compliance Officers (COs) work with pharmacies and pharmacy professionals to educate and support them as needed, ultimately ensuring CPBC standards are understood and being met. Upon completion of the practice review, action items are assigned to pharmacies and pharmacy professionals to address areas of non-compliance. A 30-day time window is given to complete these action items which are reviewed and approved by COs. Once action items are completed, the pharmacy and pharmacy professionals are reviewed again in the next cycle. Pharmacies and pharmacy professionals can be referred to the Inquiry Committee in instances where action items are not corrected, and non-compliance is not addressed.

For the 2019-2020 fiscal year, 279 community and 13 hospital pharmacy sites were reviewed. In addition, 666 community pharmacists, 77 community pharmacy technicians, 241 hospital pharmacists, and 200 hospital pharmacy technicians were reviewed.

College of Pharmacists of British Columbia

BOARD MEETING
September 18, 2020

Overall results of the practice review process have been positive, with average compliance percentages of 93% for community and 87% for hospital pharmacies before any corrective action items were completed. In the case where issues of non-compliance were identified, corrective actions were taken either during the on-site visit or in subsequent follow-up activities.

Once a practice review is completed, pharmacy professionals are invited to participate in an optional and anonymous online survey which measures the agreement rating of respondents to their PRP experience and its processes. For the 2019-2020 fiscal year, 28% of community and 30% of hospital pharmacy professionals completed the survey. Overall, feedback received in the Practice Review Survey was overwhelmingly positive with an average agreement rating of 90.47%.

For the complete data and feedback survey responses from community and hospital pharmacy practice reviews for the 2019-2020 fiscal year, see Appendix 1.

Appendix	
1	Practice Review Program Annual Report 2019-2020

College of Pharmacists
of British Columbia

Practice Review Program

Annual Report

2019 - 2020

Table of Contents

Executive Summary

Supporting the College of Pharmacists of British Columbia (CPBC) vision and mission as well as the provincial Health Professions Act quality assurance requirement, the Practice Review Program (PRP) was launched in 2015. The goal of the PRP is to ensure that British Columbians receive safe pharmaceutical care based on consistent implementation of legislated standards of practice. To support this goal, pharmacies and pharmacy professionals in BC undergo practice reviews in a cyclical manner. Feedback on the practice review process is gathered from pharmacy professionals through a voluntary Practice Review Survey.

Compliance Officers (COs) work in collaboration with pharmacy professionals throughout the practice review process to ensure pharmacies and pharmacy professionals are in full compliance with the CPBC standards of practice. Upon review completion, all non-compliance items identified during the on-site visit are resolved. All pharmacies and pharmacy professionals reviewed in 2019-2020 are in full compliance with the standards of the CPBC.

Once a practice review is completed, pharmacy professionals are invited to participate in an optional and anonymous online survey. For the 2019-2020 fiscal year, 28% of community and 30% of hospital pharmacy professionals completed the survey.

Overall results of the practice review process have been positive, with average compliance percentages of 93% for community and 87% for hospital pharmacies before any corrective action items were completed. In the case where issues of non-compliance were identified, corrective actions were taken either during the on-site visit or in subsequent follow-up activities.

Overall, feedback received in the Practice Review Survey was overwhelmingly positive with an average agreement rating of 90.47% and an average impact score of +1.85, taking into consideration all categories and practice settings. Agreement ratings measure the agreement of respondents to the PRP experience and its processes. Impact scores are measured on a scale of -5 to +5, with positive impact scores representing a positive impact, and negative impact scores representing a negative impact on pharmacy practice and patient safety.

While the majority of more qualitative commentary provided by respondents was very complementary of the PRP and its COs, areas for enhancing the program's quality and delivery

were also offered. From an enhancement perspective, some respondents suggested: improving the information technology tools supporting the program's delivery and reporting, increasing the focus on specialty practice areas and services, and providing more frequent follow-up to maintain ongoing compliance.

By listening to pharmacy professionals through its feedback process, the PRP is able to improve the execution of practice reviews, allowing pharmacy professionals to focus on the goal of the practice review; to improve compliance with established bylaws and policies as a proxy of patient safety.

Pharmacy professionals often identify areas of non-compliance in their pharmacy on their own through awareness created by *PRP Insights* articles, discussion with colleagues, and CPBC communications. The presence of the PRP helps promote compliance in pharmacies indirectly as many pharmacy professionals opt to correct these issues as soon as possible instead of waiting until a CO visits. This pre-emptive self-correction brings pharmacies into compliance sooner and reduces the amount of corrective work that must be completed by pharmacy managers within 30 days after a practice review.

Despite positive results, the PRP will continue to identify and shift focus towards addressing areas of low compliance and high patient-safety risk, make improvements to the review process to improve its effectiveness, and remain a pillar of support for pharmacies to improve their compliance and ability to provide safe and effective pharmacy care in BC.

Introduction

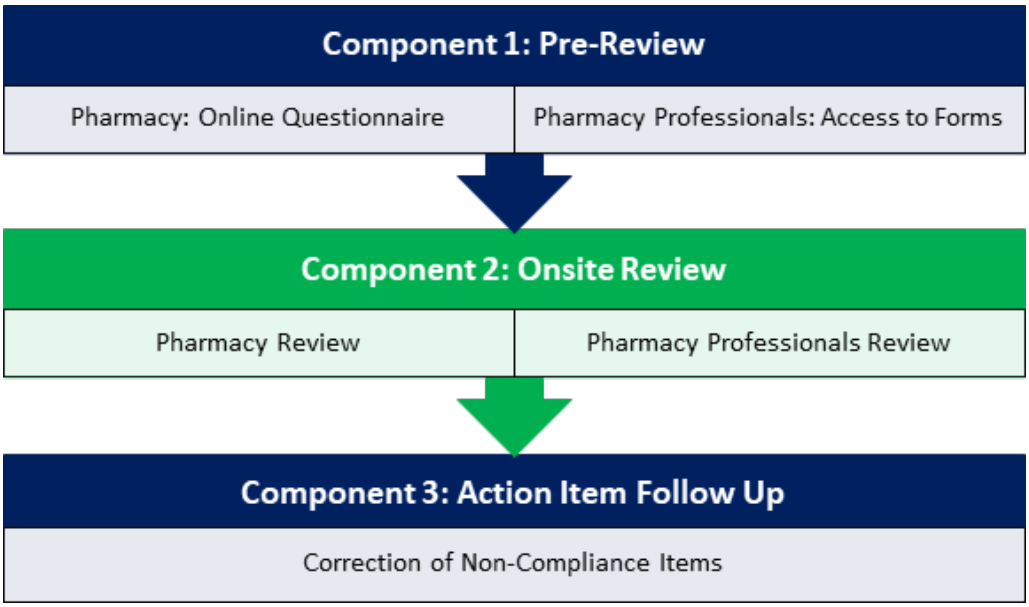
The Practice Review Program (PRP) conducts a comprehensive cyclical review of pharmacy and pharmacy professional (pharmacists and pharmacy technicians) practice, to ensure compliance with the standards of the College of Pharmacists of British Columbia. The PRP directly supports the CPBC vision of *better health through excellence in pharmacy,* as well as the mission of *regulating the pharmacy profession in the public interest by setting and enforcing standards and promoting best practices for the delivery of pharmacy care in British Columbia.* In addition, the provincial Health Professions Act requires that health regulators have quality assurance requirements in place. The PRP meets this requirement through assessment of professional practice. The PRP also uses a Practice Review Survey to evaluate the PRP's impact on pharmacy professionals and to inform ongoing program development. This report is a compilation and analysis of the data collected from practice reviews and the Practice Review Survey during fiscal year 2019-2020 (March 1, 2019 to February 29, 2020).

Background

The PRP was launched in 2015 with the support of the CPBC Board and in collaboration with the Practice Review Committee (PRC). The goal of this program was to have an in-person, comprehensive, and holistic review that enhanced collaboration between pharmacies, pharmacy professionals, and the CPBC to ensure British Columbians received safe pharmaceutical care based on consistent implementation of legislated standards of practice. Practice reviews were launched in community practice in February 2015, hospital practice in April 2017 and residential care in April 2019.

The practice review process consists of three components; pre-review preparation and scheduling, an on-site review by a compliance officer, and the completion of corrective action items. A detailed description of the entire practice review process is presented in Appendix A.

Components of a Practice Review



The review procedure includes reviewing pharmacies and pharmacy professionals approximately every 6 years with more frequent reviews in cases where concerns are identified. The cyclical nature of practice reviews ensures that all 1400+ pharmacies and 7700+ pharmacy professionals in British Columbia are regularly reviewed and in adherence to CPBC standards of practice .

Data Collection and Analysis

Practice Review Data

Site Selection and Statistics

Community pharmacies selected for practice reviews are identified and classified as either cycle-based or risk-based. Hospital pharmacies are selected for practice reviews in a cycle-based manner due to a lack of available risk data.

Pharmacies identified as cycle-based are selected and prioritized by the last date of inspection. Pharmacies identified as risk-based include new pharmacies that have not yet been reviewed or are referred from the CPBC complaints department.

For the fiscal year 2019-2020, 279 community and 13 hospital pharmacy sites were reviewed. A full breakdown of community and hospital pharmacy site statistics is presented in Appendix B.

Pharmacy Review

Community pharmacies are evaluated on 12 mandatory and four non-mandatory categories for sites that provide sterile compounding, residential care, opioid agonist treatment, and/or injectable opioid agonist treatment. A minimum of 300 prescriptions over a range of dates are also reviewed at each site as part of the evaluation for the prescriptions category.

Hospital pharmacies are evaluated on 12 mandatory categories and five non-mandatory categories. The 5 non-mandatory categories are reviewed if the service is provided at the hospital pharmacy.

Each category is comprised of sub-items, each representing an equal weight. Overall, up to 516 items are reviewed in community pharmacies and up to 330 items examined in hospital pharmacies. Full review criteria forms, review categories, and item counts for practice reviews are presented in Appendix C.

Pharmacy Professionals Review

Pharmacy professionals are observed performing regular pharmacy duties and evaluated based on four review categories critical to safe and effective pharmacy practice and specific to their scope of practice. This year, 666 community pharmacists, 77 community pharmacy technicians, 241 hospital pharmacists, and 200 hospital pharmacy technicians were reviewed.

Pharmacists are evaluated on patient identification verification, profile check, counselling, and documentation. Pharmacy technicians are evaluated on patient identification verification, product distribution, collaboration, and documentation. Full pharmacy professional review statistics and review categories for 2019-2020 are presented in Appendix D.

When reviewing the results in this report, it is important to recognize that data collected via different collection methods are **not** directly comparable due to differences in the way non-compliance items are counted. For example, community practice review data are collected via the PRP's computer application, while hospital practice review data are recorded manually in an Excel-based spreadsheet.

For the purposes of this report, the top non-compliant practice categories and related non-compliant items are outlined in order of descending frequency of occurrence.

Registrant Feedback Survey

The intent of the practice review survey is to obtain pertinent, valuable, and timely feedback from pharmacy professionals on their personal experience with the practice review process. Feedback is used by the PRP to evaluate and inform ongoing program development.

Once a practice review is completed, reviewed pharmacy professionals receive an email invitation, followed by an email reminder 12 days later (Appendix E) to provide their feedback via an online Practice Review Survey hosted by SimpleSurvey. The survey takes approximately 15-20 min to complete. Participation is optional and anonymous. All data collected via this tool are stored on application servers in Canada and are protected by Canadian privacy laws.

Survey questions are divided into Pharmacy Review and Pharmacy Professionals Review components. To facilitate the exploration of a wide range of issues and topics, a variety of question types and formats are used to gather feedback from respondents. These include dichotomous (yes/no), 7-point Likert scale, impact ratings, and open-ended comments. A detailed explanation of each collection method and how collected data were processed is presented in Appendix F.

For 2019-2020, 700 community and 394 hospital pharmacy professionals received an invitation to participate in the Practice Review Survey. Of these, 28% or 198 community and 30% or 120 hospital pharmacy professionals completed the survey (Appendix G).

Overall, 24% or 68 of the 279 community pharmacy managers who were reviewed completed the survey. Another 15% or 2 of the 13 hospital pharmacy managers reviewed provided their survey responses.

The survey is a helpful tool to capture some voluntary qualitative commentary on the PRP's strengths and weaknesses. However, it is important to note that because of the non-compulsory and self-selecting nature of the feedback survey process, the findings only represent the viewpoints of those pharmacists and technicians who completed the survey. As such, the results should be regarded as a helpful but not fully representative look into the perspectives of pharmacy managers, and pharmacy professionals in BC. Despite this limitation, the survey provides a valuable mechanism for monitoring the evolving strengths and

weaknesses of PRP processes. We expect as further survey results are received, a more representative picture of PRP performance will emerge.

Findings

Practice Review Data

Community Pharmacy

*Note: All results are arranged in order of occurrence from **most to least frequent**.*

Community pharmacies play a key role in the healthcare of patients as a regular and accessible point of contact for health information as well as a record-keeper, manager, and supplier of a patient's medications.

Data from the previous two fiscal years showed very similar non-compliance findings year-over-year, both in terms of non-compliance categories and also average compliance percentages. This year, we saw the same top 5 non-compliance categories as the previous year with minor changes in ranking order. While this may change in future cycles when pharmacies are reviewed for a second time, for now, current consistency in non-compliance categories provides a relatively clear roadmap concerning which areas community pharmacies may need increased focus.

The top non-compliance categories for community pharmacies this year are listed below. A year-over-year comparison of results is provided in Appendix H. In addition, the top non-compliance items within each of these categories is further presented in Appendix I.

N = 516 items reviewed

Average Compliance Percentage per Community Pharmacy Prior to Action Item Completion
93.17%

2019-2020

1. **Prescriptions**
2. **Inventory Management**
3. **Pharmacy Manager Responsibilities**
4. **Equipment and References**
5. **Security**

Prescriptions

As the primary piece of documentation in pharmacy practice, prescriptions represent a critical piece of information and the starting point for providing medication to a patient. The accuracy and completeness of a prescription are paramount to ensuring an appropriate documentation trail is maintained for each and every medication dispensed.

Within the prescriptions category, fax prescription requirements, emergency refills, and missing documentation on prescription hard copies represented the primary areas of non-compliance. The top 5 non-compliance items in this category remained the same compared to last year.

Inventory Management

Along with providing clinical advice and services, pharmacies and pharmacy professionals play a key role in the supply of medications to the public. Appropriate inventory management represents a key responsibility in maintaining the integrity of the drug supply and avoiding disruptions that could affect the health of patients.

Expired products being found in the dispensary, and narcotic count procedures and documentation were the most common areas of non-compliance in this category.

Pharmacy Manager Responsibilities

Pharmacy managers play one of the most important roles in the operation of a pharmacy. From hiring and screening staff, to establishing policies and procedures, to ensuring

patient confidentiality is maintained, pharmacy managers are given tremendous responsibility to ensure their pharmacy is compliant with all legislated bylaws and requirements.

In the pharmacy manager responsibilities category, establishing policies and procedures including those for new electronic record keeping, developing quality management programs, and having all required pharmacy reference material were common areas where non-compliance was found.

Equipment and References

To ensure the safe storage and dispensing of medications as well as having appropriate access to current drug information, pharmacies are required to maintain updated references and have specific pieces of equipment in good working order in the pharmacy. This ensures pharmacies are equipped with all the tools necessary to provide safe and effective pharmacy care for their patients.

The most common issues in the equipment and references category included refrigerator temperature monitoring and recording, possessing a veterinary reference, and missing required pharmacy equipment.

Security

Ensuring the safety and security of the pharmacy and medications is a requirement for pharmacy professionals. Bylaws and rules are in place to ensure pharmacies have required security features and practices to prevent and deter theft and robbery. Drug diversion puts patients and the public at risk from improperly obtained medications flowing into the community and the potential for their inappropriate use.

In the security category, the most common areas of non-compliance included having required signage, using appropriate secure storage (i.e. metal safe, physical barriers), and the security camera system.

Community Pharmacy Professionals

*Note: All results are arranged in order of occurrence from **most to least frequent**.*

Community Pharmacists

Community pharmacists play a key role in managing the medications of their patients. They serve as an accessible health resource, review patient medications for drug therapy interactions, and liaise with other health professionals regarding patient care.

Comparing data over the past two fiscal years shows the top non-compliance categories ranking in the Community Pharmacist Review did not change; they are listed below. A year-over-year comparison of results is provided in Appendix H. The top non-compliance items within each category are presented in appendix J. Counselling remains the top non-compliance category in the community pharmacist review.

N = 85 items reviewed

2019 - 2020
1. Counselling
2. Documentation
3. Patient Identification Verification
4. PharmaNet Profile Check

Counselling

Pharmacist counselling helps patients understand important drug therapy issues such as how to use their medications, what to expect, and when to seek medical attention. Pharmacists also play an important role in non-prescription drug counselling by providing advice and recommendations to help patients treat minor ailments.

The counselling category revolved around missing required counselling points and failure to provide required prescription counselling as the most common non-compliance areas.

Documentation

Maintaining proper documentation is a critical part in ensuring the paper trail for any prescription dispensed is available, clear, and complete. This ensures a clear record is available and accountability is maintained to indicate the pharmacy professional(s) who completed a particular task during the dispensing of a prescription.

Missing documentation after performing an activity that requires documentation, and not updating allergy information on PharmaNet were the most common areas of non-compliance in the documentation category.

Patient Identification Verification

Verifying a patient's identity when providing any pharmacy service helps maintain patient confidentiality and safety by ensuring pharmacy professionals are providing health information and medication to the correct patient.

