College of Pharmacists of British Columbia

**Board Videoconference**
**May 7, 2020**
**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
Katie Skelton, Government Appointee
Justin Thind, Government Appointee

**Regrets:**
Anne Peterson, 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
Laura Briard, Policy and Legislation Analyst
Kimberly Hilchie, Pharmacy Policy Consultant
Stephanie Kwok, Executive Assistant

---

1. **WELCOME & CALL TO ORDER**
   Chair Antler called the meeting to order at 4:33pm on May 7, 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.

2. **CHAIR'S UPDATES**
   Chair Antler provided an update regarding the regular June Board meeting. Board members were asked via email to provide to the Chair topics of interest to include in the Committee of the Whole agenda.

College of Pharmacists of British Columbia

Chair Antler anticipates that today's call will be the end of the emergency Board teleconferences and should there be items needing Board approval, advance notice will be given to the Board before scheduling.

**3. REGISTRAR'S UPDATES**

Registrar Nakagawa provided an update to the Board about Premier, John Horgan's announcement of BC's Restart Plan. The management team is considering how continuation of social distancing will affect College's operations.

**4. LEGISLATIVE UPDATES**

The Policy and Legislation team has completed all the necessary legislative changes in response to the COVID-19 pandemic. The team is working closely with the Ministry of Health on other bylaw amendments to be brought forward to the Board for approval at later dates.

**5. FILING OF CONSEQUENTIAL AMENDMENTS TO THE PHARMACY OPERATIONS AND DRUG SCHEDULING ACT BYLAWS TO TEMPORARILY PERMIT RETURN TO INVENTORY INJECTABLE DRUGS PREVIOUSLY DISPENSED FOR THE PURPOSE OF MEDICAL ASSISTANCE IN DYING (APPENDIX 1)**

Anu Sharma, Acting Director of Policy and Legislation presented to the Board the comments received from the public posting period of the considered amendments to the Dispensing Drugs for the Purposes of MAiD Standards, Limits and Conditions under the *Health Professions Act* and consequential amendments to the PODSA Bylaws to temporarily allow return to inventory, injectable drugs previously dispensed for the purpose of providing MAiD, approved at the April 30, 2020 Board meeting.

It was moved and seconded that the Board:

Approve the following resolution to amend the *Pharmacy Operations and Drug Scheduling Act* Bylaws consequentially:

*"RESOLVED THAT, in accordance with the authority established in section 21(1) of the Pharmacy Operations and Drug Scheduling Act and subject to the requirements in section 21(4) of the Pharmacy Operations and Drug Scheduling Act, the Board of the College of Pharmacists of British Columbia approves the proposed bylaws, as circulated, for filing with the Minister of Health."*

**CARRIED**

**6. AMENDMENTS TO PROFESSIONAL PRACTICE POLICY-58 MEDICATION MANAGEMENT (ADAPTING A PRESCRIPTION)(APPENDIX 2)**

Anu Sharma, Acting Director of Policy and Legislation presented to the Board options and recommendations for temporary amendments to PPP-58 in light of the COVID-19 public health emergency. The temporary amendments approved were:

- Permitting the adaptation of transferred prescriptions; and,
- Removing the limitation on drug categories for therapeutic substitution where there is an actual drug shortage.

College of Pharmacists of British Columbia

It was moved and seconded that the Board:

1. Approve amendments to *Professional Practice Policy 58 - Amendment to Orientation Guide – Medication Management (Adapting a Prescription)* in light of COVID-19, to be effective immediately.

2. Approve amendments to *Professional Practice Policy 58 - Orientation Guide – Medication Management (Adapting a Prescription)* in light of COVID-19, to be effective immediately.

**CARRIED**

**ADJOURNMENT**

Chair Antler adjourned the meeting at 5:45pm on May 7, 2020.

College of Pharmacists of British Columbia

# BOARD MEETING
# May 7, 2020

## 5. Filing of Consequential Amendments to the *Pharmacy Operations and Drug Scheduling Act* Bylaws to Temporarily Permit Return to Inventory Injectable Drugs Previously Dispensed for the Purpose of Medical Assistance in Dying

## DECISION REQUIRED

### Recommended Board Motion:

Approve the following resolution to amend the *Pharmacy Operations and Drug Scheduling Act* Bylaws consequentially:

*"RESOLVED THAT, in accordance with the authority established in section 21(1) of the Pharmacy Operations and Drug Scheduling Act and subject to the requirements in section 21(4) of the Pharmacy Operations and Drug Scheduling Act, the Board of the College of Pharmacists of British Columbia approves the proposed bylaws, as circulated, for filing with the Minister of Health."*

### Purpose

To approve consequential amendments to the *Pharmacy Operations and Drug Scheduling Act* ("PODSA") Bylaws to temporarily allow return to inventory, injectable drugs previously dispensed for the purpose of providing Medical Assistance in Dying ("MAiD") for filing with the Minister of Health ("the Minister").

### Background

At its meeting on April 30, 2020, the Board considered amendments to the *Dispensing Drugs for the Purposes of MAiD Standards, Limits and Conditions* under the *Health Professions Act* ("HPA") and consequential amendments to the PODSA Bylaws to temporarily allow return to inventory, injectable drugs previously dispensed for the purpose of providing MAiD. On April 30, 2020, the Board approved amendments to the HPA Bylaws *Schedule F Part 5 – Dispensing Drugs for the Purposes of MAiD Standards, Limits and Conditions* for filing with the Minister. The Board also approved consequential amendments to the PODSA Bylaws for public posting and requested a shortened public posting period from the Minister to bring the amendments

into force as soon as possible. The Board Briefing note from April 30, 2020 is attached as Appendix 1.

On April 30, 2020, the amendments to the PODSA Bylaws were publicly posted, with permission from the Minister to post for a minimum of 24 hours.

## Discussion

The consequential amendments to the PODSA Bylaws were posted on the College's website and distributed to the Minister and all regulatory colleges under the *Health Professions Act*. The public posting period ended on May 1, 2020 at 6:00 pm. A total of four responses were received, one from the BC Pharmacy Association, one from the Provincial Health Services Authority and two from registrants. All comments received were supportive of the consequential amendments.

All comments received during the public posting period are attached in Appendix 2.

## Guiding Questions

When reviewing the public posting feedback, the Board is asked to consider:

- Are there any concerns identified in the public posting feedback that need to be addressed?
- Is there anything unclear, ambiguous, or unnecessary in the consequential amendments?
- Is there anything missing from the consequential amendments?