Common non-compliance areas in the patient identification verification category revolved around not viewing ID from an unknown patient, viewing only one piece of secondary ID from an unknown patient, or not taking reasonable steps to confirm a patient representative's identity before providing pharmacy services.

PharmaNet Profile Check

Pharmacists are responsible for reviewing and updating a patient's profile on their local system and the BC-wide PharmaNet drug information network when dispensing a prescription. This critical step ensures that all medications obtained at pharmacies in British Columbia are accounted for when evaluating a patient's medication history for potential drug therapy interactions or concerns.

In the PharmaNet category, not reviewing a patient's PharmaNet profile or local profile prior to dispensing a drug, and not taking action on drug therapy problems such as non-adherence to a drug regimen or therapeutic duplications were the most common areas of non-compliance.

Community Pharmacy Technicians

Pharmacy technicians play an important role in key production and technical functions in the pharmacy. They often serve as a primary point of contact for patients, and help ensure that the correct medication is being dispensed to patients by checking prescriptions for accuracy.

The top non-compliance categories for community pharmacy technicians this year are listed below. A year-over-year comparison of results is provided in Appendix H. In addition, the top non-compliance items within each category is presented in Appendix J.

N = 78 items reviewed

2019 - 2020
1. Documentation
2. Product Distribution
3. Collaboration
4. Patient Identification Verification

Documentation

Pharmacy technicians play a part in a number of key processes in the dispensing of a prescription. Maintaining proper documentation is a critical part in ensuring the paper trail for each prescription is available, clear, and complete. In addition, proper documentation helps pharmacy professionals communicate to colleagues what tasks have already been completed for a prescription. This reduces the potential for confusion and improves accountability, to ensure prescriptions are dispensed accurately and safely.

In the documentation category, the most common non-compliance areas revolved around missing documentation after performing an activity that requires documentation, and not updating allergy information on PharmaNet.

Product Distribution

Accurately preparing and checking prescriptions represents a vital part of a pharmacy technician's role. These efforts help maintain patient safety and ensure the correct drug is given to the correct patient.

Missing required tasks during the preparation of a prescription product and its final check were the most common areas of non-compliance in the product distribution category. For example, this includes ensuring a prescription product label matches the dispensed product and a pharmacist has conducted a clinical assessment of the prescription before it is released.

Collaboration

As a part of the healthcare team, pharmacy technicians work closely with pharmacists, patients and other healthcare professionals. Being able to work effectively with patients and other healthcare professionals within their scope is vital for pharmacy technicians. Clear communication and collaboration between healthcare professionals helps avoid mix-ups and ensures patients are receiving safe and appropriate care from their healthcare team.

The most common non-compliance areas in the collaboration category included the missing identification of a pharmacy technician's registrant class during interactions with patients and practitioners, and performing tasks outside of a pharmacy technician's scope of practice.

Patient Identification Verification

Pharmacy technicians are often the first point of contact for patients. Being able to verify a patient's identity is crucial to maintaining patient confidentiality and safety by ensuring the right health information and medication are provided to the right patient.

Within the patient identification verification category, the most common non-compliance areas included not positively identifying an unknown patient and viewing only 1 piece of secondary ID from an unknown patient.

Hospital Pharmacy

*Note: All results are arranged in order of occurrence from **most to least frequent**.*

Hospital pharmacies manage and distribute medications to seriously and critically-ill patients who are often on highly complex medication regimens. Along with dispensing medications, clinical pharmacy experts in different specialty areas play a vital role on the hospital healthcare team by providing recommendations and troubleshooting drug therapy problems to achieve the best patient outcomes.

Over the past two fiscal years, we saw similar results, with only ambulatory service and pharmacy manager's responsibilities switching places with each other in ranking order.

The top non-compliance categories for hospital pharmacies this year are listed below. A year-over-year comparison of results is provided in Appendix H. In addition, the top non-compliance items within each of these categories are further presented in Appendix K.

N = 330 items reviewed

Average Compliance Percentage per Hospital Pharmacy Prior to Action Item Completion
87.37%

2019 - 2020
1. Sterile Compounding
2. Inventory Management – Nursing Unit
3. Ambulatory Service
4. Pharmacy Manager's Responsibilities
5. Equipment and References

Sterile Compounding

Hospital pharmacies are responsible for the preparation of various sterile compounds such as IV solutions. Strict rules and processes are in place when preparing sterile compounds because of the risk of contamination and potential for patient harm.

The sterile compounding category saw the use and maintenance of the sterile compounding environment, not performing required activities in the ante-area, and inappropriate storage of hazardous medications as the most common areas of non-compliance.

Inventory Management – Nursing Unit

Along with managing inventory in the dispensary, medications are also provided to nursing units by the pharmacy, including regular patient medications, frequently used and emergency medications. Despite being out of the pharmacy, the pharmacy retains responsibility for these medications and works with nursing staff to manage this out-of-dispensary inventory.

Security and storage of medications, refrigerator temperature monitoring, and food/beverage storage in medication refrigerators were the most common areas of non-compliance in the nursing unit inventory management category.

Ambulatory Service

Ambulatory service in a hospital refers to the provision of services to outpatients. In the context of pharmacy care, ambulatory service has different requirements than inpatient care. Additional steps are required to prepare and manage medications for patients who will leave the hospital with medications to take home. For example, additional information on the label and counselling on how to properly use the medication are required for outpatient prescriptions.

Within the ambulatory service category the most common non-compliance areas include missing required documentation by a pharmacy professional on outpatient prescription hardcopies, and missing components of an outpatient prescription at the time of dispensing.

Pharmacy Manager's Responsibilities

Pharmacy managers play an important role in the operation of a hospital pharmacy. In the hospital setting, pharmacy managers may be responsible for multiple hospital pharmacies and/or hospital pharmacy satellites. Hospital pharmacy satellites are physically separate areas where pharmacy services are provided which rely on support from the main hospital pharmacy.

From hiring and screening staff, to establishing policies and procedures, to ensuring safe drug distribution and storage across the hospital network, pharmacy managers are responsible for ensuring their pharmacy is compliant with all legislated bylaws and requirements.

Insufficient staffing levels, incorrect name badges, and missing aspects of a complete ongoing quality management program were the most common non-compliance areas in the pharmacy manager's responsibilities category.

Equipment and References

Hospital pharmacies contain a number of specialized pieces of equipment and hospital pharmacy professionals work in a number of specialized areas with appropriate references to support their work. Ensuring pharmacy professionals have appropriate access to important drug information, and all pharmacy equipment is in good working order is crucial for patient safety.

The equipment and references category identified the most common non-compliance areas as being inadequately equipped to perform certain pharmacy tasks and missing refrigerator requirements such as proper temperature monitoring equipment.

Hospital Pharmacy Professionals

*Note: All results are arranged in order of occurrence from **most to least frequent**.*

Hospital Pharmacists

Hospital pharmacists play a key role in managing the medications of their patients and providing clinical information to healthcare providers in the hospital. They serve as an accessible health resource, review patient medications for drug therapy concerns and interactions, and work closely with other health professionals to provide clinical expertise and recommendations.

The top non-compliance categories for hospital pharmacists this year are listed below. A year-over-year comparison of results is provided in Appendix H. In addition, the top non-compliance items within each of these categories is further presented in Appendix L.

N = 62 items reviewed

2019 - 2020
1. Counselling
2. Documentation
3. Profile Check
4. Patient Identification Verification

Counselling

Pharmacist counselling helps patients understand important drug therapy issues such as how to use their medications, what to expect, and when to seek medical attention. While patient consultation is not a requirement for hospital inpatients as their medications are managed by their hospital healthcare team, patient counselling is required for outpatient prescriptions or upon the request of an inpatient or healthcare professional.

The most common non-compliance areas within the counselling category included missing required counselling points during patient consultation.

Documentation

Clear and complete documentation is a critical part in maintaining patient safety especially in an environment where different healthcare professionals depend on the same pieces of documentation such as a hospital. Different healthcare professionals access patient charts and hospital software systems to make vital decisions about a patient's medical care. Complete and accurate documentation allows correct decisions to be made for patients.

In the documentation category the most common non-compliance items included missing documentation for activities that require documentation on the patient record or outpatient prescription.

Profile Check

Pharmacists are responsible for reviewing and updating a patient's medication profile when dispensing a prescription. This is a critical step to ensure changing medication regimens of hospital patients are being closely monitored for drug therapy problems and compatibility. In addition, pharmacists will review patient lab work to ensure issues such as kidney or liver function are addressed in their dosing recommendations and treatment plans.

In the profile check category the most common non-compliance items included assessing allergies, drug reactions and intolerances, checking drug orders for appropriate patient identifiers, and verifying identification for outpatients.

Patient Identification Verification

Verifying a patient's identity when providing any pharmacy service helps maintain patient safety by ensuring pharmacy professionals are providing health information and medication to the correct patient. In the hospital setting where there are numerous patients on any particular ward, it is also vital to properly identify patients in discussions with healthcare providers to ensure everyone is on the same page and discussing the correct patient. Mistaking the identity of a patient could lead to a patient receiving medications meant for someone else.

The most common non-compliance areas in the patient identification verification category included using only a single person-specific identifier when confirming a patient's identity, and not taking reasonable steps to confirm a patient's identity.

Hospital Pharmacy Technicians

Hospital pharmacy technicians play an important role on the healthcare team in the hospital setting. They help maintain the operation of a hospital pharmacy, prepare and distribute drug products, and collaborate with a wide range of healthcare professionals to provide correct medications to patients.

The top non-compliance categories for hospital pharmacy technicians this year are listed below. A year-over-year comparison of results is provided in Appendix H. In addition, the top non-compliance items within each of these categories is further presented in Appendix L.

N = 60 items reviewed

2019 - 2020
1. Documentation
2. Patient Identification Verification
3. Collaboration
4. Product Distribution

Documentation

Proper documentation is a critical part in ensuring the paper trail for any prescription dispensed is available, clear, and complete. In the hospital setting, pharmacy technicians are involved in the production of different types of medications including specialty compounded medications and IV mixtures. Clearly documenting the preparation and check process of each medication is important to maintain accountability and an appropriate audit trail. Understanding who performed a particular task and what went into a particular preparation can help resolve issues and clarify questions about a patient's medications.

In the documentation category the most common non-compliance areas included not recording a pharmacy technician's identity in writing after verifying allergy information or patient identification.

Patient Identification Verification

Verifying a patient's identity is important for hospital pharmacy technicians to confirm they are entering the correct information into the correct patient profiles and preparing the right medications for the right patient. For example, information entered into the wrong patient profile could lead to incorrect decisions being made for a patient.

In the patient identification verification category the most common non-compliance areas included not using two person-specific identifiers or using inappropriate identifiers to confirm the identity of a patient.

Collaboration

In the hospital setting, pharmacy technicians work closely with pharmacists and other healthcare professionals. Clear communication and collaboration between healthcare professionals helps avoid mix-ups and ensures patients are receiving safe and appropriate care from their healthcare team.

The most common non-compliance areas within the collaboration category included not identifying a pharmacy technician's registrant class during an interaction with another health professional or when answering the phone, performing patient consultation, and not reviewing a patient's allergies when updating the patient record.

Product Distribution

Accurately preparing and checking prescriptions represents a vital part of a pharmacy technician's role. These efforts help maintain patient safety and ensure the correct drug is prepared and given to the correct patient.

In the product distribution category the most common non-compliance areas included missing certain required tasks during the preparation of a prescription product and its final check.

Registrant Feedback Survey

Pharmacy Review

Overall feedback concerning the processes and impact of the PRP was positive. Survey feedback has provided the PRP with valuable information for program evaluation and development. These findings will also help to support legislative and other program planning in other departments at the CPBC. Survey results by category are reported below along with summary tables of survey results.

Practice Review Program Tools

The PRP provides online access tools to provide pharmacy managers information and instructions with respect to practice reviews. Community pharmacy managers overwhelmingly agreed (93% agreement rating) that the PRP tools provided were appropriate to the review process. Similarly, hospital pharmacy managers reported a 90% agreement in this category.

Practice Review Program Pre-Review

Pharmacy managers complete and submit a pre-review questionnaire prior to a practice review. This questionnaire outlines the criteria that COs use during the on-site review. Survey questions focus on how appropriate, beneficial, user-friendly, and challenging this tool is. Community pharmacy managers largely agreed (85% agreement rating) with the overall suitability of the items examined in the pre-review process. Hospital pharmacy managers reported an 83% agreement rating with this process. In addition, 93% of community and 100% of hospital pharmacy managers reported no technical challenges with the pre-review.

Qualitative feedback received from community pharmacy managers voiced the desire to have a more user-friendly, concise, and easy-to-navigate pre-review tool.

Pharmacy Review Scheduling Process

The Practice Review Program works with pharmacy managers to schedule practice reviews with the goal of minimizing disruption at review sites. Overall, 98% of community and

67% of hospital pharmacy managers agreed that the scheduling experience was positive and that there was adequate time to prepare for the Pharmacy Review.

Pharmacy Review

Pharmacy managers shared their feedback on the review experience in terms of duration, expectations, and the impact on regular work in the pharmacy. Overall, 94% of community and 83% of hospital pharmacy managers reported that their on-site pharmacy review experience was positive.

Pharmacy Review Results

In this category, 93% of community and 100% of hospital pharmacy managers agreed that their results accurately reflected their pharmacy review experience and their work situation. Furthermore, the categories of the review examined were considered relevant to CPBC standards of practice and patient safety.

Pharmacy Review Impact

Collectively, community and hospital pharmacy managers reported that the practice review had a positive impact on their practice. On an impact rating scale of -5 to +5, where a negative score represents a detrimental impact and a positive score represents a positive impact, community pharmacy managers reported an overall positive +2.84 impact rating while hospital pharmacy managers reported a slightly lower but still positive +2.00 impact rating. Any positive score here is considered a good sign the PRP is contributing to the advancement of pharmacy practice in a positive direction and helping to improve patient safety.

In addition, pharmacy managers ranked the areas assessed by COs they felt had the greatest impact on their practice. Community pharmacy managers highlighted documentation, prescriptions, and pharmacy manager responsibilities. Hospital pharmacy managers identified nursing unit inventory management, documentation, equipment and references, and narcotics and controlled drug substances as the pharmacy review categories having the greatest positive impact on their practice.

Pharmacy Review Summary Tables

Community Pharmacy Agreement Ratings

	Agreement Rating	Neutral Rating	Disagreement Rating
Pharmacy Review Scheduling (N = 68)	97.79%	2.21%	0.00%
Pharmacy Review (N = 68)	93.63%	6.37%	0.00%
PRP Tools (Pharmacy Review) (N = 68)	93.38%	6.25%	0.37%
Pharmacy Review Results (N = 68)	92.65%	6.62%	0.73%
PRP Pre-Review (N = 68)	85.29%	13.73%	0.98%

Hospital Pharmacy Agreement Ratings

	Agreement Rating	Neutral Rating	Disagreement Rating
Pharmacy Review Results (N = 2)	100.00%	0.00%	0.00%
PRP Tools (Pharmacy Review) (N = 2)	90.00%	10.00%	0.00%
PRP Pre-Review (N = 2)	83.33%	16.67%	0.00%
Pharmacy Review (N = 2)	83.33%	16.67%	0.00%
Pharmacy Review Scheduling (N = 2)	66.67%	33.33%	0.00%

Community Pharmacy Review Impact Ranking (Highest Impact = 3 points, Second Highest Impact =2 points, Third Highest Impact = 1 point) (N=68)	
Documentation	140
Prescriptions	71
Pharmacy Manager's Responsibilities	49
Security	35
Equipment and References	33
Inventory Management	23
Dispensary	14
Owner/Director Responsibilities	14
Dispensed Products	11
Confidentiality	11
External to Dispensary	7

***Overall Impact Score = Sum of (points X votes) for each level of impact (Highest, Second Highest, Third Highest)*

Hospital Pharmacy Review Impact Ranking (Highest Impact = 3 points, Second Highest Impact =2 points, Third Highest Impact = 1 point) (N=2)	
Inventory Management – Nursing Units	3
Patient Records and Documentation	3
Narcotic and Controlled Drug Substances	2
Equipment and References	2
Pharmacy Manager's Responsibilities	1
Security	0
Dispensed Products	0
Drug Orders	0
Confidentiality	0
Inventory Management - Pharmacy	0
After Hours Services	0

***Overall Impact Score = Sum of (points X votes) for each level of impact (Highest, Second Highest, Third Highest)*

Pharmacy Professionals Review

Overall, 198 community pharmacy professionals and 120 hospital pharmacy professionals completed the post-review survey. Community pharmacies had 184 pharmacists and 14 pharmacy technicians respond, while hospital pharmacies had 69 pharmacists and 50 pharmacy technicians participate. The differences in respondent distribution across practice settings are not surprising as the ratio of pharmacists to pharmacy technicians reviewed in the community in 2019-2020 was 90:10 compared to hospital pharmacies where this ratio was 55:45.

Practice Review Program Tools

An online survey and supporting educational tools were available to assist pharmacy professionals prepare for their practice review. To assess the value of these tools, pharmacy professionals were asked if they accessed these tools prior to the review. Users were prompted to provide feedback on the value of including clear instructions, website navigation and information, as well as educational tool support. Community pharmacists and pharmacy technicians reported agreement ratings of 89% and 84% respectively on the positive value of these educational tools. Hospital pharmacists and pharmacy technicians reported an agreement rating of 89% and 91% respectively.

Feedback received from registrants pointed out that some registrants did not know about the PRP tools or forgot to read them. Knowing this, the PRP will look more closely at our communications with registrants to ensure they are made aware of the various tools available to them.