## Recommendations

That the Board approve the consequential amendments to the PODSA Bylaws (Appendix 3 and 4) to temporarily allow return to inventory, injectable drugs previously dispensed for the purpose of providing MAiD.

## Next Steps

If approved by the Board, the proposed bylaws would be filed with the Minister as required under s. 21(4) of PODSA, with a request to shorten the filing period. The amended bylaws will come into effect after the filing period (to be determined by the Minister) assuming that they are not disallowed by the Minister.

Staff have developed a ReadLinks article to communicate the amendments to registrants and the public (see Appendix 5).

| **Appendix** | |
|---|---|
| 1 | April 30, 2020 Board Briefing Note on Amendments to *Health Professions Act* Bylaws – *Dispensing Drugs for the Purposes of Medical Assistance in Dying Standards, Limits and Conditions* |
| 2 | Comments/Feedback received during public posting period |
| 3 | Consequential Amendments to the *Pharmacy Operations and Drug Scheduling Act* Bylaws (track changes) |
| 4 | Schedule of amendments to the *Pharmacy Operations and Drug Scheduling Act* Bylaws |
| 5 | Draft ReadLinks article |

College of Pharmacists of British Columbia

# BOARD MEETING
# April 30, 2020

## 8. Amendments to *Health Professions Act* Bylaws – *Dispensing Drugs for the Purposes of Medical Assistance in Dying Standards, Limits and Conditions*

## DECISION REQUIRED

### Recommended Board Motions:

1. Approve the following resolution to amend the *Health Professions Act* Bylaws Schedule F Part 5 – Dispensing Drugs for the Purposes of Medical Assistance in Dying Standards, Limits and Conditions to temporarily allow return to inventory, injectable drugs previously dispensed for the purpose of providing MAiD:

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

2. Approve the following resolution to amend the *Pharmacy Operations and Drugs Scheduling Act* Bylaws consequentially:

   *"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, as circulated.*

### Purpose

To propose amendments to the *Dispensing Drugs for the Purposes of Medical Assistance in Dying ("MAiD") Standards, Limits and Conditions* under the *Health Professions Act* ("HPA") and consequential amendment to the *Pharmacy Operations and Drug Scheduling Act* ("PODSA") Bylaws to temporarily allow return to inventory, injectable drugs previously dispensed for the purpose of providing MAiD.

## Background

The College has authority under the HPA to establish, monitor and enforce standards of practice.[1] Under this authority, the College has established standards of practice that apply to full pharmacists dispensing drugs for the purposes of MAiD.[2] Pharmacists who dispense drugs for MAiD must comply with the College's bylaws as well as the British Columbia Pharmacy Protocols for MAiD developed by the Provincial Medical Assistance in Dying Working Group's Sub-Committee on Pharmacy.[3]

At present the *Dispensing Drugs for the Purposes of MAiD Standards, Limits and Conditions* require that "The full pharmacist must contact the prescribing medical practitioner or nurse practitioner after the scheduled date and time of drug administration to collaborate relating to the return, within 72 hours of the patient's death, of any unused and partially used medications to the pharmacist for disposal".

Recently, Health Canada listed medications used for MAiD as "Tier 3" drug shortages.[4] "Tier 3" drugs shortages are those that have the greatest potential impact on Canada's drug supply and health care system. Impact is based on low availability of alternative supplies, ingredients or therapies. Many of the drugs used in the MAiD intravenous drug protocol are listed as "Tier 3" drug shortages, and these drugs may also be used in the treatment of patients with COVID-19 who require critical care.

## Discussion

In response to current shortages of drugs used for MAiD, a temporary amendment is proposed to the *Dispensing Drugs for the Purposes of MAiD Standards, Limits and Conditions* to temporarily allow return to inventory, injectable drugs previously dispensed for the purpose of providing MAiD. The proposed amendment would include the following exemption:

> *If there is a shortage of medication for medical assistance in dying, a pharmacist may accept for return to inventory, injectable medication previously dispensed for the purpose of providing medical assistance in dying if they are satisfied that:*

---

[1] As per section 16(2)(d) of the *Health Professions Act,* "A college has the following objects: to establish, monitor and enforce standards of practice to enhance the quality of practice and reduce incompetent, impaired or unethical practice amongst registrants".

[2] *Health Professions Act* Bylaws Schedule F, Part 5 – Dispensing Drugs for the Purposes of Medical Assistance in Dying Standards, Limits and Conditions, http://library.bcpharmacists.org/6_Resources/6-1_Provincial_Legislation/5195-HPA_Bylaws_MAID.pdf.

[3] This group is comprised of the Health Authorities of B.C., the College of Pharmacists of B.C., the College of Physicians and Surgeons of B.C., the College of Registered Nurses of B.C., the B.C. Pharmacy Association, the Canadian Society of Hospital Pharmacies (B.C. Branch), and the B.C. Ministry of Health.

[4] Health Canada Tier 3 shortages list, https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/covid19-interim-order-drugs-medical-devices-special-foods/information-provisions-related-drugs-biocides/tier-3-shortages.html#wb-auto-5

a) *the medication has not left the possession of the prescribing medical practitioner or nurse practitioner, or a licensed health care professional assigned by the physician or nurse practitioner and the integrity of the medications can be verified;*
b) *each dose is unused and in the original sealed tamper proof kit; and,*
c) *the medication has been maintained in accordance with the manufacturer's requirements and any other applicable requirements.*

Recently, the College of Physicians and Surgeons of British Columbia and the British Columbia of Nursing Professionals temporarily modified their standards, limits and conditions for MAiD to allow physicians and nurse practitioners to delegate or assign the return of MAiD drugs to a another physician, nurse practitioner, licensed practical nurse, registered nurse, registered psychiatric nurse or pharmacist to the pharmacy. This change is in effect during the COVID-19 public health emergency in British Columbia. The proposed amendment reflects this temporary change.

In addition to the proposed amendment to the *Dispensing Drugs for the Purposes of MAiD Standards, Limits and Conditions* noted above, a consequential amendment to the PODSA Bylaws is also required.

The current PODSA Bylaws state that "no registrant may accept for return to stock or reuse any drug previously dispensed except in accordance with the *Residential Care Facilities and Homes Standards of Practice* or the *Hospital Pharmacy Standards of Practice*". The proposed consequential amendment to the PODSA Bylaws includes a reference to the *Dispensing Drugs for the Purpose of Medical Assistance in Dying Standards, Limits and Conditions.*

The proposed amendments have been reviewed by the Provincial Medical Assistance in Dying Working Group's Sub-Committee on Pharmacy. These amendments are also supported by the Ministry of Health.

## Guiding Questions

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

- Do the proposed amendments address the issue of current COVID-19 related drug shortages for drugs used in MAiD?
- Do the proposed amendments ensure clarity?
- Is there anything missing from the proposed amendments?

## Next Steps

- If approved by the Board, submit proposed amendments to the *Dispensing Drugs for the Purposes of MAiD Standards, Limits and Conditions* to the Ministry of Health for filing (with a request to shorten the filing period);
- If approved by the Board, post the consequential PODSA Bylaw amendment on the College website for the period approved by the Ministry of Health;
- Pending review of any feedback received, the consequential PODSA Bylaws amendment will be brought to the Board for approval as soon as possible; and,
- Communication of the amendments to the public and registrants.

## Recommendation

Staff recommends that the Board approve the proposed amendments to the *Dispensing Drugs for the Purposes of MAiD Standards, Limits and Conditions* (see Appendix 1 and 2) under the HPA and consequential amendment to the PODSA Bylaws (see Appendix 3).

| **Appendix** | |
|---|---|
| 1 | Amendments to the *HPA Bylaws Schedule F Part 5 – Dispensing Drugs for the Purposes of Medical Assistance in Dying Standards, Limits and Conditions* |
| 2 | Schedule of amendments to the *HPA Bylaws Schedule F Part 5 – Dispensing Drugs for the Purposes of Medical Assistance in Dying Standards, Limits and Conditions* |
| 3 | Consequential Amendments to the PODSA Bylaws (track changes) |

# HPA BYLAWS SCHEDULE F
# Part 5 – DISPENSING DRUGS FOR THE PURPOSES OF MEDICAL ASSISTANCE IN DYING STANDARDS, LIMITS AND CONDITIONS

## STANDARDS

1. The full pharmacist must work in a collaborative team based approach with the medical practitioner or nurse practitioner throughout the process.

2. The full pharmacist must discuss and confirm with the prescribing medical practitioner or nurse practitioner:
   (a) The patient's drug therapy;
   (b) The patient's eligibility and consent for medical assistance in dying;
   (c) The protocol selected;
   (d) The scheduled time and date for the administration of medical assistance in dying;
   (e) The time required to order and prepare the drugs;
   (f) Completion of the medication administration record; and
   (g) The procedures for returning unused drugs to the pharmacy.

3. The full pharmacist must ensure that the drugs dispensed for the purposes of medical assistance in dying are **labeled** as required by the current Standards of Practice and that the drugs are labeled in order of the administration as per the protocol selected.

4. The full pharmacist must **dispense** the drugs:
   (a) In a sealed tamper proof kit;
   (b) With a medication administration record listing all of the drugs included in the kit that also identifies the order of their administration; and
   (c) With the written agreed upon procedures in (2) (g).

5. The full pharmacist must contact the prescribing medical practitioner or nurse practitioner after the scheduled date and time of drug administration to collaborate relating to the return, within 72 hours of the patient's death, of any unused and partially used medications to the pharmacist for disposal. Upon receipt of the returned medications and the medication administration record from the prescribing medical practitioner or nurse practitioner, the full pharmacist must review the medication administration record for reconciliation of returned medications.

   Notice: May 5, 2020 Effective immediately and for the duration of the COVID-19 public health emergency in British Columbia, the prohibition on return and re-use of previously dispensed medical assistance in dying medications is subject to the following exemption. If there is a shortage of medication for medical assistance in dying, a pharmacist may accept for return to inventory, injectable medication previously dispensed for the purpose of providing medical assistance in dying if they are satisfied that:
   a) the medication has not left the possession of the prescribing medical practitioner or nurse practitioner, or a licensed health care professional assigned by the physician or nurse practitioner; and the integrity of the medication can be verified;
   b) each dose is unused and in the original sealed tamper proof kit; and,
   c) the medication has been maintained in accordance with the manufacturer's requirements and any other applicable requirements.

5.6. The full pharmacist who dispenses a substance in connection with the provision of medical assistance in dying must provide the B.C. Ministry of Health with the information referred to in Schedule 7 of the *Regulations for the Monitoring of Medical Assistance in Dying* made under the *Criminal Code* (Canada), as well as the additional information required for provincial oversight, monitoring and reporting purposes. The information shall be documented on the provincial form designated for this purpose and submitted to the


College of Pharmacists of British Columbia | 200-1765 West 8th Ave Vancouver, BC, V6J 5C6 | Tel: 604.733.2493 | www.bcpharmacists.org

B.C. Ministry of Health within 6 business days after the day on which the substance is scheduled to be administered to the patient. The information to be documented by the full pharmacist includes but is not limited to the following:

(a) The date and time the drugs were dispensed;
(b) The name and signature of the medical practitioner or nurse practitioner to whom the drugs were dispensed; and
(c) If the medical practitioner or nurse practitioner to whom the drugs were dispensed is not known to the pharmacist, that the pharmacist confirmed the prescribing medical practitioner's or nurse practitioner's identity by means of photo identification.

6.1. The full pharmacist must comply with any request for information or provision of records sought by the B.C. Ministry of Health for the purpose of oversight and monitoring of medical assistance in dying.

~~6.~~7. The following Standards of Practice do not apply to medical assistance in dying:

(a) Sections 6(5) (c) and (e), 6(6), 10 (1) and (2), 11(4)(f) and (g), and 12 of the Health Professions Act Bylaws, Schedule F, Part 1;
(b) Sections 13(5) and (8) of the Health Professions Bylaws, Schedule F, Part 2; and
(c) Sections 8 and 9 of the Health Professions Act Bylaws, Schedule F, Part 3.

~~7.~~8. Where there is an inconsistency between this Part and any other Part of Schedule F, the provisions of this Part prevail.

## LIMITS

1. Only a full pharmacist may dispense drugs for the purposes of medical assistance in dying.

2. A full pharmacist may delegate to a pharmacy technician any aspect of the preparation of drugs for the purposes of medical assistance in dying that is within a pharmacy technician's scope of practice.

3. A full pharmacist must only dispense the drugs for medical assistance in dying directly to the prescribing medical practitioner or nurse practitioner.