Pharmacy Professionals Review

Pharmacy professionals were asked if they believe that the Pharmacy Professionals Review reflects the standards of practice outlined by the CPBC; whether the review was conducted as expected based on pre-review materials; and whether the review was conducted in a manner that limits disruption of their practice. Community pharmacists and pharmacy technicians reported a very positive 92% and 98% agreement rating respectively. Hospital

pharmacists and pharmacy technicians reported a slightly lower 86% and 94% agreement rating respectively.

Hospital pharmacists also shared in their feedback that it was sometimes difficult to keep up with their regular duties during the review when no replacement staffing was scheduled. Understanding this concern is important for the PRP to address this in future review process changes. Adjustments can then be made to PRP processes and communications to ensure expectations of time and input required are realistic and the review process is as minimally intrusive as possible.

Pharmacy Professionals Review Results

Both in-person on the day of the review and in-writing after the review, results are shared with pharmacy professionals. Areas of non-compliance are identified and action items are assigned to correct outstanding issues. In the post-review feedback survey, pharmacy professionals are asked whether they felt their review results accurately reflected their practice and whether they felt the focus areas of the review were relevant to pharmacy practice in British Columbia.

Community pharmacists reported an 87% agreement that their results appropriately addressed any identified areas of concern during the review. Community pharmacy technicians reported a 100% agreement rating in this regard. Hospital pharmacists reported an 86% agreement while hospital pharmacy technicians reported a 97% agreement with their review results. While still very positive, pharmacists reported a lower agreement with their review results compared to pharmacy technicians. The PRP will continue to monitor these numbers each year.

Pharmacy Professionals Review Impact

Pharmacy professionals provided feedback on how they perceived the practice review impacts on their practice. Pharmacy professionals completing the Practice Review Survey reported that the practice review had an overall positive impact on their practice.

Community pharmacists ranked documentation and counselling as having the greatest positive impact on their practice. The range of overall impact scores received from community pharmacists varied from being moderately positive (+1.67) to good (+2.68).

Community pharmacy technicians ranked documentation and patient identification verification as having the greatest impact on their practice. The range of overall impact scores received from community pharmacy technicians ranged from +1.29 to +3.5.

Hospital pharmacists ranked counselling and patient identification verification as having the greatest positive impact on their practice. Compared to their community counterparts, hospital pharmacists reported a lower magnitude and range of overall impact scores. Hospital pharmacist impact scores ranged between +0.62 to +1.2. These scores were generally a modest improvement over impact scores from the previous year. This indicates a year-over-year increase in the perceived positive impact of practice reviews to hospital pharmacists, and is a trend that we will work on sustaining going forward.

Hospital pharmacy technicians ranked patient identification verification and documentation as having the greatest impact on their practice. Overall impact scores were lower in magnitude and range than their community counterparts but still remained positive (+1.26 to +2.34). Similar to hospital pharmacists, these scores represented a modest improvement over results from the previous year.

This year, hospital compliance officers reported taking additional efforts to go over the reason and purpose of the program, the structure of the review, what to expect including PRP focus areas, and explaining the “why” behind certain requirements for hospital pharmacy professionals. This has led to a number of positive comments from pharmacy professionals and may have contributed to the increase in perceived positive impact reported by hospital pharmacy professionals across the board.

However, in general, the reason for relatively lower impact scores in the hospital setting compared to community practice, while not confirmed, could be related to differences in procedures, processes and areas of specialization between hospital and community pharmacies. For example, some pharmacy professionals may not regularly perform counselling in a specialized hospital pharmacy role. The PRP does not currently assess the clinical

knowledge of pharmacy professionals, and instead focuses on assessing key foundational areas of pharmacy practice identified as having the greatest impact on patient safety. The PRP acknowledges that pharmacy professionals would like to be assessed on their clinical practice and knowledge, and will consider this during future program development. In the meantime, we will continue to monitor feedback and make iterative changes as we go forward. The foregoing impact scores offer much opportunity for improvement and will be addressed in future PRC action planning.

Action Items / Action Item Portal

After the completion of a practice review, action items related to non-compliance issues are assigned to pharmacy professionals for corrective action. In this feedback survey, pharmacy professionals were asked if they felt they had sufficient time to complete action items, if instructions on completing action items were clear, and if the tools and resources provided were useful and user friendly. Community pharmacy professionals felt the action item portal was reasonable with an agreement rating of 84%, however this agreement was much lower than their hospital pharmacy counterparts (93%). IT issues with action items were identified as an area of concern in received feedback. Community pharmacy professionals had trouble accessing and using the action item portal, experienced browser and mobile device incompatibility issues. Hospital pharmacy professionals did not like using an excel form for action item completion, and suggested alternatives such as being able to use online forms.

Pharmacy professionals were asked about their experience submitting their action items. Overall, 83% of community and 91% of hospital respondents reported having no technical difficulties when submitting action items. Of those who reported technical difficulties, 93% of community and 80% of hospital pharmacy professionals reported receiving satisfactory technical support from the PRP. This represents a significant improvement over 2018-2019 results. At that time, only 76.5% of respondents on average had no technical difficulties and 69% of those who reported technical difficulties received satisfactory technical support.

Compliance Officers

As representatives of the CPBC, COs play a vital and visible role in the practice review process. Pharmacy professionals were asked about their experience with their assigned CO. This included their perspectives on the CO's knowledge of bylaws, professionalism, and overall support and collaboration with pharmacy professionals throughout the review process. Results in this category were overwhelmingly positive from community and hospital professionals, with a 97% and 99% agreement rating respectively.

Pharmacy Professionals Review Summary Tables

Community Pharmacy Professionals Agreement Ratings

	Agreement Rating	Neutral Rating	Disagreement Rating
Pharmacy Technician Review Results (N = 14)	100.00%	0.00%	0.00%
Pharmacy Technician Review (N = 14)	97.62%	2.38%	0.00%
Compliance Officers (N = 198)	96.87%	1.82%	1.31%
Pharmacist Review (N = 184)	92.39%	6.16%	1.45%
PRP Tools (Pharmacist) (N = 184)	88.91%	10.11%	0.98%
Pharmacist Review Results (N = 184)	86.96%	11.14%	1.90%
PRP Tools (Pharmacy Technician) (N = 14)	84.29%	11.43%	4.28%
Action Item Portal (N = 198)	83.84%	14.09%	2.07%

Hospital Pharmacy Professionals Agreement Ratings

	Agreement Rating	Neutral Rating	Disagreement Rating
Compliance Officers (N = 119)	99.33%	0.67%	0.00%
Pharmacy Technician Review Results (N = 50)	97.00%	2.00%	1.00%
Pharmacy Technician Review (N = 50)	94.00%	6.00%	0.00%
Action Items (N = 119)	92.98%	7.02%	0.00%
PRP Tools (Pharmacy Technician) (N = 50)	91.00%	9.00%	0.00%
PRP Tools (Pharmacist) (N = 69)	88.77%	11.23%	0.00%
Pharmacist Review Results (N = 69)	86.23%	13.04%	0.73%
Pharmacist Review (N = 69)	85.99%	12.56%	1.45%

Community Pharmacists Review Impact Rating (N = 184)

Category	*Overall Impact Rating*
Documentation	***+2.68***
Counselling	***+2.52***
Patient Identification Verification	***+2.15***
PharmaNet Profile Check	***+1.67***

Rate the impact to your practice after the Pharmacy Review on a scale of -5 to +5. Use 0 as the baseline (i.e. before the practice review).

Community Pharmacy Technicians (N = 14)

Category	*Overall Impact Rating*
Documentation	***+3.50***
Patient Identification Verification	***+2.71***
Collaboration	***+1.79***
Product Distribution	***+1.29***

Rate the impact to your practice after the Pharmacy Review on a scale of -5 to +5. Use 0 as the baseline (i.e. before the practice review).

Hospital Pharmacists (N = 69)

Category	*Overall Impact Rating*
Counselling	***+1.20***
Patient Identification Verification	***+0.78***
Documentation	***+0.78***
Profile Check	***+0.62***

Rate the impact to your practice after the Pharmacy Review on a scale of -5 to +5. Use 0 as the baseline (i.e. before the practice review).

Hospital Pharmacy Technicians (N = 50)

Category	*Overall Impact Rating*
Patient Identification Verification	***+2.34***
Documentation	***+1.92***
Collaboration	***+1.32***
Product Distribution	***+1.26***

Rate the impact to your practice after the Pharmacy Review on a scale of -5 to +5. Use 0 as the baseline (i.e. before the practice review).

Application of Findings

The findings from the Practice Review Survey have reinforced its utility in identifying opportunities to improve the PRP's effectiveness in pursuing its mandates. Feedback survey results are regularly reviewed by PRP staff to ensure early identification of potential areas of compliance concern as well as ways of providing timely and helpful responses to pharmacy professionals. As a collaborative program the feedback is appreciated and valued as a key component of the PRP's internal quality assurance and program development efforts.

Overall responses indicate a positive response to, and uptake of, the PRP by pharmacy professionals. As review programs are often seen as cumbersome and time-consuming, we are pleased that the PRP's focus on working collaboratively with pharmacy professionals throughout the review process has resulted in strong and relatively positive feedback.

Since the inception of the program, the PRP has continuously made iterative changes in a number of areas including scheduling, IT and process changes, and developing additional review focus areas to address feedback received. With each year of operation, the PRP is finding a gradual reduction in the number of program changes needed. This is likely attributed to all the feedback received from pharmacy professionals since the beginning of the program and the improvements that have been made so far. For reference, a full list of program improvements as a result of feedback to the PRP over time is presented in Appendix M.

This year a significant program change made by the PRP involved the scheduling of residential care pharmacy reviews. Due to the unique nature of residential care practice and the number of additional inspection items that are evaluated, the PRP implemented an additional day of review time for COs to be able to complete residential care practice reviews.

Survey and data findings also drive the regular PRP publication called *PRP Insights*. *PRP Insights* are articles written and available through *Readlinks* on the CPBC website that address areas identified by the PRP review process, as being of interest or educational need for pharmacy professionals. The publication of articles plays a key role in maintaining patient safety by raising awareness, educating, and clarifying issues to pharmacy professionals in order to improve compliance in their practice. This year the PRP program published *PRP Insights* on 7 topics, which addressed pharmacy renovations, blister packing and patient records, updating

pharmacy information, hospital outpatient medications, residential care, updating allergies and intolerances in the hospital, and the role of the hospital pharmacy manager when scheduling for practice reviews (Appendix N).

Along with feedback received through surveys, COs also receive informal feedback from pharmacy professionals through normal conversation. By being in-touch with the sentiments of pharmacy professionals, COs play a key role in interdepartmental collaboration. One example of this is providing real world feedback during bylaw and policy updates including PODSA ownership requirements, Opioid Agonist Treatment policies, and electronic record keeping updates. It is expected that this information sharing will continue to add an important voice to the HPA and PODSA bylaw modernization projects as well as the mandatory incident reporting project currently underway at the CPBC.

In addition to effecting change and improvements, the Practice Review Survey also reinforces the strengths in the PRP. A strong consensus (98%) exists amongst pharmacy professionals that the PRP contributes in a variety of ways to improved practice. In addition, the ongoing focus on collaboration, open communication, and shared learning with pharmacy professionals by our COs provides the foundation for positive review experiences. Our COs and their impact on the overall program is an area of great pride for the PRP. Pharmacy professional feedback is very positive for each component of the review process, including identifying the review as positively impacting practice overall. This supports the strong Practice Review Program foundation and ongoing development. Additionally, a positive impact on practice coupled with ensuring standards of pharmacy practice in British Columbia are met ultimately enhances patient safety through excellence in pharmacy.

Despite the positive responses, the PRP continues to strive to improve the impact of practice reviews for pharmacy professionals by effectively and openly communicating with pharmacy professionals to share program objectives, outcomes and changes.

Conclusion

Findings

Overall results of practice reviews have been positive, with our data showing an average compliance percentage of about 93% for community pharmacy reviews and 87% for hospital pharmacy reviews. While these results are generally positive, it is important to emphasize that the PRP department views this result as more work still needs to be done in order to move closer towards our goal of 100% compliance. The PRP considers improving compliance with established bylaws and policies as a proxy to improving patient safety. As a result, regardless of how compliant a pharmacy practice may be, our COs will focus on addressing each and every non-compliant item that is identified with pharmacy professionals. Each non-compliant item, triggers a discussion with pharmacy professionals to help them recognize the importance of and establish concrete corrective actions to achieve compliance going forward.

Along with the direct practice reviews conducted by the PRP, it is also important to recognize the far-reaching indirect effects that the presence of a mandatory enforcement program like the PRP can have on compliance. Pharmacy professionals are aware that all pharmacies and pharmacy professionals in British Columbia will undergo a practice review at some point. Knowing this, the PRP believes that along with professional expectations this adds an extra incentive for pharmacy professionals to maintain a high level of voluntary compliance. By being compliant, the number of corrective action items and changes that must be made within the 30 day post-review window is minimized while patient safety is enhanced. Both these direct and indirect effects on compliance are ways in which the PRP fulfills its duty as a regulatory college according to the Health Professions Act to maintain continuing competency and quality assurance.

The year-over-year comparison of top non-compliance categories and items reveals many similarities with findings from prior review years. This information helps us both validate and if necessary adjust our approaches to practice reviews. Increasingly, we are more confident that the information we have gathered is indeed reflective of common non-compliance issues in the field. This awareness helps COs hone in on telltale signs that something may be missing.

COs use their experience and expertise to ask the right questions, observe the right people, and know when to dig deeper. Overall this understanding helps COs more effectively identify potential issues during their limited time at a pharmacy and have outstanding concerns corrected quickly to increase patient safety.

In addition, while trickle down learning effects and peer-to-peer information sharing is observed by COs in pharmacy practice, their impacts are likely limited. We would otherwise expect average non-compliance counts to trend down, or top non-compliance categories to shift to other areas year-over-year.

These observations further highlight the need for the PRP to continue conducting practice reviews as common non-compliance areas continue to be identified and trickle down learning effects alone are not sufficient to correct these issues.

In our registrant feedback survey, we analyzed the vast amounts of information received to understand the sentiments and perspectives of pharmacy professionals. This feedback plays a crucial part in program development and the iterative changes that are made to improve the PRP. Below are some of the more prominent messages that stood out in our review of pharmacy professional feedback.

Community pharmacy managers voiced a desire for the pharmacy pre-review tool to become more user friendly, concise and easy to navigate. While the practice review was seen by community pharmacy managers as having a positive impact on their practice overall, improvements to documentation were seen as the most impactful part of the review. Community pharmacy managers also voiced the desire for future practice reviews to look at clinical decision making and specialized services such as medication reviews, adaptations, and immunizations.

Community pharmacists shared that they were not always aware of the PRP support tools available to them or forgot to read them. This tells us improved emphasis and messaging surrounding these support tools may be needed. Some community pharmacists felt the review focused more on trivial issues rather than on broader patient safety. While the PRP review criteria does encompass a large list of items that must be inspected for, each are fundamental to patient safety in their own way. However, this long list of items combined with the lack of

clinical knowledge assessment for pharmacy professionals may lead to the impression that the PRP is focusing on smaller details rather than the bigger picture. Ensuring each individual piece of the pharmacy puzzle is in the right place is what helps the PRP ensure the big picture of patient safety can be met. The mandate of the PRP remains aligned with the vision of the CPBC, which is *better health through excellence in pharmacy,* and the PRP recognizes that there is more work to be done to communicate to pharmacy professionals the reason "why" we approach reviews the way we do.

Community pharmacy professionals further voiced their desire to have the PRP review more specialty practice activities, and praised compliance officers for their knowledge and professionalism. In addition, community pharmacy professionals want the CPBC to better understand real world working conditions and the pressures that community pharmacy professionals face. This is something that the PRP has taken concrete steps to acknowledge and improve through changes such as not scheduling reviews during the busy winter holiday period, and using our observations in the field to guide common sense bylaw changes such as in our PODSA bylaw modernization project. The PRP also recognizes that there are often many things that pharmacy professionals may have wanted to change about their practice but may not have had an opportunity to do so. This could be due to a lack of consensus amongst staff and/or owners, or a lack of buy-in and understanding of its importance. Compliance officers often help create consensus amongst staff by being able to see the current state of the pharmacy, explain what changes are legally required, how they are important, and how a pharmacy's work could look like after the change.

An unexpected piece of feedback received was that a number of community pharmacy professionals asked for an increase in the length of the practice review, an increased frequency of reviews, as well as regular follow ups to ensure compliance. This feedback from practicing professionals helps acknowledge and reinforce the important role the PRP's efforts play in supporting pharmacy compliance.

Action item portal access, saving, and technical difficulties were identified as another area of concern for pharmacy professionals. The PRP has been working closely with the IT department to address these concerns while developing an updated platform for the program.

In the hospital setting, pharmacists expressed difficulties keeping up with their regular duties during practice reviews without having replacement staff available. The PRP aims to perform practice reviews by seeking ways to be as minimally intrusive as possible. Further exploration into this issue based on the feedback received will help guide any further adjustments to the program.

Some hospital pharmacists didn't feel the Pharmacy Professionals Review had much of an impact to their practice, while others thought the most impactful part of the review was counselling. This is likely due to the higher number of specialty practice areas in the hospital environment where pharmacists may play unique roles. While the Pharmacy Professionals Review may not perfectly assess the work environment of each and every pharmacy professional, it encompasses areas that are fundamental to the practice of the majority of pharmacy professionals. The PRP continues to monitor and adjust accordingly so as to help improve the perceived impact of the program for pharmacy professionals.

Some hospital pharmacy professionals commented that they would have liked compliance officers to spend more time with them so as to provide a more thorough picture of their work for COs. The PRP aims to maintain a balance between being able to perform a comprehensive review while being minimally intrusive to work obligations. Comments such as this highlight the fine line that must be considered between professionals who want more rigorous practice reviews, and those who want less.

Lastly, hospital pharmacy professionals shared strong positive comments about their experiences with compliance officers. However, they felt that responding to compliance action items could be accomplished in a better manner than through an excel form being sent back and forth. Suggestions for alternatives included employing online forms, or live spreadsheets such as Google Sheets to make discussions around action items easier to address.

Future Development

Going forward, the PRP department will continue to capture and evaluate data and feedback obtained during practice reviews. We will look at unique ways to identify and examine any trends which may be developing in the profession. This can be accomplished by further

building on the information gathered from existing tools as well as developing new tools and methods in the future.

As our understanding of common non-compliance areas increases with baseline data established during this cycle, the PRP is able to use this information to potentially shift the focus of practice reviews in subsequent cycles. For example, eliminating high compliance, low patient safety-risk inspection items and replacing them with lower compliance issues, linked to high safety-risk items could increase the effectiveness and impact of the PRP on growing concerns about patient safety.

In the upcoming year, the PRP will continue to work on our residential care review processes as we gain more experience and insight into conducting these specialty reviews.

The PRP and IT department have been working closely together to develop an updated version of the PRP application. At present, pharmacy professionals are linked to a pharmacy where they are currently employed and reviewed at that location. However, pharmacy professionals who are away or ill during the CO's pharmacy visit are unable to be reviewed at a later date under the existing system. With the launch of the updated PRP application, COs will gain the ability and flexibility to review pharmacy professionals independent of where they are working at that time if necessary.

The PRP will also train compliance officers in new and revised compliance review categories that accompany emerging pharmacy legislation. This includes areas such as mandatory medication incident reporting and specialty compounding.

Prior to the next cycle of practice reviews, the Practice Review Committee will have the opportunity to evaluate the Practice Review Program and recommend changes to its objectives and the desired goals of the collected data to the Board. The PRP will then be able to consult with experts in the areas of study design, data analysis, and statistics to make necessary changes to ensure that any data collected and analyzed is conducted in a manner that achieves the goals of the program.

In response to the breaking development of the COVID-19 pandemic just after the 2019-2020 fiscal year, the PRP is currently exploring different opportunities and formats to resume practice review activity in the safest way possible. This may be through a combination of

personal protective equipment, remote review activities, and in-person visits with appropriate precautions. Maintaining the health and well-being of pharmacy professionals, the public, and compliance officers is of the utmost importance.

Appendix A: Practice Review Process (Detailed)

The practice review process consists of three components that are completed over a 2-3 month period. The first component, the pre-review, involves collaborating with pharmacy managers to determine scheduling of the on-site review, email confirmation and access to the online pre-review questionnaire with supporting online educational tools.

Selected community pharmacies are notified via email at least 1 month prior to the scheduled review date. Hospital pharmacies are notified via email at least 2 months prior to the scheduled review date. Pharmacy managers are asked to complete and submit an online pharmacy pre-review in preparation for the upcoming visit. This allows them to compare the practice at their pharmacy to the legislation, standards, and expectations for all pharmacies in British Columbia.

Follow up phone calls are made to pharmacy managers by PRP staff to confirm dates, address potential concerns, and reinforce the collaborative nature of the review. The pre-review questionnaire is available online to all pharmacy managers and takes approximately 2-3 hours to complete. The time spent completing this questionnaire can be applied toward non-accredited continuing education annual requirements for pharmacy managers. The first component of the review is complete once the pre-review online questionnaire is submitted.

Pharmacy professionals are also provided with a number of resources to help them prepare for their Pharmacy Professionals Review. This includes emailed instructions, pharmacy professional review forms available online, an online FAQ, PRP support tools for community pharmacy professionals, and direct support available from PRP staff.

The second component of the practice review is comprised of an in-person review by a CPBC Compliance Officer (CO). This review includes evaluation of up to 516 unique, equally-weighted items and processes that directly relate to CPBC standards of practice (Appendix C). During the on-site review, pharmacy professionals are observed performing day-to-day pharmacy activities including patient interactions. Pharmacist reviews focus on compliance with standard processes related to patient identification verification, profile check, counselling, and documentation. Pharmacy technician reviews focus on compliance with standard processes related to patient identification verification, product distribution, collaboration, and

documentation. The review of the pharmacy site takes about 6-7 hours to complete while each professional review requires about 2-3 hours to complete. Pharmacies that service residential care facilities are allocated an additional day of review time so as to accommodate their specific requirements and processes. During the on-site review, the goal of the CO is to work collaboratively with professionals, ensuring minimal disruption to the regular operation of the pharmacy while promoting the bilateral sharing of knowledge.

At the end of the on-site visit, pharmacy managers and pharmacy professionals are provided a verbal debrief followed by a written report. Both debriefs identify any non-compliance action items that require attention by the pharmacy manager and the pharmacy professionals. By discussing action items in person and then reinforcing them in writing, pharmacy managers and professionals are given the opportunity to ask COs questions about the nature of any issues identified and how best to correct them. Through this added level of engagement, pharmacy professionals are better able to enter their 30 day action item completion period with a clear sense of what is required and why.

For the third component, community pharmacy professionals correct and report their action item compliance requirements through an online action item portal. Hospital pharmacy professionals correct and report their action items via a customized Excel spreadsheet that is emailed to their CO. This variance is due to differences in data collection methods between the two types of reviews. However, collaboration with the CPBC IT department is underway to migrate information collected from both types of reviews to a unified PRP application.

Once identified action items have been addressed by the pharmacy and its pharmacy professionals, they are submitted to the CO for approval of their alignment with the standards of practice of the CPBC. However, a pharmacy or pharmacy professional can be referred to the Inquiry Committee in cases where action items are not corrected, and non-compliance is not addressed. For the fiscal year 2019-2020, 1 referral was made to the Inquiry Committee.

After the practice review has been completed and closed, all participants are invited to provide feedback by completing the Practice Review Survey.

Appendix B: Site Selection Breakdown

Community Pharmacy Sites Reviewed

Site Type	District 1	District 2	District 3	District 4	District 5	Total
Cycle-Based	41	11	18	12	6	**88**
Risk-Based (Complaints)	27	10	11	4	3	**55**
Risk-Based (New Openings – no review since pre-opening)	34	71	12	14	5	**136**
Totals	**102**	**92**	**41**	**30**	**14**	**279**

District 1 *- Metro Vancouver,* ***District 2*** *- Fraser Valley,* ***District 3*** *- Vancouver Island/Coastal,* ***District 4*** *- Kootenay/Okanagan,* ***District 5*** *- Northern BC*

Hospital Pharmacy Sites Reviewed

	District 6	District 7
Hospital Pharmacies Reviewed	5	8
Total		**13**

District 6 *– Urban Hospitals,* ***District 7*** *– Community Hospitals*

Appendix C: Practice Review Forms and Criteria

Community Pharmacy Review Form

http://library.bcpharmacists.org/5_Programs/5-2_PRP/5164-PRP_PharmReview_Form.pdf

Hospital Pharmacy Review Form

http://library.bcpharmacists.org/5_Programs/5-2_PRP/5209-PRP_Hospital_PharmReview_Form.pdf

Community Pharmacist Review Form

http://library.bcpharmacists.org/5_Programs/5-2_PRP/5163-PRP_PharmProReview_Form.pdf

Community Pharmacy Technician Review Form

http://library.bcpharmacists.org/5_Programs/5-2_PRP/5234-PRP_Community_PT_ProReview.pdf

Hospital Pharmacist Review Form

http://library.bcpharmacists.org/5_Programs/5-2_PRP/5300-PRP_Hospital_PSPharmProReview_Form.pdf

Hospital Pharmacy Technician Review Form

http://library.bcpharmacists.org/5_Programs/5-2_PRP/5301-PRP_Hospital_PTPharmProReview_Form.pdf

Community Pharmacy Review Categories and Item Counts

CATEGORY	# ITEMS
External to Dispensary	20
Dispensary	7
Security	22
Equipment & References	47
Prescriptions	57
Confidentiality	15
Inventory Management	40
Dispensed Products	17

Documentation	43
Pharmacy Manager Responsibilities	45
Owner and Director Responsibilities	7
Non-Sterile Compounding	8
Sterile Compounding*	**26**
Residential Care*	**114**
Opioid Agonist Treatment*	**43**
Injectable Opioid Agonist Treatment*	**5**
Total	**516**

**Optional categories that would only be reviewed for community pharmacies that offer these services*

Hospital Pharmacy Review Categories and Item Counts

CATEGORY	# ITEMS
Pharmacy Security	3
Equipment & References	18
Drug Orders	10
Confidentiality	10
Inventory Management – Pharmacy	8
Inventory Management – Nursing Units	20
Narcotics and Controlled Drug Substances	30
Dispensed Products	36
Patient Records / Documentation	18
After Hours Services	6
Pharmacy Manager Responsibilities	59
Owners and Directors Responsibilities	6
Non-sterile Compounding*	13
Sterile Compounding*	21
Residential Care*	6
Bulk Repackaging*	24

Ambulatory / Outpatient Services*	45
Total	**330**

**Optional categories that would only be reviewed for hospital pharmacies that offer these services*

Appendix D: Pharmacy Professional Review Statistics and Review Categories

Number of Community Pharmacy Professionals Reviewed

Pharmacists	**666**
Pharmacy Technicians	**77**

Community Pharmacist Review Categories and Item Counts

CATEGORY	# ITEMS
Patient Identification Verification	6
PharmaNet Profile Check	17
Counselling	28
Documentation	34
Total	**85**

Community Pharmacy Technician Review Categories and Item Counts

CATEGORY	# ITEMS
Patient Identification Verification	6
Product Distribution	33
Collaboration	24
Documentation	15
Total	**78**

Number of Hospital Pharmacy Professionals Reviewed

Pharmacists	**241**
Pharmacy Technicians	**200**

Hospital Pharmacist Review Categories and Item Counts

CATEGORY	# ITEMS
Patient Identification Verification	3
Profile Check	21
Counselling	21
Documentation	17
Total	**62**

Hospital Pharmacy Technician Review Categories and Item Counts

CATEGORY	# ITEMS
Patient Identification Verification	3
Product Distribution	45
Collaboration	4
Documentation	8
Total	**60**

Appendix E: Practice Review Survey

Sample Practice Review Survey Invitation

College of Pharmacists of British Columbia

Dear Name,

The goal of the Practice Review Program is to have all registrants and practice settings not only meet, but exceed College standards. We encourage you and your staff to continue to self-assess your pharmacy and practice on a regular basis in order to provide your patients with "better health through excellence in pharmacy".

This email confirms that your Pharmacy Professionals Review conducted at PHARMACY between Review Dates is now complete. A full Pharmacy Professionals Review report is available on eServices.

We invite and encourage you to complete a voluntary survey on the Practice Review Program at http://questionnaire.simplesurvey.com/f/l/PRPCommunityPracticeRegistrantFeedbackSurvey2019-20 before Due Date. If you are a Pharmacy Manager, you only need to complete the survey once.

Regards,
Ashifa Keshavji, B.Sc.(Pharm.), R.Ph.
Director of Practice Reviews and Quality Assurance | *College of Pharmacists of BC*
604.733.2440 | 1.800.663.1940 | www.bcpharmacists.org

Sample Email Reminder

College of Pharmacists of British Columbia

Dear **Name**

This is a reminder to complete the voluntary Practice Review Program Feedback Evaluation Survey by Due Date . Please ignore this email if you have already completed the survey. We appreciate your feedback.

Sincerely,
Ashifa Keshavji, B.Sc.(Pharm.), R.Ph.
Director of Practice Reviews and Quality Assurance | *College of Pharmacists of BC*
604.733.2440 | 1.800.663.1940 | www.bcpharmacists.org

Survey Questions

Practice Review Program Tools Section Questions:

1. I received clear instruction on how to access the Practice Review Program information on the College website.
2. The Practice Review Program webpage has clear information about the program, including the overall review process.
3. I received clear instructions on how to complete the Pharmacy Pre-Review.
4. The How-To-Guide and the Pharmacy Pre-Review Tutorial were helpful resources. **(Community Only)**
5. The selection email received from the College contained appropriate and clear information. **(Hospital Only)**
6. The “Practice Reviews in Progress” poster was a valuable resource for my staff. **(Hospital Only)**

Practice Review Program Pre-Review Section Questions:

1. The online Pharmacy Pre-Review tool was user-friendly.
2. The pre-review took an appropriate amount of time.
3. I had clear expectations of the Pharmacy Review after completing the Pharmacy Pre-Review.

- *How many hours did it take you to complete the Pharmacy Pre-Review online?*
- *Did you experience any technical difficulties when completing the online Pharmacy Pre-Review?*
- *Did you receive satisfactory technical support from the PRP department?*
- *How could the online Pharmacy Pre-Review tool be improved?*

Pharmacy Review Scheduling Process Section Questions:

1. The PRP department was helpful when I had questions or concerns related to scheduling.
2. I had adequate time to prepare for the Pharmacy Review.
3. I had clear instructions on how to schedule the Pharmacy Professionals Reviews. **(Hospital Only)**

- *How could the scheduling process be improved?*

Pharmacy Review Section Questions:

1. The duration of the Pharmacy Review was sufficient to thoroughly review my pharmacy.
2. The Pharmacy Review was conducted as expected from the Pharmacy Pre-Review and the program information received.
3. The Pharmacy Review was conducted in a manner that was as least disruptive to my pharmacy as possible.

Pharmacy Review Results Section Questions:

1. My Pharmacy Review results accurately reflected the review.
2. The categories of the Pharmacy Review are relevant to patient safety.

Pharmacy Review Impact Section Questions:

- *Rate the impact to your pharmacy after the Pharmacy Review. Use 0 as the baseline (i.e. before the practice review).*
- *Rank the top 3 areas in the Pharmacy Review that have the highest positive impact on your pharmacy after the review.*
- *How has the pharmacy review impacted your pharmacy overall?*
- *How could the pharmacy review better assess your pharmacy?*
- *Is there any other area of pharmacy practice that should also be included in the Pharmacy Review?*

Practice Review Program Tools (Pharmacy Professionals) Section Questions:

1. I received clear instructions on how to access the Practice Review Program information on the College website.
2. The Practice Review Program webpage has clear information about the program, including the overall review process.
3. I read the Pharmacy Professionals Review Form before my review.
4. I understood what to expect from a Pharmacy Professionals Review after reading the form.
5. The PRP Support Tools for the focus areas were helpful resources. **(Community Only)**

Pharmacy Professionals Review Section Questions:

1. My Pharmacy Professionals Review reflects minimum standards as set by the College under the 4 focus areas.
2. The Pharmacy Professionals Review was conducted as expected from the program information I received.
3. My Pharmacy Professionals Review was conducted in a manner that was as least disruptive to my practice as possible.

Pharmacy Professionals Review Results Section Questions:

1. My Pharmacy Professional Review results accurately reflected the review.
2. The focus areas of the Pharmacy Professionals Review are relevant to my practice.

Pharmacy Professionals Review Impact Section Questions:

- *Rate the impact to your practice after the Pharmacy Review. Use 0 as the baseline (i.e. before the practice review).*
- *How has the Pharmacy Professionals Review impacted your practice overall?*
- *How could the Pharmacy Professionals Review better assess your practice?*

Action Items / Action Item Portal Section Questions:

1. I had sufficient time to complete my action item(s).
2. I received clear instructions on how to review my action items and submit them on the Action Item portal. **(Community Only)**
3. The Action Item Tutorial was helpful. **(Community Only)**
4. The Action Item Portal was user-friendly. **(Community Only)**
5. I received clear instructions on how to review and submit my action item(s). **(Hospital Only)**

- *Did you experience any technical difficulties when submitting your action item(s)?*
- *Did you receive satisfactory technical support from the PRP department?*
- *How could the Action Item Portal/submitting action items be improved?*

Compliance Officer Section Questions:

My Compliance Officer:

1. Was knowledgeable in current bylaws.
2. Was polite and professional.
3. Was able to answer my questions during and/or after the review.
4. Provided adequate support to complete my action item(s).
5. Made me feel comfortable to ask questions or seek clarification.

Additional Feedback Section Questions:

- *Please provide any feedback on the Practice Review Program that has not been addressed in the survey*

Appendix F: Survey Data Collection and Processing Methodology

Overall Rating Score

The 7-point Likert scale provides respondents the opportunity to rate their agreement/disagreement to practice review related statements. Responses range from *strongly agree* to *strongly disagree*. When analyzing responses, *agree* and *strongly agree* indicated agreement, while *disagree* and *strongly disagree* indicated disagreement, and *somewhat agree*, *neutral,* and *somewhat disagree* indicated a neutral response.

Responses to several statements within each category are collected. For example, in the Compliance Officers category, responses to 5 individual statements are collected. The overall rating score combines the feedback of all 5 statements into an overall rating to provide a measure of performance for the Compliance Officers category as a whole. Managing data in this manner allows for a large volume of discrete data points to be more easily interpreted and actionable. These overall rating scores provide a substantive summary of collected responses, ultimately providing a proxy measurement of the PRP's performance according to pharmacy professionals.