4. A full pharmacist must not dispense a drug to a prescribing medical practitioner or nurse practitioner for medical assistance in dying unless the prescription is in writing and includes confirmation that it is for medical assistance in dying.

5. A full pharmacist must not participate in dispensing drugs intended to provide medical assistance in dying:
   (a) To themselves or a family member;
   (b) To someone who has made the pharmacist a beneficiary under the person's will or to someone whom the pharmacist has reason to believe has made them a beneficiary under the person's will; or
   (c) In circumstances where the pharmacist will receive financial or other material benefit from the person's death, other than the standard compensation for their services relating to the dispensing of drugs.

6. A full pharmacist must not perform any activity that may imply he or she is leading the medical assistance in dying process, and may not:
   (a) Assess whether a person satisfies the criteria for medical assistance in dying set out in section 241.2 of the Criminal Code; or

(b) Adapt a prescription for medical assistance in dying.

## CONDITIONS

1. The full pharmacist has the requisite competency, knowledge and skills to prepare and/or dispense the prescription for medical assistance in dying.



College of Pharmacists of British Columbia | 200-1765 West 8th Ave Vancouver, BC, V6J 5C6 | Tel: 604.733.2493 | www.bcpharmacists.org

## SCHEDULE OF AMENDMENTS

Schedule F – Part 5 – Part 5 – Dispending Drugs for the Purposes of Medical Assistance in Dying Standards, Limits and Conditions of bylaws of the College of Pharmacists of British Columbia made under the authority of the *Health Professions Act* are amended in light of COVID-19 related drug shortages to temporarily allow return to inventory, injectable drugs previously dispensed for the purpose of providing Medical Assistance in Dying, as follows:

1. Section 5 is repealed and replaced by the following:

   The full pharmacist must contact the prescribing medical practitioner or nurse practitioner after the scheduled date and time of drug administration to collaborate relating to the return, within 72 hours of the patient's death, of any unused and partially used medications to the pharmacist for disposal. Upon receipt of the returned medications and the medication administration record from the prescribing medical practitioner or nurse practitioner, the full pharmacist must review the medication administration record for reconciliation of returned medications.

   Notice: May 5, 2020 Effective immediately and for the duration of the COVID-19 public health emergency in British Columbia, the prohibition on return and re-use of previously dispensed medical assistance in dying medications is subject to the following exemption. If there is a shortage of medication for medical assistance in dying, a pharmacist may accept for return to inventory, injectable medication previously dispensed for the purpose of providing medical assistance in dying if they are satisfied that:

   a) the medication has not left the possession of the prescribing medical practitioner or nurse practitioner, or a licensed health care professional assigned by the physician or nurse practitioner; and the integrity of the medication can be verified;
   b) each dose is unused and in the original sealed tamper proof kit; and,
   c) the medication has been maintained in accordance with the manufacturer's requirements and any other applicable requirements.

***Pharmacy Operations and Drug Scheduling Act - BYLAWS***

***Table of Contents***

3B. Application for Pharmacy Licence Reinstatement – Telepharmacy
3C. Application for Pharmacy Licence Reinstatement – Hospital
3F. Application for Pharmacy Licence Reinstatement – Pharmacy Education Site
4A. Application for Pharmacy Closure
4B. Application for Unanticipated Temporary Pharmacy Closure
4C. Closure for Suspended Pharmacy
5. Manager/Direct Owner/Indirect Owner – Proof of Eligibility
6. Manager/Direct Owner/Indirect Owner – Notice of Ineligibility
7. Indirect Owner – Email Contacts
8A. Application for Change of Direct Owner
8B. Application for Change of Indirect Owner(s)
8C. Application for Change of Manager
8D. Application for Change of Corporation Name
8E. Application for Change of Operating Name
8F. Application for Change of Location
8G. Application for Change of Layout
10A. Pharmacy Pre-Opening Inspection Report – Community
10B. Pharmacy Pre-Opening Inspection Report – Community Telepharmacy

**Definitions**

1 In these bylaws:

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

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

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

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

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

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

**"community pharmacy"** means a pharmacy licensed to sell or dispense drugs to the public, but does not include a telepharmacy;

**"*Community Pharmacy Standards of Practice*"** means the standards, limits and conditions for practice established under section 19(1)(k) of the *Health Professions Act* respecting community pharmacies;

**"controlled drug substances"** means a drug which includes a substance listed in the Schedules in the regulations made pursuant to the *Controlled Drugs and Substances Act* (Canada), and Part G of the *Food and Drug Regulations* (Canada);

**"controlled prescription program"** means a program approved by the board, to prevent prescription forgery and reduce inappropriate prescribing of drugs;

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

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

**"direct supervision"** means real time audio and visual observation by a full pharmacist of pharmacy services performed at a telepharmacy consistent with a pharmacy manager's responsibilities as set out in section 18(2);

**"dispensary"** means the area of a community pharmacy or a telepharmacy that contains Schedule I and II drugs;

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

**"electronic signature"** means

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

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

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

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

**"health authority"** includes

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

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

**"hospital pharmacy"** means a pharmacy licensed to operate in or for a hospital;

**"hospital pharmacy satellite"** means a physically separate area on or outside the hospital premises used for the provision of pharmacy services which is dependent upon support and administrative services from the hospital pharmacy;

**"*Hospital Pharmacy Standards of Practice*"** means the standards, limits and conditions for practice established under section 19(1)(k) of the *Health Professions Act* respecting hospital pharmacies;

**"incentive"** has the same meaning as in Part 1 of Schedule "F" of the bylaws of the College under the *Health Professions Act;*

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

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

**"outsource prescription processing"** means to request another community pharmacy to prepare or process a prescription drug order;

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

**"personal health information"** has the same meaning as in section 25.8 of the *Health Professions Act*;

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

**"pharmacy education site"** means a pharmacy

(a) that has Schedule I, II and III drugs, but no controlled drug substances,
(b) that is licensed solely for the purpose of pharmacy education, and
(c) from which pharmacy services are not provided to any person;

**"pharmacy security"** means

(a) measures to prevent unauthorized access and loss of Schedule I, IA, II and III drugs, and controlled drug substances,
(b) measures providing for periodic and post-incident review of pharmacy security,
(c) measures to protect against unauthorized access, collection, use, disclosure or disposal of personal health information;

**"pharmacy services"** has the same meaning as in section 1 of the bylaws of the College under the *Health Professions Act*;

**"pharmacy technician"** has the same meaning as in section 1 of the bylaws of the College under the *Health Professions Act*;

**"prescription drug"** means a drug referred to in a prescription;

**"professional products area"** means the area of a community pharmacy that contains Schedule III drugs;

**"professional service area"** means the area of a community pharmacy that contains Schedule II drugs;

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

**"*Residential Care Facilities and Homes Standards of Practice*"** means the standards, limits and conditions for practice established under section 19(1)(k) of the *Health Professions Act* respecting residential care facilities and homes;

**"rural and remote community"** means a community set out in Schedule "H";

**"Schedule I, Schedule IA, Schedule II, or Schedule III"**, as the case may be, refers to the drugs listed in Schedule I, IA, II or III of the *Drug Schedules Regulation*;

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

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

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

**"*Telepharmacy Standards of Practice*"** means the standards, limits and conditions for practice established under section 19(1)(k) of the *Health Professions Act* respecting the operation of telepharmacies.