The formulas below outline the overall rating score calculation used. The limitation of using overall rating scores is that while it provides an overview of performance within a category there is the potential for loss of specific feedback related to individual statements. Poor scores and positive scores will lower and raise an overall rating score respectively, however, which specific statement within a category may have led to the positive or negative shift would not be known using an overall rating score. This concern can readily be addressed as overall rating scores that raise concern can be investigated further by reviewing more detailed data.

Overall Rating Score Calculation

$$Agreement\ Rating\ \% = \frac{\#\ Agree + \#\ Strongly\ Agree}{Total\ \#\ of\ Responses}\ x\ 100$$

$$Neutral\ Rating\ \% = \frac{\#\ Somewhat\ Agree + \#\ Neutral + \#\ Somewhat\ Disagree}{Total\ \#\ of\ Responses}\ \text{x}\ 100$$

$$Disagreement\ Rating\ \% = \frac{\#\ Disagree + \#\ Strongly\ Disagree}{Total\ \#\ of\ Responses}\ x\ 100$$

Overall Impact Rating

Impact rating questions ask respondents to rate how they feel the practice review has impacted their practice. A scale of +5 to -5 was used with 0 identified as the baseline of no impact at all. A positive score indicates a positive impact on practice while a negative score indicates a negative impact on practice.

Feedback collected from impact rating questions is analyzed and collated into an overall impact rating with the formula below. Using an averaging approach, information from hundreds of individual impact rating scores are combined and interpreted as a whole. Substantively summarizing data in this way enhances understanding and allows the PRP to make responsive changes as necessary.

A limitation of using the overall impact rating is that averaging can obscure information related to the distribution of responses. For example, an average score of +2.5 does not tell us whether the majority of scores received were around +2.5, or whether half of the scores received were +5 and the other half were 0. Similar to overall rating scores, the entirety of the raw data for impact rating questions is available for review if further analysis is required.

Overall Impact Rating Calculation

$$Overall\ Impact\ Rating = \frac{Sum\ of\ impact\ scores}{Total\ count\ of\ impact\ scores}$$

Impact Ranking

Respondents are also asked to rank the impact specific categories of the review had on their practice. The impact ranking is calculated by assigning points for the top three impact areas reported by each respondent and adding up the scores for each impact area. A vote for highest impact area is given 3 points, second highest 2 points, and third highest 1 point. A

limitation to impact rankings is that these questions only ask for the top 3 impact areas, and may not accurately reflect other review categories which could be impactful as well but may be number 4 on the list or lower.

Open-Ended Comments

Qualitative data obtained from open-ended comments provides valuable feedback on respondents' personal experiences. Each comment is reviewed by PRP staff and grouped into themes. When theming, PRP staff review each submission to identify the underlying message within the comment. To minimize the risk of misinterpretation, comments that do not clearly fit within an existing category are placed in a category of their own. These single outlier comments, while small in number, are still valuable as they provide insight that may otherwise not be available to the PRP team. Once comments are themed they are added to a tally. For example, the comment:

> "*The website is not user friendly. My browser was not supported, College email response was 3 days later. Even then the only suggestion was to download Chrome. I use Safari, a commonly used browser. This should be an option for members to use*."

is themed "would like Safari compatibility" and tallied with that category.

This process of theming comments was implemented with the goal of improving interpretation of the large amount of raw comment data. While the PRP recognizes a limitation of theming comments is that not all individual nuances in comments can be captured through theming, the benefit of being able to clearly identify and act on trends is felt to outweigh the risk of losing some of the individual nuances in comments. Risks associated with theming are minimized through retaining all raw data to allow for the review of individual comments. Respondent comments are a valuable part of the overall data collected to establish a clear picture of PRP performance.

Appendix G: Survey Responses and Practice Reviews Completed by District and Practice Setting

Survey Responses by Practice Setting

Community Pharmacy Feedback Survey Statistics	
Partial Responses	52 (7%)
Complete Responses*	198 (28%)
Total Responses	250 (36%)

* Only completed surveys included for analysis

68 of the 198 community pharmacy respondents were pharmacy managers

25 of the 68 community pharmacy managers were pharmacy owners/directors

Hospital Pharmacy Feedback Survey Statistics	
Partial Responses	17 (4%)
Complete Responses*	120 (30%)
Total Responses	137 (35%)

*Only completed surveys included for analysis

2 of the 120 hospital pharmacy respondents were pharmacy managers

Appendix H: Top Non-Compliance Categories Year-Over-Year Comparison

*Note: All results are arranged in order of occurrence from **most to least frequent**.*

Community Pharmacy

2017 - 2018	2018 - 2019	2019 - 2020
1. Prescriptions	1. Inventory Management	1. Prescriptions
2. Inventory Management	2. Prescriptions	2. Inventory Management
3. Pharmacy Manager Responsibilities	3. Pharmacy Manager Responsibilities	3. Pharmacy Manager Responsibilities
4. Equipment and References	4. Security	4. Equipment and References
5. External to Dispensary	5. Equipment and References	5. Security

Community Pharmacists

2017 - 2018	2018 - 2019	2019 - 2020
1. Counselling	1. Counselling	1. Counselling
2. Documentation	2. Documentation	2. Documentation
3. Patient Identification Verification	3. Patient Identification Verification	3. Patient Identification Verification
4. PharmaNet	4. PharmaNet	4. PharmaNet

Community Pharmacy Technicians

2017 - 2018*	2018 - 2019	2019 - 2020
1. Documentation 2. Product Distribution 3. Collaboration 4. Counselling 5. Patient Identification Verification	1. Documentation 2. Collaboration 3. Product Distribution 4. Patient Identification Verification	1. Documentation 2. Product Distribution 3. Collaboration 4. Patient Identification Verification

Note: In 2017-2018, Community Pharmacy Technician review criteria changed from Patient Identification Verification, Documentation, Profile Check,and Counselling to Patient Identification Verification, Documentation, **Product Distribution, and **Collaboration**. As a result, action items for the whole year spanned across up to 6 categories (because of the 2 new replacements).*

Hospital Pharmacy

2017 - 2018	2018 - 2019	2019 - 2020
1. Inventory Management – Nursing Unit 2. Pharmacy Manager Responsibilities 3. Narcotics & Controlled Substances 4. Sterile Compounding 5. Equipment & References	1. Sterile Compounding 2. Inventory Management – Nursing Unit 3. Pharmacy Manager Responsibilities 4. Ambulatory Services 5. Equipment and References	1. Sterile Compounding 2. Inventory Management – Nursing Unit 3. Ambulatory Service 4. Pharmacy Manager's Responsibilities 5. Equipment and References

Hospital Pharmacists

2017 - 2018	2018 - 2019	2019 - 2020
1. Patient Identification Verification 2. Counselling	1. Counselling 2. Patient Identification Verification 3. Documentation	1. Counselling 2. Documentation 3. Profile Check 4. Patient Identification Verification

Hospital Pharmacy Technicians

2017 - 2018	2018 - 2019	2019 - 2020
1. Patient Identification Verification 2. Documentation 3. Product Distribution 4. Collaboration	1. Patient Identification Verification 2. Documentation 3. Collaboration 4. Product Distribution	1. Documentation 2. Patient Identification Verification 3. Collaboration 4. Product Distribution

Appendix I: Community Pharmacy Review Top Non-Compliance Items

Prescriptions

N = 57 items reviewed

2019 – 2020	
Rank 1	Missing name and/or fax number of the pharmacy intended to receive the transmission.
2	Pharmacists must document in the client's record any emergency refill of the prescription, the rationale for the decision, and any appropriate follow-up plan.
3	The written confirmation of the registrant who verified the patient **allergy information** is missing on a prescription hard copy.
4	The written confirmation of the registrant who verified the **patient identification** is missing on a prescription hard copy.
5	The written confirmation of the registrant who **performed the consultation** is missing on a prescription hard copy.

Inventory Management

N = 40 items reviewed

2019 – 2020	
Rank 1	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.
2	Missing date and signature of the **responsible pharmacist** when conducting narcotic counts.
3	Missing date and signature of the **person(s) who completed** narcotic count.
4	Narcotic counts were not conducted at a minimum of every 3 months.

5	Forward to the College a copy of any report sent to the appropriate office at Health Canada.

Pharmacy Manager Responsibilities

N = 45 items reviewed

2019 – 2020	
Rank 1	Procedures were not established for (i) inventory management, (ii) product selection, and (iii) proper destruction of unusable drugs and devices.
2	An ongoing quality management program that monitors staff performance, equipment, facilities and adherence to the Community Pharmacy Standards of Practice has not been developed.
3	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.
4	Policies and procedures were not established to specify the duties to be performed by pharmacy professionals and support persons.
5	Ensure the pharmacy contains the reference material and equipment approved by the board from time to time.

Equipment and References

N = 47 items reviewed

2019 – 2020	
Rank 1	At the start and end of each work day, record the minimum and maximum temperatures reached since the last monitoring, on the Temperature Form. Also record the current refrigerator temperature.
2	Maintain the refrigerator temperature between +2°C to +8°C.
3	The dispensary of all community pharmacies at a minimum must have the equipment outlined as per PODSA Bylaw (3)(2)(w): The pharmacy was missing **stirring rods** (glass or plastic).
4	The pharmacy does not have a current reference applicable to veterinary drugs though it does dispense drugs for veterinary use.

5	The dispensary of all community pharmacies at a minimum must have the equipment outlined as per PODSA Bylaw (3)(2)(w): The pharmacy was missing **funnels** (glass or plastic).

Security

N = 22 items reviewed

2019 – 2020	
Rank 1	A community pharmacy must clearly display at all external entrances that identify the premises as a pharmacy, and at the dispensary counter signage provided by the College.
2	Security camera system does not have date/time stamp images that are archived and available for no less than 30 days.
3	Schedule IA drugs were not kept in a locked metal safe.
4	Some schedule I and II drugs, controlled drug substances or personal health information, were not secured by physical barriers.
5	Under the Personal Information Protection Act (PIPA) pharmacies are required to post visible and clear signage informing customers that the premise is monitored by cameras.

Appendix J: Community Pharmacy Professionals Review Top Non-Compliance Items

Community Pharmacists

Counselling

N = 28 items reviewed

2019 – 2020	
Rank 1	The pharmacist/patient consultation for a prescription did not include action to be taken in the event of a **missed dose**.
2	The pharmacist/patient consultation for a prescription did not include the **strength** of the drug.
3	The pharmacist/patient consultation for a prescription did not include the **purpose** of the drug.
4	The pharmacist did not provide patient consultation for a schedule 1 prescription.
5	The pharmacist/patient consultation for a prescription did not include information on **when to seek medical attention**.

Documentation

N = 34 items reviewed

2019 – 2020	
Rank 1	Unable to tell whether patient **allergy** information was verified or not because the pharmacist did not record that on the prescription.
2	Unable to tell whether **patient identification** was verified or not because the pharmacist did not record that on the prescription.
3	The pharmacist did not update allergy information onto PharmaNet.

4	The pharmacist verified **patient identification** but did not include his/her written confirmation for doing so on the prescription hardcopy.
5	Unable to tell whether **counselling** occurred or refused by patient because pharmacist did not self-identify for that on the prescription.

Patient Identification Verification

N = 6 items reviewed

2019 – 2020	
Rank 1	The pharmacist did not view any ID from an unknown patient.
2	The pharmacist did not ID patient before providing service that concerns a patient's PHI.
3	The pharmacist viewed only 1 piece of secondary ID from an unknown patient.
4	The pharmacist did not ID patient's representatives before providing service that concerns a patient's PHI.

PharmaNet Profile Check

N = 17 items reviewed

2019 – 2020	
Rank 1	The pharmacist did not review the patient's personal health information stored on the PharmaNet database before dispensing a drug.
2	The pharmacist did not review a patient's local patient profile for drug therapy problems.
3	The pharmacist did not take action on a patient’s degree of compliance.
4	The pharmacist did not take action on a therapeutic duplication.

Community Pharmacy Technicians

Documentation

N = 15 items reviewed

2019 – 2020	
Rank 1	Unable to tell whether patient **allergy information** was verified or not because the pharmacy technician did not self-identify for that on the prescription.
2	Unable to tell whether **patient identification** was verified or not because the pharmacy technician did not self-identify for that on the prescription.
3	The pharmacy technician did not update allergy information onto PharmaNet.
4	The pharmacy technician verified **patient identification** but did not self-identify for that on the prescription.
5	The pharmacy technician performed the **final check** but did not self-identify for that on the prescription.

Product Distribution

N = 33 items reviewed

2019 – 2020	
Rank 1	The pharmacy technician **performing the final check** of a prepared prescription did not ensure that the prescription **product label matches** the manufacturer's label with respect to the **drug.**
2	The pharmacy technician **performing the final check** of a prepared prescription did not ensure that a **pharmacist has completed a clinical assessment** of the prescription after reviewing the patient profile.
3	The pharmacy technician, when **performing the final check** of a prescription product, did not ensure that the prescription **product label matches** the manufacturer's label with respect to the **DIN**.
4	The pharmacy technician, when **performing the final check** of a prescription product, did not ensure that the prescription **product label matches** the prescription information with respect to the **dosing instructions** including the frequency, interval or maximum daily dose.

5	The pharmacy technician, when **performing the final check** of a prescription product, did not ensure that the prescription **product label matches** the manufacturer's label with respect to **strength**.

Collaboration

N = 24 items reviewed

2019 – 2020	
Rank 1	The pharmacy technician did not identify his or her registrant class in an interaction with a **patient**.
2	The pharmacy technician did not identify his or her registrant class in an interaction with a **practitioner**.
3	The pharmacy technician performed a task described in (i) sections 12: **Counselling a Prescription**.
4	The pharmacy technician performed a task described in (i) sections 6(5): **Clinical**.
5	The pharmacy technician did not use effective written communication skills.

Patient Identification Verification

N =6 items reviewed

2019 – 2020	
Rank 1	The pharmacy technician did not view any ID from an unknown patient.
2	The pharmacy technician viewed only 1 piece of secondary ID from an unknown patient.
3	The pharmacy technician did not ID a patient before providing service that concerns a patient's PHI.

Appendix K: Hospital Pharmacy Review Top Non-Compliance Items

Sterile Compounding

N = 21 items reviewed

2019 - 2020	
Rank 1	Personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate-generating activities were not performed in the ante-area.
2	Sterile products were not prepared and distributed in an environment that is in accordance with the USP Pharmaceutical Compounding – Sterile Products Guidelines (USP Chapter <797>).
3	Hazardous drugs were not stored separately from other inventory to prevent contamination.
4	Ceiling/flooring/equipment/chairs were not non-porous, smooth, free from cracks, non-shedding, cleanable and disinfectable.
5	A demarcation line was absent. There was no visible line on the floor that separates the room into areas for different purposes.

Inventory Management – Nursing Unit

N = 20 items reviewed

2019 - 2020	
Rank 1	Appropriate security and storage of all Schedule I, II, and III drugs and controlled drug substances for all aspects of pharmacy practice including operation of the pharmacy without a registrant present was not ensured.
2	Minimum and maximum refrigerator temperatures were not consistently recorded at the start and end of each work day on a nursing unit.
3	A constant temperature-recording device or digital minimum/maximum thermometer (with probe) to monitor both the current refrigerator temperature and the minimum/maximum temperatures reached was not used.
4	Drugs on the nursing unit were not protected from contamination.

5	Food and/or beverages were found in medication refrigerators on a nursing unit.

Ambulatory Service

N = 45 items reviewed

2019 - 2020	
Rank 1	The written confirmation of the registrant who verified the patient identification was missing on the outpatient prescription hard copy.
2	The written confirmation of the registrant who verified the patient allergy information was missing on the outpatient prescription hard copy.
3	An outpatient prescription did not include the identification number from the practitioner's regulatory college at the time of dispensing.
4	An outpatient prescription did not include the full address of the patient, including postal code at the time of dispensing.
5	The written confirmation of the registrant who identified and addressed a drug therapy problem is missing on the outpatient prescription hard copy.

Pharmacy Manager's Responsibilities

N = 59 items reviewed

2019 – 2020	
Rank 1	Registrant and support persons staff levels were not sufficient to ensure that workload volumes and patient care requirements are met at all times in accordance with the bylaws, Code of Ethics and standards of practice.
2	Incorrect registrant class or other status was identified on a badge.
3	The hospital pharmacy manager did not develop, document and implement an ongoing quality management program that documents periodic audits of the drug distribution process.
4	The hospital pharmacy manager did not develop, document and implement an ongoing quality management program that includes a process to review patient-oriented recommendations.
5	The hospital pharmacy manager did not develop, document and implement an ongoing quality management program that includes a process to review a full pharmacist's documentation notes in the hospital's medical records.

Equipment and References

N = 18 items reviewed

2019 - 2020	
Rank	
1	The hospital pharmacy or hospital pharmacy satellite was not adequately equipped to provide safe and proper medication compounding, dispensing and/or preparation of medication orders, and for the provision of patient-oriented and administrative pharmacy services.
2	The minimum and maximum refrigerator temperatures were not consistently recorded at the start and end of each work day in the pharmacy.
3	The College of Pharmacists of BC license displayed in the hospital pharmacy was expired.
4	A pharmacy medication refrigerator was not equipped with a constant temperature-recording device or digital minimum/maximum thermometer (with probe).
5	Standard bar fridges (small volume combination fridge/freezer with one exterior door) were used to store vaccines or biologicals in the pharmacy.

Appendix L: Hospital Pharmacy Professionals Review Top Non-Compliance Items

Hospital Pharmacists

Counselling

N = 21 items reviewed

2019 - 2020	
Rank 1	The pharmacist did not provide information regarding action to be taken in the event of a **missed dose**.
2	The pharmacist did not provide information regarding **how to monitor** the response to therapy.
3	The pharmacist did not provide prescription **refill information** when providing drug consultation to an outpatient or the outpatient's representative, or to an inpatient on request.
4	The pharmacist did not discuss **storage requirements** when providing drug consultation to an outpatient or the outpatient's representative, or to an inpatient on request.
5	The pharmacist did not identify the **name and strength** of the drug when providing drug consultation to an outpatient or the outpatient's representative, or to an inpatient on request.

Documentation

N = 17 items reviewed

2019 – 2020	
Rank 1	The pharmacist did not document directly in the patient record all activities and information pertaining to the drug therapy of the patient.
2	The pharmacist did not document recommendations for changes in drug selection, dosage, duration of therapy, and/or route of administration.
3	The pharmacist did not document allergies, adverse drug reactions and intolerances.

4	The pharmacist verified patient identification, but did not include his/her written confirmation for doing so on an outpatient prescription.
5	The pharmacist verified patient allergy information, but did not include his/her written confirmation for doing so on an outpatient prescription.

Profile Check

N = 21 items reviewed

2019 - 2020	
Rank 1	The pharmacist did not have a process to assess allergies, adverse drug reactions and intolerances before dispensing the patient's drug and at appropriate intervals thereafter.
2	The pharmacist did not check the drug order for the patient's name, location and/or hospital number.
3	The pharmacist did not positively identify an **outpatient** by viewing one piece of primary identification or two pieces of secondary identification.

Patient Identification Verification

N = 2 items reviewed

2019 - 2020	
Rank 1	A pharmacist **did not take reasonable steps to confirm the identity** of a patient, patient's representative, registrant or practitioner before providing any pharmacy service, including but not limited to (a) establishing a patient record, (b) updating a patient's clinical information, (c) providing a printout of an in-pharmacy or requesting a PharmaNet patient record, (d) establishing, deleting, or changing a patient keyword, (e) viewing a patient record, (f) answering questions regarding the existence and content of a patient record, (g) correcting information, and (h) disclosing relevant patient record information to another registrant for the purpose of dispensing a drug or device, and/or for the purpose of monitoring drug use.
2	A pharmacist did not use at least **two person-specific identifiers** to confirm the identity of a patient before providing any pharmacy service to the patient.
3	A pharmacist did not **positively identify an outpatient** by viewing one piece of primary identification or two pieces of secondary identification.

Hospital Pharmacy Technicians

Documentation

N = 8 items reviewed

2019 - 2020	
Rank 1	The pharmacy technician **verified patient allergy information**, but did not include his/her written confirmation for doing so.
2	The pharmacy technician **verified patient identification**, but did not include his/her written confirmation for doing so.
3	The pharmacy technician **verified patient identification**, but **did not include his/her written confirmation** for doing so on the **outpatient** prescription.
4	The registrant **verified patient allergy information**, but **did not include his/her written confirmation** for doing so on the **outpatient** prescription.
5	An **outpatient** prescription **did not include** the written confirmation of the registrant who verified the patient **allergy information** at the time of dispensing.

Patient Identification Verification

N = 3 items reviewed

2019 - 2020	
Rank 1	The registrant used **only one person-specific identifier** to confirm the identity of a patient before providing pharmacy services.
2	The registrant **used a patients room and/or bed number** as a person-specific identifier to confirm the identity of a patient before providing pharmacy services.
3	The registrant **did not use any person-specific identifiers** to confirm the identity of a patient before providing pharmacy services to the patient.
4	The registrant **did not review any identification documents** before providing pharmacy services to an outpatient.

Collaboration

N = 4 items reviewed

2019 - 2020	
Rank 1	The pharmacy technician, when **interacting with a practitioner**, did not identify his or her registrant class.
2	The pharmacy technician, when **answering the telephone**, did not identify his or her registrant class.
3	The pharmacy technician, when **requesting patient information on the phone with a nurse**, did not identify his/her registrant class.
4	The pharmacy technician was **observed participating in the pharmacist/patient consultation** for Schedule I, II or III drugs in person (or by telephone).
5	The pharmacy technician, when gathering, reviewing, entering and/or updating the information required to create and/or maintain a patient record, **did not review the patient's allergies**.

Product Distribution

N = 45 items reviewed

2019 - 2020	
Rank 1	The registrant, when performing the **final check**, did not ensure that the prescription product and the prescription product label matched the product information: the **drug**.
2	The registrant, when **preparing** a prescription product, did not ensure that the prescription product label matched the product information: the **quantity**.
3	The registrant, when performing the **final check** of a prescription product, did not **ensure that a pharmacist had completed a clinical assessment** of the prescription by reviewing the patient profile.

Appendix M: PRP Changes Resulting From Feedback

Feedback Received	Action Taken
Practice reviews at the end of December are disruptive to pharmacies	Practice review schedule modified • No reviews Dec 15-Jan3 • Replaced with CO training
Scheduling of reviews could be more efficient and less disruptive	Increase in scheduling from 2 PPRs to 3 PPRs per day
Flexibility needed to accommodate multiple shifts including graveyard and weekends	Practice Review schedules allow for irregular review times to accommodate pharmacy schedules
Technical difficulties with Pharmacy Pre-Review	IT updates to online Pharmacy Pre-Review
Additional time required to complete Pharmacy Pre-Reviews	Processes implemented to grant extensions for Pharmacy Pre-Reviews
Practice reviews need to reflect diverse practice types	Addition of practice specific question sets
Scheduling emails not received by pharmacy manager	Implementation of phone confirmation
Pharmacy managers required assistance in coordinating staff schedules for reviews	PRP staff provides extra support for scheduling process
Effectiveness of survey questions and tools evaluated	Change in format of survey data collection
Responsiveness of communication with the College could be improved	1 business day response time implemented
Focus areas for PPRs did not effectively reflect pharmacy technician scope	Pharmacy technician specific focus areas implemented
Compatibility issues with Safari (Apple) browser users	College's IT department review and interim communication solutions implemented
Need for continuous IT improvement to better support internal and external users	PRP and the IT department collaboration to explore solutions

Residential Care Review required more time	Allotted additional day for residential care review
Registrants learning from each other's reviews	Insights Articles developed (2019-2020) • Undergoing Pharmacy Renovations? Don't Forget to Report Layout Changes to the College • Blister Packs and Preventing Errors Through Maintenance of Patient Records • Why You Need to Keep Your Pharmacy Information Updated (And How To Do It) • Hospital Pharmacies Providing Pharmacy Services to Outpatients: Releasing Medications • Residential Care • Updating a Patient's Allergies, Adverse Drug Reactions and Intolerances in a Hospital Setting • Pharmacy Managers Role in Scheduling Staff for Professionals Reviews (Hospital Practice)
Legislation is ambiguous/difficult to interpret	Review feedback and results used to inform legislative updates for: • PODSA Ownership and Bylaw Modernization • Security Bylaw • Electronic record keeping • Counselling Bylaw • Opioid Agonist Treatment (OAT) Policies • Mandatory Medication Incident Reporting

Appendix N: 2019-2020 PRP Insights Articles

Undergoing Pharmacy Renovations? Don't Forget to Report Layout Changes to the College
https://www.bcpharmacists.org/readlinks/undergoing-pharmacy-renovations-don%E2%80%99t-forget-report-layout-changes-college

Blister Packs and Preventing Errors Through Maintenance of Patient Records
https://www.bcpharmacists.org/readlinks/blister-packs-and-preventing-errors-through-maintenance-patient-records

Why You Need to Keep Your Pharmacy Information Updated (And How To Do It)
https://www.bcpharmacists.org/readlinks/why-you-need-keep-your-pharmacy-information-updated-and-how-do-it

Hospital Pharmacies Providing Pharmacy Services to Outpatients: Releasing Medications
https://www.bcpharmacists.org/readlinks/hospital-pharmacies-providing-pharmacy-services-outpatients-releasing-medications

PRP Insights - Residential Care
https://www.bcpharmacists.org/readlinks/prp-insights-residential-care

PRP Insights: Updating a Patient's Allergies, Adverse Drug Reactions and Intolerances in a Hospital Setting
https://www.bcpharmacists.org/readlinks/prp-insights-updating-patient%E2%80%99s-allergies-adverse-drug-reactions-and-intolerances-hospital

PRP Insights: Pharmacy Managers Role in Scheduling Staff for Professionals Reviews (Hospitals Practice)
https://www.bcpharmacists.org/readlinks/prp-insights-pharmacy-managers-role-scheduling-staff-professionals-reviews-hospitals

College of Pharmacists of British Columbia

8. Practice Review Committee: Practice Review Program Annual Report

Tracey Hagkull

Chair, Practice Review Committee

James Van

Community Pharmacy Compliance Officer

College of Pharmacists of British Columbia

Outline

- Background
- Practice Review Findings
- Feedback Survey Findings
- Practice Review Impact and Patient Safety
- Next Steps

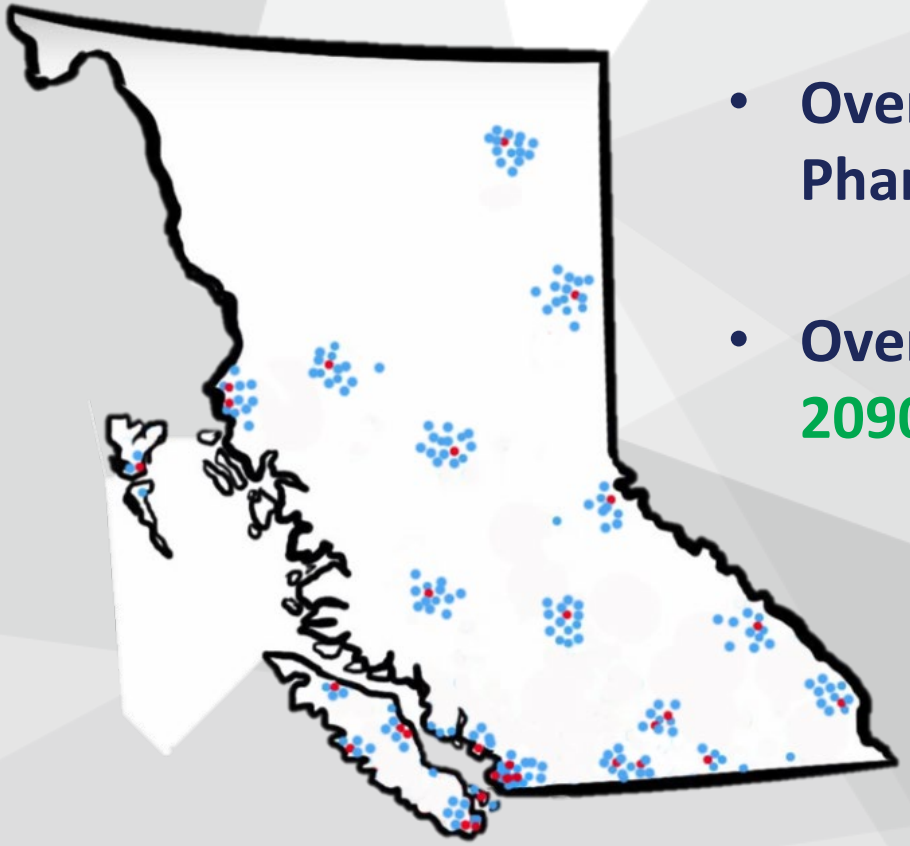
College of Pharmacists of British Columbia

Background

2012-2014	2015	2017	2019
•Changes to quality assurance program initiated •Consultations and program development •Knowledge Assessment Exam discontinued	•Community practice reviews launched	•Hospital practice reviews launched	•Residential Care category launched (optional specialty service category)

College of Pharmacists of British Columbia

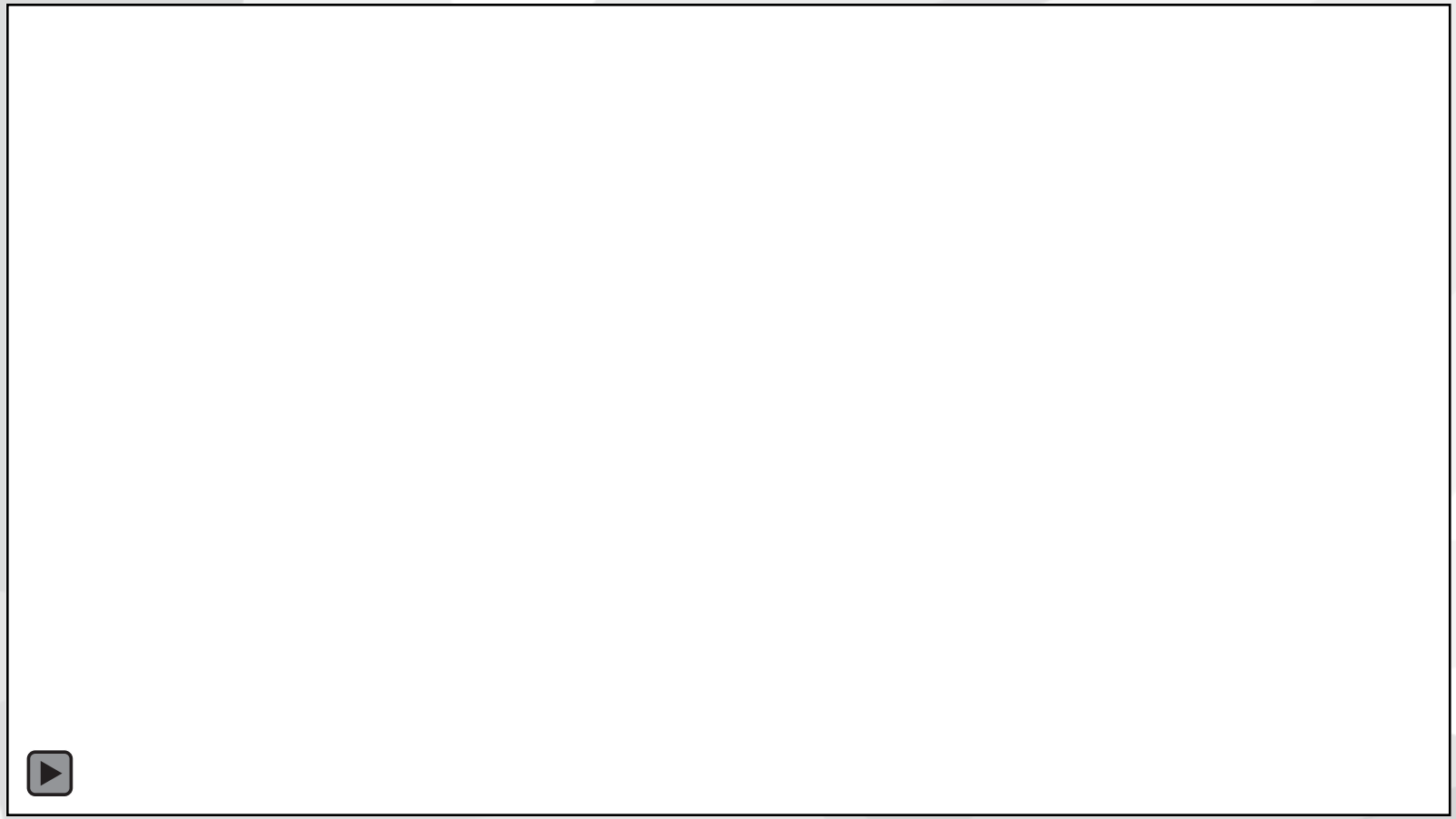
Pharmacy Demographics



- Over 1380 Community & 70 Hospital Pharmacies
- Over 4520 Community Pharmacy & 2090 Hospital Pharmacy Professionals

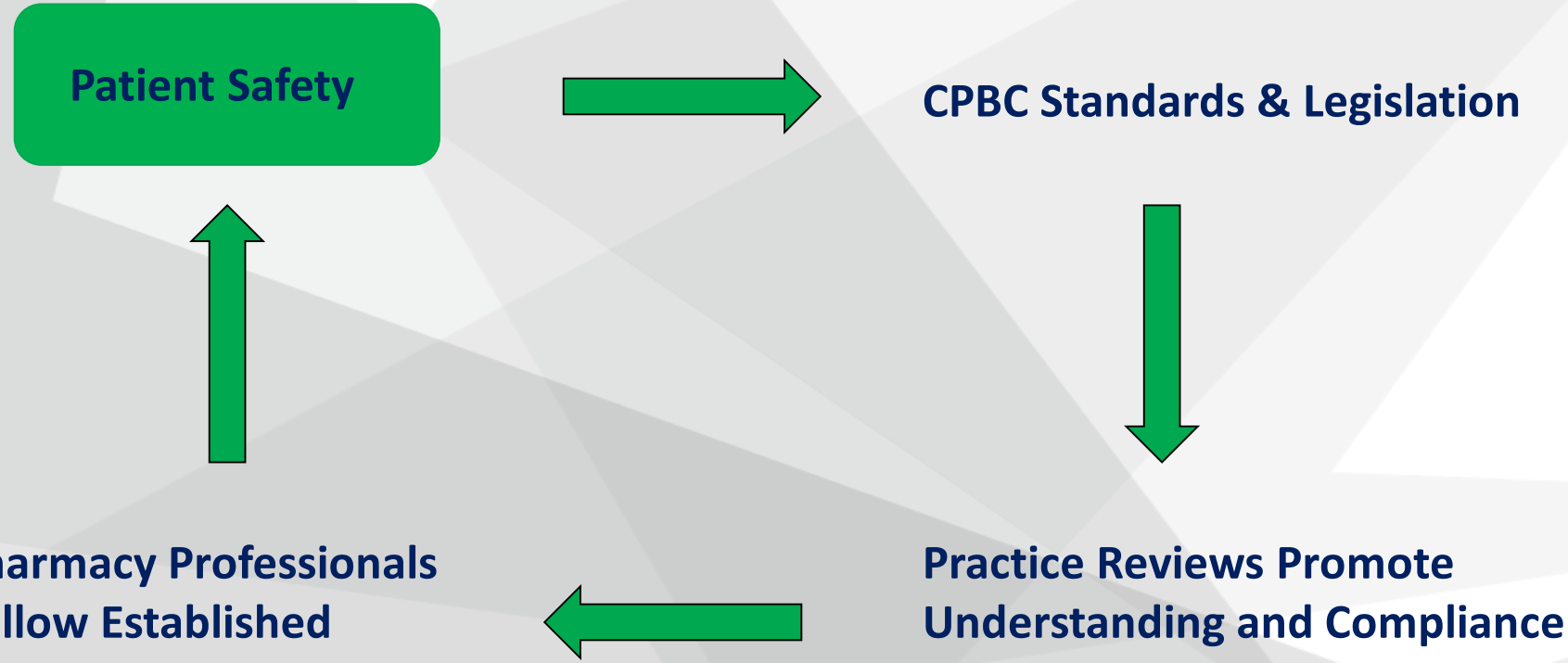
College of Pharmacists of British Columbia