## PART I – Pharmacy Licences

### Licence Types

2 (1) The registrar may issue a licence for any of the following:

(a) a community pharmacy;

(b) a hospital pharmacy;

(c) a pharmacy education site; or

(d) a telepharmacy.

### New Community Pharmacy Licence

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

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

(a) an application in Form 1A;

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

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

(d) Form 10A;

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

(f) a copy of the pharmacy's valid business licence issued by the jurisdiction to the direct owner, if applicable.

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

(a) an email contact of each indirect owner;

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

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

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

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

(a) an email contact of each indirect owner;

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

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

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

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

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

(b) indirect owner(s); and

(c) the manager.

**Community Pharmacy Licence Renewal**

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

(a) an application in Form 2A;

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

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

(d) a copy of the current British Columbia Company Summary or the most recently filed BC Annual Report, if a direct owner is or includes a corporation.

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

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

(b) indirect owner(s); and

(c) the manager.

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

**Community Pharmacy Licence Reinstatement**

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

(a) an application in Form 3A;

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

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

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

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

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

(b) indirect owner(s); and

(c) the manager.

**New Hospital Pharmacy Licence**

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

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

(a) an application in Form 1C;

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

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

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

(4) A pharmacy located in a hospital which dispenses drugs to staff, out-patients or the public and which is not owned or operated by a health authority, must be licensed as a community pharmacy or telepharmacy.

**Hospital Pharmacy Licence Renewal**

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

(a) an application in Form 2C; and

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

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

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

**Hospital Pharmacy Licence Reinstatement**

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

(a) an application in Form 3C; and

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

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

**New Pharmacy Education Site Licence**

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

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

(a) an application in Form 1F; and

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

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

**Pharmacy Education Site Licence Renewal**

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

(a) an application in Form 2F; and

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

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

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

**Pharmacy Education Site Licence Reinstatement**

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

(a) an application in Form 3F; and

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

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

**New Telepharmacy Licence**

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

(a) an application in Form 1B;

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

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

(d) Form 10B;

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

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

**Conditions for Telepharmacy Licence**

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

(a) the proposed telepharmacy will be the only telepharmacy or community pharmacy located in the rural and remote community,

(b) the proposed telepharmacy is located at least 25 kilometers away from any other telepharmacy or community pharmacy,

(c) the proposed name on the external signage of the telepharmacy described in section 18(2)(r) includes the word "telepharmacy",

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

(e) the central pharmacy applicant and the telepharmacy will have the same direct owner, and

(f) the central pharmacy is in compliance, and the telepharmacy will be in compliance, with the *Telepharmacy Standards of Practice*.

(2) A telepharmacy licence issued under subsection (1) is valid only for the location stated on the telepharmacy licence.

**Telepharmacy Licence Renewal**

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

(a) an application in Form 2B;

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

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

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

**Telepharmacy Licence Reinstatement**

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

(a) an application in Form 3B;

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

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

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

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

**Unlawful Operation**

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

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

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

## PART II - All Pharmacies

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

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

(a) Form 8A;

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

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

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

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

(a) Form 8B;

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

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

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

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

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

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

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

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

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

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

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

**Changes to the Pharmacy Premises and Name**

17 (1) If there is a change in the name of a corporation that is a direct owner, the registrar may amend the pharmacy licence, and telepharmacy licence if applicable, upon receipt of the following from the direct owner:

(a) Form 8D;

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

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

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

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

(a) Form 8D;

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

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

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

(a) Form 8E;

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

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

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

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

(a) Form 8F;

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

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

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

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

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

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

(a) Form 8G;

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

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

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

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

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

(a) an application in Form 4A;

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

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

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

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

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

18 (1) A full pharmacist may not act as manager of more than one pharmacy location, unless the pharmacy of which the full pharmacist is manager includes

(a) a telepharmacy,

(b) a hospital pharmacy,

(c) a hospital pharmacy satellite, or

(d) a pharmacy education site.

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

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

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

(c) establish policies and procedures

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

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

(iii) for pharmacy security,

(iv) for emergency preparedness, and

(v) for drug recall of pharmacy inventory;

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

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

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

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

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

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

(j) ensure that

(i) registrant and support persons staff levels are commensurate with workload volumes and patient care requirements are met at all times in accordance with the bylaws, Code of Ethics and standards of practice, and

(ii) meeting quotas, targets or similar measures do not compromise patient safety or compliance with the bylaws, Code of Ethics or standards of practice;

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

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

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

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

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

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

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

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

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

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

(u) advise the registrar if the pharmacy is providing pharmacy services over the internet, and provide to the registrar the internet address of every website operated or used by the pharmacy;

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

(w) require anyone who will access the in-pharmacy computer system to sign an undertaking in a form approved by the registrar to maintain the confidentiality of patient personal health information;

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

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

(z) ensure that no incentive is provided to a patient or patient's representative for the purpose of inducing the patient or patient's representative to

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) advise the registrar in writing of the disposition of all drugs and prescription records at the time of a closure, in accordance with policies approved by the board,

(iii) provide the registrar with a copy of the return invoice and any other documentation sent to Health Canada in respect of the destruction of all controlled drug substances,

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

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

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

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

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

(4) Subsection (2)(z) does not prevent a manager, direct owner or indirect owner(s) from

(a) providing free or discounted parking to patients or patient's representatives,

(b) providing free or discounted delivery services to patients or patient's representatives, or

(c) accepting payment for a drug or device by a credit or debit card that is linked to an incentive.