Overview



College of Pharmacists of British Columbia

The Goal



College of Pharmacists of British Columbia

Practice Reviews Conducted 2019-2020

	Pharmacies	Pharmacists	Pharmacy Technicians
Community	279	666	77
Hospital	13	241	200
Total	292	907	277

College of Pharmacists of British Columbia

2019 – 2020 Practice Review Findings

College of Pharmacists of British Columbia

Top Non-Compliance Categories (Year-Over-Year)

Community Pharmacy

2017 – 2018	2018 – 2019	2019 – 2020
Prescriptions	Inventory Management	Prescriptions
Inventory Management	Prescriptions	Inventory Management
Pharmacy Manager Responsibilities	Pharmacy Manager Responsibilities	Pharmacy Manager Responsibilities
Equipment and References	Security	Equipment and References
External to Dispensary	Equipment and References	Security

College of Pharmacists of British Columbia

Top Non-Compliance Categories (Year-Over-Year)

Community Pharmacists

2017 – 2018	2018 – 2019	2019 – 2020
Counselling	Counselling	Counselling
Documentation	Documentation	Documentation
Patient Identification Verification	Patient Identification Verification	Patient Identification Verification
PharmaNet Profile Check	PharmaNet Profile Check	PharmaNet Profile Check

College of Pharmacists of British Columbia

Top Non-Compliance Categories (Year-Over-Year)

Community Pharmacy Technicians

2017 – 2018*	2018 – 2019	2019 – 2020
Documentation	Documentation	Documentation
Product Distribution	Collaboration	Product Distribution
Collaboration	Product Distribution	Collaboration
Counselling	Patient Identification Verification	Patient Identification Verification
Patient Identification Verification		

**RPT-specific focus areas implemented in 2017-2018*

College of Pharmacists of British Columbia

Top Non-Compliance Categories (Year-Over-Year)

Hospital Pharmacy

2017 – 2018	2018 – 2019	2019 – 2020
Inventory Management – Nursing Unit	Sterile Compounding	Sterile Compounding
Pharmacy Manager Responsibilities	Inventory Management – Nursing Unit	Inventory Management – Nursing Unit
Narcotic and Controlled Substances	Pharmacy Manager Responsibilities	Ambulatory Services
Sterile Compounding	Ambulatory Services	Pharmacy Manager Responsibilities
Equipment and References	Equipment and References	Equipment and References

College of Pharmacists of British Columbia

Top Non-Compliance Categories (Year-Over-Year)

Hospital Pharmacists

2017 – 2018	2018 – 2019	2019 – 2020
Patient Identification Verification	Counselling	Counselling
Counselling	Patient Identification Verification	Documentation
	Documentation	Profile Check
		Patient Identification Verification

College of Pharmacists of British Columbia

Top Non-Compliance Categories (Year-Over-Year)

Hospital Pharmacy Technicians

2017 – 2018	2018 – 2019	2019 – 2020
Patient Identification Verification	Patient Identification Verification	Documentation
Documentation	Documentation	Patient Identification Verification
Product Distribution	Collaboration	Collaboration
Collaboration	Product Distribution	Product Distribution

College of Pharmacists of British Columbia

Post-Review

- After on-site review, pharmacy professionals work with COs to correct non-compliance items over the next 30 days.
- Once all non-compliance items are resolved and approved, the review is complete.
- Upon completion, pharmacies and pharmacy professionals are considered to be in compliance with bylaws at that point and can provide feedback.

College of Pharmacists of British Columbia

2019 – 2020 Feedback Survey Findings

College of Pharmacists of British Columbia

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Registrant Feedback Survey

Community Response Rate:

- 36% of reviewed pharmacy registrants responded (N = 198)

Hospital Response Rate:

- 35% of reviewed pharmacy registrants responded (N = 120)

College of Pharmacists of British Columbia

Feedback Survey Findings – Community

Pharmacy Professionals MOST Satisfied with:	Pharmacy Professionals LEAST Satisfied with:
Pharmacy Technician Results (100.00% - Agreement Rating)	**Action Item Portal** (83.84% - Agreement Rating)
Pharmacy Review Scheduling (97.79% - Agreement Rating)	**PRP Tools – Pharmacy Technicians** (84.29% - Agreement Rating)
Pharmacy Technician Review (97.62% - Agreement Rating)	**Pharmacy Pre-Review** (85.29% - Agreement Rating)

College of Pharmacists of British Columbia

Impact Ratings – Community

Impact Rating (-5 to +5 scale)

"Rate the impact to your practice after the Practice Review on a scale of -5 to +5. Use 0 as the baseline (i.e. before the practice review)."

- Negative score = Negative impact on practice
- Positive score = Positive impact on practice
- Zero = No impact on practice

College of Pharmacists of British Columbia

Impact Ratings – Community

Pharmacy Review Overall Impact Rating (-5 to +5 scale)
+2.84

Most Impactful Areas of Pharmacy Review to Practice:
Documentation
Prescriptions
Pharmacy Manager's Responsibilities
Security

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Impact Ratings – Community

Pharmacists Review Impact Rating (-5 to +5 scale)	
Documentation	+2.68
Counselling	+2.52
Patient Identification Verification	+2.15
PharmaNet Profile Check	+1.67

Pharmacy Technicians Review Impact Rating (-5 to +5 scale)	
Documentation	+3.50
Patient Identification Verification	+2.71
Collaboration	+1.79
Product Distribution	+1.29

College of Pharmacists of British Columbia

Grouped Comment Highlights - Community

- Pharmacy pre-review tool should be more user-friendly, concise, and easy to navigate
- Improvements to documentation were most impactful part of review
- PRP should look at clinical decision-making and specialized services (i.e. med reviews, adaptations, and immunizations)
- Not always aware of PRP support tools for Pharmacy Professionals Review
- Review included some components that were not important to pharmacy practice

College of Pharmacists of British Columbia

Grouped Comment Highlights - Community

- COs were professional and knowledgeable
- Expected standards of practice are difficult to meet in their current environment
- Possible increase in length, frequency, or follow-ups of reviews to ensure compliance
- Some technical difficulties using the Action Item Portal

College of Pharmacists of British Columbia

Feedback Survey Findings – Hospital

Pharmacy Professionals MOST Satisfied with:	Pharmacy Professionals LEAST Satisfied with:
Pharmacy Review Results (100.00% - Agreement Rating)	**Pharmacy Review Scheduling** (66.67% - Agreement Rating)
Compliance Officers (99.33% - Agreement Rating)	**Pharmacy Review** (83.33% - Agreement Rating)
Pharmacy Technician Review Results (97.00% - Agreement Rating)	**Pharmacy Pre-Review** (83.33% - Agreement Rating)

College of Pharmacists of British Columbia

Impact Ratings – Hospital

Pharmacy Review Overall Impact Rating (-5 to +5 scale)
+2.00

Most Impactful Areas of Pharmacy Review to Practice:
Inventory Management – Nursing Units
Patient Records and Documentation
Narcotic and Controlled Drug Substances
Equipment and References

College of Pharmacists of British Columbia

Impact Ratings – Hospital

Pharmacists Review Impact Rating (-5 to +5 scale)	
Counselling	+1.20
Patient Identification Verification	+0.78
Documentation	+0.78
Profile Check	+0.62

Pharmacy Technicians Review Impact Rating (-5 to +5 scale)	
Patient Identification Verification	+2.34
Documentation	+1.92
Collaboration	+1.32
Product Distribution	+1.26

College of Pharmacists of British Columbia

Grouped Comment Highlights - Hospital

- Difficult to keep up with regular duties without replacement staff
- Some hospital pharmacists didn't feel much of an impact to their practice
  - For those that did feel an impact, the most impactful was counselling
- Some would like COs to spend more time with them to provide a better picture of their work
- Strong positive comments about experiences with COs
- Suggested alternatives to responding to action items other than using manual excel forms being sent back and forth

College of Pharmacists of British Columbia

Practice Review Impact and Patient Safety

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Patient Safety And the Practice Review Program

- PRP's primary focus is to ensure patients receive safe pharmacy care based on consistent implementation of legislated standards of practice.
- PRP advances the goal of patient safety in many ways, including:
  - Supporting Patient Safety Through Compliance
  - Ongoing Monitoring and Improvement
  - Information Gathering and Dissemination

College of Pharmacists of British Columbia

Supporting Patient Safety Through Compliance

- Compliance as a proxy for patient safety.
- PRP reviews pharmacies and pharmacy professionals for compliance with legislated standards.
- Compliance trend data collected helps COs utilize limited inspection time more effectively.
- Correction of non-compliant items ensures College standards are being met and to support delivery of safe patient care.

College of Pharmacists of British Columbia

Ongoing Monitoring and Improvement

- Anonymous and voluntary survey collects feedback from pharmacy professionals.
- Ensuring practice reviews are positively impactful supports compliance and promotes patient safety.
- Feedback allows PRP to continuously evaluate and make iterative improvements to the program.

College of Pharmacists of British Columbia

Information Gathering and Dissemination

- Information and observations gathered by COs help identify practice trends
- COs help pharmacy professionals interpret information contained in bylaws and promote understanding
- Broad information sharing supports goal of enhancing patient safety
  - *PRP Insights* articles help disseminate important information to pharmacy professionals

College of Pharmacists of British Columbia

PRP Insights 2019-2020

Undergoing Pharmacy Renovations? Don’t Forget to Report Layout Changes to the College
Blister Packs and Preventing Errors Through Maintenance of Patient Records
Why You Need to Keep Your Pharmacy Information Updated (And How To Do It)
Hospital Pharmacies Providing Pharmacy Services to Outpatients: Releasing Medications
PRP Insights - Residential Care
Updating a Patient’s Allergies, Adverse Drug Reactions and Intolerances in a Hospital Setting
Pharmacy Managers Role in Scheduling Staff for Professionals Reviews (Hospitals Practice)

College of Pharmacists of British Columbia

Compliance Officer Insights

- “I find pharmacy managers often will pre-emptively self-correct non-compliant issues they find out about because they know we will be coming at some point anyways.”
- “There are so many times registrants are actually GLAD to see me(us). They are nervous and tentative, but usually part-way through the review they are grateful that we are there to either point out deficiencies or respond directly to practice questions so they can ensure they are doing things correctly.”
- “I want to mention that most of the time registrants are happy to see me; especially at the rural sites because sometimes they may feel more unheard in their small town by the College.”
- “I’ve seen sometimes patient counselling points go unmentioned because some pharmacists think they are irrelevant. After discussing it with them, I can see the “A-Ha!“ moment when they realize how much it impacts patient safety.”

College of Pharmacists of British Columbia

Next Steps

- Overall positive results but there's more to be done
- Collected data will inform future changes and shifts in inspections
- Upcoming PRP application will harmonize community and hospital inspection systems and improve functionality
- Alternative inspection models currently being explored due to COVID-19

College of Pharmacists of British Columbia

Questions

College of Pharmacists of British Columbia

BOARD MEETING
September 18, 2020

9. 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 September 2020
    c. Action Items & Business Arising
    d. Strategic Plan 2020/21 – 2024/25 Update
iii. Approval of June 12, 2020 Draft Board Meeting Minutes **[DECISION]**
iv. Committee Updates
v. Audit and Finance Committee: Finance Report: July Financials
vi. Approval of June 11, 2020 Draft Committee of the Whole Meeting Minutes **[DECISION]**
vii. Pharmacists' Access to Laboratory Values
viii. Recommendations to Modernize the Provincial Health Profession Regulatory Framework
ix. Deputy Registrar Appointment **[DECISION]**

College of Pharmacists of British Columbia

BOARD MEETING
September 18, 2020

2b.i. Chair's Report

INFORMATION ONLY

It is my pleasure to provide this report for the September 2020 Board meeting. Since the previous Board Meeting report (June 2020), I have been involved in the following activities as Board Chair:

General:

- Liaised with Registrar, Vice Chair and Board to plan September 2020 Board meeting
- Reviewed draft June 2020 board meeting and Committee of the Whole meeting minutes
- Attended regular teleconferences with Registrar and Vice-Chair on Board items including those related to September board meeting
- Met with Registrar and Vice Chair to provide the Board's mid-point feedback to Registrar
- Communications regarding Registrar evaluation process
- Completed reappointment submissions for Crown Agencies and Board Resourcing Office (CABRO)
- Liaised with Board members and potential guest speaker future Board meetings
- Answered general questions/queries of fellow Board members

Events:

- Attended NAPRA Annual Meeting of Members, with Registrar and CEO, June 23, 2020

Committees:

- Application Committee
- Audit and Finance Committee
- Governance Committee
- Registrar Evaluation and Succession Planning Committee

College of Pharmacists
of British Columbia

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 24, 2020

Non-profit Tax Return – Filed August 19, 2019

Non-profit Information Return – Filed August 19, 2019

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

Chief Operating Officer

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College of Pharmacists of British Columbia

BOARD MEETING
September 18, 2020

2b.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, the Board will be asked to consider a one-time extension of the deadline to July 2020, in light of the COVID-19 pandemic.**	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. This is set to begin in early 2021.**	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 PRIME and updated SCS document No further update at this point. The current status is still in effect.**	02-2018	IN PROGRESS
4.	Motion: If new requirements are deemed necessary, direct the Registrar to propose that the Ministry of Health consider amending their PharmaNet Professional and Software Compliance Standards document to enhance the software security requirements of the local pharmacy computer systems."	02-2018	IN PROGRESS

	MOTIONS/ACTION ITEMS	RELEVANT BOARD MEETING	STATUS
	Status: Ministry of Health has posted conformance standards and will come into effect December 31/2020.		
5.	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
6.	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: The Ministry of Health has recently requested that a working group be established to explore potential effects of the removal of restrictions on pharmacist injection and intranasal administration of medications in British Columbia. The College and Ministry have drafted a terms of reference and timeline for this working group. The first meeting of the working group was held on October 28, 2019. An update from the first meeting was provided to the Board at the November 2019 Board meeting. The second meeting of the working group was scheduled for February 12, 2020, however cancelled as the Ministry of Health staff we unavailable to attend. The meeting will be rescheduled. Due to emerging priorities related to COVID-19, the planned meeting of the Drug Administration Committee (DAC) to discuss next steps was cancelled. The DAC met on May 25, 2020, the DAC's recommendation on next steps is included in the June Board consent agenda materials. Further, the DAC met on August 14 2020, and information on potential next steps is included in the September Board meeting materials.**	02-2019	IN PROGRESS
7.	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 early August– Draft Model Standards for Continuous Quality Improvement and Medication Incident Reporting sent for**	09-2019	IN PROGRESS

	MOTIONS/ACTION ITEMS	RELEVANT BOARD MEETING	STATUS
	external stakeholder feedback by September 30, 2020. The current status is still in effect.		
8.	Direct the Registrar to review the impact of COVID-19 on the finances of the College before proceeding with operationalizing the fee increases planned for the end of 2020. **Status: The Registrar has reviewed the June financials. A report will be provided at the September Board meeting.**	04-2020	IN PROGRESS

College of Pharmacists of British Columbia

BOARD MEETING
September 18, 2020

2b.ii Registrar's Update
d) Strategic Plan 2020/21 to 2024/25 Update

INFORMATION ONLY

Purpose

To provide an update on the Strategic Plan as of September 2020.

Background

The Board-approved Strategic Plan was recently reviewed by the Committee of the Whole on June 11, 2020. The Management Team also reviewed the Strategic Plan on June 24 and 25th with the focus on operationalizing it, planning action items, resourcing, etc.

Subsequent meetings have been held with key personnel and updates re the Strategic Plan is a regular item on the Management Team's meeting agendas.

Discussion

Work completed to date, includes:

Goal One

- Completed a jurisdiction scan of standards of practice of other BC health regulators as well as each Pharmacy Regulatory Authorities (PRA's) across Canada to determine whether standards of practice are located in a stand-alone document or embedded in bylaw and to identify whether their standards or practice are principle-based or detailed.
- Mapped existing CPBC standards of practice to the NAPRA Model Standards of Practice to determine gaps in current practice.
- Reviewed the existing standards of practice to identify misalignments with current practice as well as using feedback obtained from Practice Reviews and action item follow up.
- Established a working group with representation from each CPBC Department.