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

(6) A pharmacy education site's manager must ensure that only registrants and instructors are present in the pharmacy education site and must also comply with subsections (2)(a), (b), (c)(ii), (d), (e), (i), (p), (ee)(i) and (ee)(ii).

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

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

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

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

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

**Sale and Disposal of Drugs**

19 (1) Schedule I, II, and III drugs and controlled drug substances must only be sold or dispensed from a pharmacy.

(2) A registrant must not sell or dispense a quantity of drug that will not be used completely prior to the manufacturer's expiry date, if used according to the directions on the label.

(3) If the manufacturer's expiry date states the month and year but not the date, the expiry date is the last day of the month indicated.

(4) Every registrant practising in a pharmacy is responsible for the protection from loss, theft or unlawful sale or dispensing of all Schedule I, II, and III drugs and controlled drug substances in or from the pharmacy.

(5) A registrant must not sell, dispense, dispose of or transfer a Schedule I drug except

(a) on the prescription or order of a practitioner,

(b) for an inventory transfer to a pharmacy by order of a registrant in accordance with the policies approved by the board,

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

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

(6) Drugs included in the controlled prescription program must not be sold or dispensed unless

(a) the registrant has received the prescription on the prescription form approved by both the board and the College of Physicians and Surgeons of British Columbia, and

(b) the prescription form is signed by the patient or the patient's representative upon receipt of the dispensed drug.

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

(7) A new prescription from a practitioner is required each time a drug is dispensed, except for

(a) a part-fill,

(b) a prescription authorizing repeats,

(c) a full pharmacist-initiated renewal or adaptation, or

(d) an emergency supply for continuity of care.

(8) Subsection (6) does not apply to prescriptions written for

(a) residents of a facility or home subject to the requirements of the *Residential Care Facilities and Homes Standards of Practice*, or

(b) patients admitted to a hospital.

**Drug Procurement/Inventory Management**

20 (1) In this section:

**"premises"** means:

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

(2) A full pharmacist may authorize the purchase of Schedule I, II, or III drugs or controlled drug substances only from

(a) a wholesaler or manufacturer licensed to operate in Canada, or

(b) another pharmacy in accordance with the policies approved by the board.

(3) A registrant must record a transfer of drugs that occurs for any reason other than for the purpose of dispensing in accordance with a practitioner's prescription.

(4) All drug shipments must be delivered unopened to

(a) the pharmacy, or

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

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

(6) A full pharmacist must not purchase Schedule I, II and III drugs and controlled drug substances unless they are for sale or dispensing in or from a pharmacy.

**Interchangeable Drugs**

21 When acting under section 25.91 of the *Health Professions Act,* a full pharmacist must determine interchangeability of drugs by reference to Health Canada's Declaration of Equivalence, indicated by the identification of a Canadian Reference Product in a Notice of Compliance for a generic drug.

**Returned Drugs**

22 No registrant may accept for return to stock or reuse any drug previously dispensed except in accordance with section 11(3) of the *Residential Care Facilities and Homes*

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

**Records**

23 (1) All prescriptions, patient records, invoices and documentation in respect of the purchase, receipt or transfer of Schedule I, II and III drugs and controlled drug substances must be retained for a period of not less than three years from the date

(a) a drug referred to in a prescription was last dispensed, or

(b) an invoice was received for pharmacy stock.

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

(3) Registrants, support persons, managers, direct owners, and indirect owners must not, for commercial purposes, disclose or permit the disclosure of information or an abstract of information obtained from a prescription or patient record which would permit the identity of the patient or practitioner to be determined.

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

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

(3) For purposes of subsection (2):

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## PART III – Community Pharmacies

### Community Pharmacy's Manager – Quality Management

24 (1) A community pharmacy's manager must establish and maintain written quality management policies and procedures that

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

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

(c) include a process for reporting, documenting and following up on known, alleged and suspected errors, incidents and discrepancies.

(2) If a community pharmacy is a central pharmacy, the quality management policies and procedures in subsection (1) must include all telepharmacies associated with the central pharmacy and must comply with the *Telepharmacy Standards of Practice.*

### Community Pharmacy and Telepharmacy Premises

25 (1) In locations where a community pharmacy or telepharmacy does not comprise 100 per cent of the total area of the premises, the community pharmacy manager or the central pharmacy manager in the case of a telepharmacy, must ensure that

(a) the professional products area extends not more than 25 feet from the perimeter of the dispensary and is visually distinctive from the remaining areas of the premises by signage, and

(b) a sign reading "Medication Information" is clearly displayed to identify a consultation area or counter at which a member of the public can obtain a full pharmacist's advice.

(2) Subject to subsection (3), the dispensary area of a community pharmacy or a telepharmacy must

(a) be at least 160 square feet,

(b) be inaccessible to the public by means of gates or doors across all entrances,

(c) include a dispensing counter with at least 30 square feet of clear working space, in addition to service counters,

(d) contain adequate shelf and storage space that is clean and organized,

(e) contain a double stainless steel sink with hot and cold running water,

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

(g) contain a refrigerator.

(3) A telepharmacy that was authorized by the registrar to provide pharmacy services as a telepharmacy remote site as of January 1, 2017 is exempt from the requirements in subsections (2)(a) and (c) until such time as it commences a renovation of all or part of the premises.

(4) In all new and renovated community pharmacies or telepharmacies, an appropriate area must be provided for patient consultation that

(a) ensures privacy and is conducive to confidential communication, and

(b) includes, but is not limited to, one of the following:

(i) a private consultation room, or

(ii) a semiprivate area with suitable barriers.

**Community Pharmacy and Telepharmacy Security**

26 (1) A community pharmacy or telepharmacy must:

(a) keep Schedule IA drugs in a locked metal safe inside the dispensary that is secured in place and equipped with a time delay lock set at a minimum of five minutes;

(b) install and maintain a security camera system that:

(i) has date/time stamp images that are archived and available for no less than 30 days; and

(ii) is checked daily for proper operation; and

(c) install and maintain motion sensors in the dispensary.

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

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

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

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

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

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

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

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

(2.1) A community pharmacy or telepharmacy that exists on the date this provision comes into force and is not renovated during the period must comply with sections 26(2)(a)(ii) and (b)(ii) no later than three years after the date that provision comes into force.

(2.2) For the purposes of subsection (2), a full pharmacist is deemed to be present at a telepharmacy when he or she is engaged in direct supervision of the telepharmacy.