Next Steps

Over the next couple of months staff will:

- Continue reviewing hospital standards of practice.
- Begin documenting current collaborative engagement with all healthcare regulators.

College of Pharmacists of British Columbia

BOARD MEETING
September 18, 2020

2b.iii Approval of June 12, 2020 Draft Board Meeting Minutes

DECISION REQUIRED

Recommended Board Motion:

Approve the June 12, 2020 draft Board meeting minutes as circulated.

Appendix	
1	http://library.bcpharmacists.org/2_About_Us/2-1_Board/Board_Videoconference_Minutes-20200612.pdf

College of Pharmacists of British Columbia

BOARD MEETING
September 18, 2020

2b.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 met six times since the June 2020 Board meeting. The committee reviewed nine pharmacy files. Six files were incomplete renewals, two had false/misleading information and one pharmacy file was an eligibility-related case.

ii. Audit and Finance Committee
The Audit and Finance Committee met on August 20, 2020 to review the June financial reports and the COVID-19 impacts on the 2020/21 budget. After reviewing projected multi-year budget scenarios, the Audit and Finance Committee recommended that the budget-approved fee increases be implemented by the Board. The committee also discussed preliminary planning regarding the 2021/22 annual budget.

iii. Discipline Committee
The Discipline Committee had 2 hearings held via videoconference and 0 files heard in court for the period of May 2020 to July 2020. There are five files in progress and one pending file.

iv. Drug Administration Committee
The Drug Administration Committee met once (on August 14) since the June 2020 Board meeting to review and approve of the amendments to the Drug Administration by Injection and Intranasal Route, Standards, Limits and Conditions.

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

vi. Governance Committee

The Governance Committee met on August 27, 2020 via videoconferencing. The committee reviewed the June 12, 2020 Board meeting evaluation survey results and discussed about the following survey comments:

- Continuing education topics (concept of curated group of readings);
- Board meeting format and frequency;
- Board meeting guest speaker shortlist;
- Board meeting visibility protocol;
- San'yas Indigenous Cultural Safety Training for the Board; and
- Timeliness of Board package.

The committee agreed by consensus to expand the Board Vice-Chair role to include an educational portfolio and to continue to monitor comments that come in via the Board meeting evaluation survey. Meeting format and frequency will remain status quo and the committee recommended that the San'yas Indigenous Cultural Safety Training be included in the Board member orientation.

The committee also discussed about the role of Board members on Board committees. This item will be brought to the September Board Committee of the Whole meeting for further discussion with the Board.

vii. Inquiry Committee

The Inquiry committee met four times via videoconference and thirteen times via teleconference for the period of May 2020 to July 2020. Ninety-six files were reviewed or disposed of, of which fifty files were new files, twenty-nine were reconsideration files, and seventeen were PODSA s. 18 report files. 259 calls/tips were received during this reporting period and thirty-three formal complaints were received. The increase in number of files disposed by the Inquiry Committee for the months of May to July 2020 was attributed to Registrants requesting for reconsideration of the terms in their Consent Agreements and registrants breaching terms of their Consent Agreement.

viii. Jurisprudence Examination Subcommittee

The Jurisprudence Examination Subcommittee has not met since the last Board meeting.

ix. Legislation Review Committee

The Legislation Review Committee met on August 18 and 27, 2020. They discussed the items brought forward to the Board's September 2020 meeting. These include: the removal of natural health products from the Drug Schedules Regulation; implementing of the National Association of Pharmacy Regulatory Authorities' Model Standards for Pharmacy Compounding; and, amendments to fee schedules under the *Health Professions Act* and the *Pharmacy Operations and Drug Scheduling Act.* In addition, they received an update on the work being undertaken by the Drug Administration Committee, and on the upcoming legislation-related items.

x. Pharmacy Advisory Committee

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

xi. Practice Review Committee

The Practice Review Committee has not met since the last Board meeting.

xii. Quality Assurance Committee

The Quality Assurance Committee met by videoconference through Microsoft Teams on Thursday June 18th, 2020 and discussed the following agenda items:

- Decision item: no recommendation to Board on further CE exemptions for 2021
- Decision item: continue with 2020 CE Audits
- Review item: responses to the new PDAP Portal and PDAP Mobile Survey

The committee plans to review PDAP policies at their next meeting (October /November date TBD).

xiii. Registrar Evaluation and Succession Planning Committee

The Registrar Evaluation and Succession Planning Committee met on August 18, 2020 via videoconference. The committee reviewed the 2020 Registrar's evaluation calendar and discussed the adjustments necessary due to the impact of COVID-19.

xiv. Registration Committee

The Registration Committee met once (on August 26, 2020) since the June 2020 Board meeting. The committee reviewed two extension request files, one for the jurisprudence examination and the other for a pre-registration application.

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

College of Pharmacists of British Columbia

BOARD MEETING
September 18, 2020

2b.v. Audit and Finance Committee: Finance Report (July Financials)

INFORMATION ONLY

Purpose

To report on the highlights of the **July 2020** financial reports.

Background

The July 2020 financial reports reflect **five month's** activity over a **five month period**. The Appendices to this briefing note include the following:

- A Statement of Financial Position;
- A summary Statement of Revenue and Expenditures; and,
- Detailed reports on Revenue and on Expenditures.

Statement of Financial Position

The College's cash position is well funded to meet payables with a balance of over $2,119,000. Investments totalled just over $4,750,000. Payables and accruals are just over $500,000.

The Working Capital Ratio (a test of liquidity) is 1.1.

Revenue

The total *Licensure revenues* are slightly under budget, by about $126,000 or 3%. This is primarily due to one-time fees, particularly Jurisprudence Exam fees as well as the 2020 UBC grads being unable to register as full pharmacists. *Other revenues* (administrative fees, etc.) are under budget by about $11,000, mainly due to fines received, while Grant revenue is under budget due to timing until the one remaining grant milestone payment has completed the next milestone. Investment income is under budget by about $10,000, while Joint Venture income is right on budget. The combined result is that actual revenues are under budget, approximately $150,000 or 4% under budget.

Expenses

Total Year to Date Actual expenditures are considerably under budget, by almost $779,000 or 16%. See the variance analysis which follows for details. Much of the under-budget variances are due to changes in operations due to COVID-19.

Variance analysis by department:

Department	Budget	Actual	Comment
Board & Registrar's Office	337,161	244,548	Reduced travel and accommodation and conferences.
Finance and Administration	873,306	825,163	Reduced professional development, some timing re IT projects.
Information Technology	1,010,825	830,060	Timing as project priorities changed due to COVID-19
Registration & Licensure	437,056	373,731	Salary gapping and reduced committee travel and accommodation.
Quality Assurance	139,352	117,093	Timing.
Practice Review	707,883	595,726	Reduced travel and accommodation for committee meetings and compliance officers as well as timing re outside services.
Complaints Resolution	798,652	638,764	Salary gapping and timing re legal and outside services.
Policy and Legislation	234,063	203,567	Salary gapping.
Communications & Engagement	176,621	166,540	Timing re engagement activities.
Projects (PODSA Modernization)	53,570	0	Timing re outside services.
Amortization	123,702	118,002	
Total Expenses	4,892,191	4,113,194	16% under budget. ($778,997)

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

College of Pharmacists of BC

Statement of Financial Position

As at July 31, 2020

ASSETS	
Cash and Cash Equivalents	2,119,054
Investments	4,750,256
Receivables	61,224
Prepaid Expense and Deposits	284,433
Current Assets	7,214,966
Investments in College Place Joint Venture	1,479,565
Development Costs	147,310
Property & Equipment	687,424
Non-current Assets	2,314,299
Total Assets	**9,529,265**

LIABILITIES AND NET ASSETS	
Payables and Accruals	519,702
Capital Lease Obligations (Current)	5,107
Deferred Revenue	5,929,619
Deferred Contributions	60,237
Total Current Liabilities	6,514,666
Capital Lease Obligations (non-current)	32,719
Total Liabilities	6,547,385
Total Net Assets	2,981,880
Total Liabilites and Net Assets	**9,529,265**

College of Pharmacists of BC

Statement of Revenue and Expenses

For the 5 months ended July 31, 2020

	Budget YTD 2020/21	Actual YTD 2020/21	Variance ($) (Budget vs. Actual)	Variance (%) (Budget vs. Actual)
Revenue				
Licensure revenue	3,968,993	3,843,225	(125,769)	(3%)
Non-licensure revenue	202,776	177,980	(24,796)	(12%)
Transfer from Balance Sheet	-	-	-	0%
Total Revenue	**4,171,769**	**4,021,205**	**(150,565)**	(4%)
Total Expenses Before Amortization	4,768,490	3,995,192	773,298	16%
Amortization	123,702	118,002	5,699	5%
Total Expenses Including Amortization	**4,892,191**	**4,113,194**	**778,997**	16%
Net Surplus/(Deficit) of revenue over expenses after amortization expense	**(720,422)**	**(91,990)**	**628,432**	

College of Pharmacists of BC

Statement of Revenue

For the 5 months ended July 31, 2020

	Budget YTD 2020/21	Actual YTD 2020/21	Variance ($) (Budget vs. Actual)	Variance (%) (Budget vs. Actual)
Revenue				
Pharmacy fees	1,517,986	1,484,048	(33,938)	(2%)
Pharmacists fees	2,066,689	1,998,951	(67,738)	(3%)
Technician fees	384,318	360,225	(24,093)	(6%)
Licensure revenue	**3,968,993**	**3,843,225**	**(125,769)**	**(3%)**
Other revenue (fines/assessments, late fees, certificate of letter of standing)	39,987	29,288	(10,700)	(27%)
Grant Revenue	5,567	1,560	(4,007)	(72%)
Investment income	54,533	44,443	(10,090)	(19%)
College Place joint venture income	102,689	102,689	0	0%
Non-licensure revenue	**202,776**	**177,980**	**(24,796)**	**(12%)**
Transfer from Balance Sheet	-	-	-	0%
Total Revenue	**4,171,769**	**4,021,205**	**(150,565)**	(4%)

College of Pharmacists of BC

Statement of Expenses

For the 5 months ended July 31, 2020

	Budget YTD 2020/21	Actual YTD 2020/21	Variance ($) (Budget vs. Actual)	Variance (%) (Budget vs. Actual)
Expenses				
Board and Registrar's Office	337,162	244,549	92,613	27%
Finance, Human Resources and Administration	873,306	825,163	48,143	6%
Information Technology	1,010,825	830,060	180,766	18%
Registration and Licensure	437,056	373,731	63,325	14%
Quality Assurance	139,352	117,093	22,259	16%
Practice Reviews	707,883	595,726	112,157	16%
Complaints and Investigations	798,652	638,764	159,888	20%
Policy and Legislation	234,063	203,567	30,496	13%
Communications and Engagement	176,621	166,540	10,081	6%
Projects	53,570	-	53,570	100%
Total Expenses Before Amortization	4,768,490	3,995,192	773,298	16%
Amortization	123,702	118,002	5,699	5%
Total Expenses Including Amortization	**4,892,191**	**4,113,194**	**778,997**	16%

College of Pharmacists of British Columbia

BOARD MEETING
September 18, 2020

2b.vi Approval of June 11, 2020 Draft Committee of the Whole Meeting Minutes

DECISION REQUIRED

Recommended Board Motion:

Approve the June 11, 2020 draft Committee of the Whole meeting minutes as circulated.

Appendix	
1	June 11, 2020 Draft Committee of the Whole Meeting Minutes (and appendices)

College of Pharmacists of British Columbia

Committee of the Whole Meeting
June 11, 2020
Via Video Conference

MINUTES

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

Staff:
Bob Nakagawa, Registrar
David Pavan, Deputy Registrar
Ashifa Keshavji, Director of Practice Reviews and Quality Assurance
Doreen Leong, Director of Registration and Licensure
Mary O'Callaghan, Chief Operating Officer
Anu Sharma, Acting Director of Policy and Legislation
Gillian Vrooman, Director of Communications and Engagement
Stephanie Kwok, Executive Assistant

Guest:
Karen Graham, CEO, Panacea Canada Inc

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1. **WELCOME & CALL TO ORDER**
   Chair Antler called the meeting to order at 8:32am on June 11, 2020.

   Chair Antler acknowledged the Coast Salish People on whose unceded traditional territories the meeting is being chaired from, the Coast Salish, Squamish and Tsleil-Waututh First Nations. She also recognized that participants are joining from other First Nations unceded traditional territories across BC.

2. **COVID-19 AND THE STRATEGIC PLAN SESSION**
   Karen Graham, CEO, Panacea Canada Inc, facilitated a session with the Board on the impact of COVID-19 on the College strategic direction. The Board discussed the learnings from the major disruption brought about by COVID-19 and identified considerations for the Board in order to serve and protect the public.

College of Pharmacists of British Columbia

3. BLACK LIVES MATTER

Chair Antler led a discussion with the Board on Black Lives Matter in preparation for consideration at the Board meeting on June 12th.

Registrar Nakagawa reported that a working group has been established to develop a plan to guide the College in raising awareness of the racism faced by Black people in BC.

The Board is in support of the work that the College has committed to take on in this regard. A message from the Registrar about Black Lives Matter will be posted after the Board meeting.

4. A WHITE PAPER ON TEAM-BASED PRIMARY HEALTH CARE IN BRITISH COLUMBIA

Barbara Gobis, Director, UBC Pharmacists Clinic and Peter Zed, UBC Professor and Associate, Practice Innovation presented on the context and opportunities for Pharmacists in team-based primary health care.

ADJOURNMENT

Chair Antler adjourned the meeting at 2:09pm on June 11, 2020.

College of Pharmacists of British Columbia

BOARD MEETING
September 18, 2020

2b.vii Pharmacists' Access to Laboratory Values

INFORMATION ONLY

Purpose

To provide an update to the Board on the access to laboratory values initiative.

Background

In British Columbia, community-based pharmacists do not have direct access to patient-specific laboratory results necessary for therapeutic decision making and monitoring of drug therapy. At present, pharmacists working within the province's health authorities can directly access laboratory test results through integrated health information systems (i.e., electronic health records). However, community-based pharmacists must request laboratory test results from either the patient directly or another healthcare provider (with the patient's permission) within the patient's circle of care who does have access.

Across the country, pharmacist access to laboratory data varies by province. Currently, pharmacists in Alberta, Manitoba, Quebec and Prince Edward Island have the authority to order and/or interpret laboratory values[1].

The College has sought to expand pharmacist access to laboratory data for over five years:

- One of the goals in the 2014 Strategic Plan included the introduction of legislation supporting access to patient laboratory data.
- An objective in the 2018 Strategic Plan was to seek greater access to patient laboratory values to enhance pharmacists' ability to provide quality, timely service to patients.
- While not specifically noted in the 2020 Strategic Plan, one of that Strategic Plan's goals (i.e., that the public is given evidence-informed, patient-centred, team based care) aligns well with an aim to enhance access to laboratory values.

Discussion

Expanding pharmacist access to laboratory values has proven challenging, as it is not a goal that the College can achieve on its own. It relies on the Province of British Columbia and/or private companies, to implement a technological solution. However, in understanding the value of this initiative from a public safety perspective, the College has continued to work on it.

[1] https://www.pharmacists.ca/cpha-ca/assets/File/pharmacy-in-canada/Scope%20of%20Practice%20in%20Canada_June2020.pdf

In 2019, the College engaged with many stakeholders to move this initiative forward, including:

- Laboratory and Blood Services Branch, Ministry of Health;
- Provincial Laboratory Information Solution staff, Ministry of Health;
- Excelleris Technologies, a health technology company and subsidiary of LifeLabs;
- David Loukidelis, former BC Privacy Commissioner, to discuss potential legal issues within the *Laboratory Services Act*, *E-Health (Personal Health Information Access and Protection of Privacy) Act* and other privacy legislation; and,
- Pharmacy regulatory authorities across Canada.

Recently, in June 2020, College staff communicated with staff from the Pharmacists Clinic at the UBC Faculty of Pharmaceutical Sciences ("the Pharmacists Clinic"). The Pharmacists Clinic has been working closely with the Provincial Health Services Authority ("PHSA") to obtain approval to access CareConnect, and are anticipating access to that system in fall 2020. CareConnect is British Columbia's secure, view-only Electronic Health Record solution. It offers healthcare providers access to an integrated, view of patient-centric information to support the delivery of patient care. CareConnect is widely used within the provincial health authorities, with over 66,000 healthcare professionals enrolled to support direct patient care.

In July 2020, College staff received communication from PHSA indicating support for community-based pharmacists to have access to CareConnect. In fact, staff from PHSA have submitted a funding proposal to support broad deployment across the province, and is awaiting a response from the Ministry of Health. The PHSA also noted that the College could support this work by identifying its privacy-related requirements and processes.

Next Steps

In support of the PHSA proposal to expand access to CareConnect, the College will communicate with the Ministry of Health, with respect to its privacy requirements and related processes.

College of Pharmacists of British Columbia

BOARD MEETING
September 18, 2020

2b.ix Deputy Registrar Appointment

DECISION REQUIRED

Recommended Board Motion:

Appoint Mary O'Callaghan as Deputy Registrar of the College of Pharmacists of British Columbia in accordance with the Health Professions Act Bylaws section 22, subsection 2, effective immediately.

Purpose

In the event that the Registrar is unavailable or unable to perform his duties, an appointed Deputy Registrar may act in his place. This is a Board appointment as per section 22, subsection 2 of the *Health Professions Act Bylaws.*

22(2) If a deputy registrar is appointed by the Board,

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

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

Background

Since Deputy Registrar Pavan is on leave until further notice, it would be advisable to appoint another Deputy Registrar at this time.