(3) Subject to subsection (5), a community pharmacy or a telepharmacy must clearly display at all external entrances that identify the premises as a pharmacy, and at the dispensary counter signage provided by the College.

(4) The manager, direct owner or indirect owner(s) of a community pharmacy or telepharmacy that does not stock IA drugs must complete a declaration attesting that Schedule IA drugs are never stocked on the premises.

(5) A pharmacy that is never open to the public and has no external signage identifying it as a pharmacy is exempt from the requirements in subsection (3).

**Permitted Activities of a Community Pharmacy without a Full Pharmacist Present**

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

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

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

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

(c) the hours when a full pharmacist is on duty are posted.

(3) Subject to subsection (2) if a full pharmacist is not present, only the following activities may be carried out:

(a) pharmacy technicians may access the dispensary to perform activities outlined in section 4 of the *Community Pharmacy Standards of Practice*, that do not require pharmacist supervision, except if any such activity involves patient interaction; and

(b) receive drug shipments under section 20(4).

(3) Nothing contained in this section relieves a pharmacy manager of their responsibilities under section 18(2)(a).

**Outsource Prescription Processing**

28 (1) A community pharmacy may outsource prescription processing if

(a) all locations involved in the outsourcing are community pharmacies,

(b) all prescriptions dispensed are labeled and include an identifiable code that provides a complete audit trail for the dispensed drug, and

(c) a notice is posted informing patients that the preparation of their prescriptions may be outsourced to another pharmacy.

(2) The manager of an outsourcing community pharmacy must ensure that all applicable standards of practice are met in processing prescriptions at all locations involved in the outsourcing.

(3) In this section, “community pharmacy” includes a hospital pharmacy.

## PART IV – Hospital Pharmacies

**Hospital Pharmacy’s Manager – Quality Management**

29 (1) A hospital pharmacy’s manager must establish and maintain written quality management policies and procedures that

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

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

(c) include a process for reporting, documenting and following up on known, alleged and suspected errors, incidents and discrepancies,

(d) document periodic audits of the drug distribution process,

(e) include a process to review patient-oriented recommendations,

(f) include a process that reviews a full pharmacist's documentation notes in the hospital's medical records,

(g) include a process to evaluate drug use, and

(h) regularly update policies and procedures for drug use control and patient-oriented pharmacy services in collaboration with the medical and nursing staff and appropriate committees.

(2) If sample drugs are used within a hospital, the hospital pharmacy's manager must ensure that the pharmacy oversees the procurement, storage and distribution of all sample drugs.

**After Hours Service**

30 (1) If continuous pharmacy services are not provided in a hospital, the hospital pharmacy's manager must ensure that urgently needed drugs and patient-oriented pharmacy services are available at all times by

(a) providing a cabinet which must

(i) be a locked cabinet or other secure enclosure located outside of the hospital pharmacy, to which only authorized persons may obtain access,

(ii) be stocked with a minimum supply of drugs most commonly required for urgent use,

(iii) not contain controlled drug substances unless they are provided by an automated dispensing system,

(iv) contain drugs that are packaged to ensure integrity of the drug and labeled with the drug name, strength, quantity, expiry date and lot number, and

(v) include a log in which drug withdrawals are documented, and

(b) arranging for a full pharmacist to be available for consultation on an on-call basis.

(2) When a hospital pharmacy or hospital pharmacy satellite is closed, the premises must be equipped with a security system that will detect unauthorized entry.

## PART V – Telepharmacies

**Telepharmacy Operation**

31 (1) A telepharmacy must not remain open and prescriptions must not be dispensed

without a full pharmacist physically present on duty at the telepharmacy, unless

(a) a full pharmacist at the central pharmacy is engaged in direct supervision of the telepharmacy in accordance with the *Telepharmacy Standards of Practice*, and

(b) subject to subsection (2), a pharmacy technician is physically present on duty at the telepharmacy.

(2) A telepharmacy located at an address listed in Schedule "G" is exempt from the requirements in subsection (1)(b).

(3) A telepharmacy must have a security system that prevents the public and non-pharmacy staff from accessing the professional services area and the dispensary area, including any area where personal health information is stored.

(4) Prescriptions and labels relating to prescriptions dispensed at a telepharmacy must identify the prescription as having been dispensed at that telepharmacy.

(4.1) Prescriptions and labels relating to prescriptions dispensed at a pharmacy listed in Schedule "F" must distinguish between those dispensed when it is operating as a telepharmacy from when it is operating as a community pharmacy.

(5) The manager of a central pharmacy, or a full pharmacist designated by the manager, must

(a) inspect and audit its telepharmacy at least 4 times each year, at intervals of not less than 2 months,

(b) record each inspection and audit in the prescribed form, and

(c) provide the inspection and audit records to the registrar immediately upon request.

(6) A telepharmacy located at an address listed in Schedule "G" must perform a monthly count of narcotics at the telepharmacy and retain a record of each monthly count signed by the supervising pharmacist for three years at both the central pharmacy and the telepharmacy location, and provide the signed record to the registrar immediately upon request.

(7) A telepharmacy must not continue to provide pharmacy services for more than 30 days after

(a) its location ceases to be a rural and remote community,

(b) a community pharmacy is established within the community, or

(c) a community pharmacy is established within 25 kilometers of the location of the telepharmacy.

(8) In accordance with sections 18(2)(c) and (d), a telepharmacy must have policies and procedures on site that outline the methods for ensuring the safe and

effective distribution of pharmacy products and delivery of pharmaceutical care by the telepharmacy.

(9) All transactions in PharmaNet must be distinguishable between the central pharmacy and telepharmacy.

## PART VI – PharmaNet

### Application of Part

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

### Definitions

33 In this Part:

**"patient record"** means the patient record described in section 11(2) of the *Community Pharmacy Standards of Practice* and in the *British Columbia Professional and Software Conformance Standards, Electronic Health Information Exchange* as the "patient record (pharmacy)".

"**PharmaNet**" means "PharmaNet" as defined in section 1 of the *Information Management Regulation*, B.C. Reg. 74/2015;

### Operation of PharmaNet

34 A pharmacy must connect to PharmaNet.

### Data Collection, Transmission of and Access to PharmaNet Data

35 (1) A registrant must enter the prescription information and record it in PharmaNet at the time of dispensing and keep the patient record current.

(2) A registrant may collect and record patient information in PharmaNet, or access, use and disclose a patient's PharmaNet record only for the purposes of:

(a) dispensing a drug;

(b) providing patient consultation;

(c) evaluating a patient's drug usage;

(d) claims adjudication and payment by an insurer; or

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

(3) A registrant must revise information in PharmaNet pertaining to corrected billings for prescriptions billed to the patient or a payment agency other than PharmaCare and record the reason for the revision within 120 days of the original entry in PharmaNet.

(4) A registrant must reverse information in PharmaNet, for any drug that is not released to the patient or the patient's representative, and record the reason for

the reversal no later than 30 days from the date of the original entry of the prescription information in PharmaNet.

(5) If a registrant is unable to comply with the deadlines in subsection (3) or (4), he or she must provide the information required to make the correction to the Ministry of Health as soon as possible thereafter.

## PART VII – Confidentiality

### Confidentiality

36 A registrant must take reasonable steps to confirm the identity of a patient, patient's representative, registrant or practitioner before providing any pharmacy service that requires accessing, using or disclosing of patient personal health information.

## PART VIII – College

### Forms

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

### Use, Disclosure and Retention of Criminal Record History Information

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

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

## CPBC Legislation

**From:** jmorris@netidea.com
**Sent:** May 1, 2020 6:26 AM
**To:** CPBC Legislation
**Subject:** MAID revisited

**Follow Up Flag:** Follow up
**Flag Status:** Flagged

Hello to interested parties: Yes of course you should return the unused injectables to the pharmacy. It is done by the physician and pharmacist so it is not in an uncontrolled setting. Our costs to the system should always be in mind. My pharmacist number is 12056 and I have seen and participated in MAID and I always advocated for its judicious use.
James Morris

College of Pharmacists of British Columbia

# Feedback Form for Posted Draft Bylaws

**Instructions**

Thank you for providing your feedback on the College's draft Bylaws. To better facilitate the collation of feedback, please use the following form. The form is divided into 4 columns:

**Column 1:** Indicate which section, subsection or appendix of the Bylaws for which you are providing comments.

**Column 2:** Due to some sections carrying over multiple pages, please indicate the page number for ease of reference.

**Column 3:** Indicate the text for which you are provided suggested changes and include new or amended text.

**Column 4:** Indicate the reason for your suggested changes (e.g. scientific journal, published guidelines etc.). Please keep your explanations as brief as possible.

**Example:**

| Section, Subsection or Appendix | Page # | Comment (provide current and new text when applicable) | Rationale |
|---|---|---|---|
| 1.3 Sample Section | 5 | The requirements should include A, B and C… | The following reference supports this statement… |

There is an opportunity to provide general comments on the draft Bylaws following the table.

**PLEASE RETURN FEEDBACK FORM TO LEGISLATION@BCPHARMACISTS.ORG BY THE DATE INDICATED ON THE COLLEGE WEBSITE.**

Note: Timelines are typically 60 or 90 day posting periods. Refer to College website for specific deadlines. Forms that are submitted after deadline will not be accepted.



tel 604.733.2440 800.663.1940 fax 604.733.2493 800.377.8129 200 / 1765 WEST 8TH AVE VANCOUVER BC V6J 5C6 BCPHARMACISTS.ORG

College of Pharmacists of British Columbia

**Stakeholder Comments**

| Section, Subsection or Appendix | Page # | Comment (provide current and new text when applicable) | Rationale |
|---|---|---|---|
| 22 | 21-22 | I think that the unused medications from MAiD service should be allowed to be returned to the pharmacy's inventory given that a full pharmacist confirms that the medication has not been opened or used - especially during this time of drug shortage. | It's a waste to dispose of a medication that has not been opened or used - the MAiD medications would been handled by medical professionals only such as physicians, and NPs so we are not worried about any tampering as well.<br>It's no different than when a long-term care pharmacy receives |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |



tel 604.733.2440 800.663.1940 fax 604.733.2493 800.377.8129 200 / 1765 WEST 8TH AVE VANCOUVER BC V6J 5C6 BCPHARMACISTS.ORG

College of Pharmacists of British Columbia

| General Comments |
| --- |
| |

| Comments submitted by: | |
| --- | --- |
| **Name of individual** | Keunchul Wee |
| **Name of organization** | Pharmasave |
| **Date** | May 1st, 2020 |



tel 604.733.2440 800.663.1940 fax 604.733.2493 800.377.8129 200 / 1765 WEST 8TH AVE VANCOUVER BC V6J 5C6 BCPHARMACISTS.ORG

College of Pharmacists of British Columbia

# Feedback Form for Posted Draft Bylaws

**Instructions**

Thank you for providing your feedback on the College's draft Bylaws. To better facilitate the collation of feedback, please use the following form. The form is divided into 4 columns:

**Column 1:** Indicate which section, subsection or appendix of the Bylaws for which you are providing comments.

**Column 2:** Due to some sections carrying over multiple pages, please indicate the page number for ease of reference.

**Column 3:** Indicate the text for which you are provided suggested changes and include new or amended text.

**Column 4:** Indicate the reason for your suggested changes (e.g. scientific journal, published guidelines etc.). Please keep your explanations as brief as possible.

**Example:**

| Section, Subsection or Appendix | Page # | Comment (provide current and new text when applicable) | Rationale |
|---|---|---|---|
| 1.3 Sample Section | 5 | The requirements should include A, B and C… | The following reference supports this statement… |

There is an opportunity to provide general comments on the draft Bylaws following the table.

**PLEASE RETURN FEEDBACK FORM TO LEGISLATION@BCPHARMACISTS.ORG BY THE DATE INDICATED ON THE COLLEGE WEBSITE.**

Note: Timelines are typically 60 or 90 day posting periods. Refer to College website for specific deadlines. Forms that are submitted after deadline will not be accepted.



tel 604.733.2440 800.663.1940 fax 604.733.2493 800.377.8129 200 / 1765 WEST 8TH AVE VANCOUVER BC V6J 5C6 BCPHARMACISTS.ORG

College of Pharmacists of British Columbia

**Stakeholder Comments**

| Section, Subsection or Appendix | Page # | Comment (provide current and new text when applicable) | Rationale |
|---|---|---|---|
| 22 | 21,22 | PHSA supports this amendment. | The amendment increases flexibility in the prudent management of medication, optimizing access for all patients who may benefit from it. |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |



tel 604.733.2440 800.663.1940 fax 604.733.2493 800.377.8129 200 / 1765 WEST 8TH AVE VANCOUVER BC V6J 5C6 BCPHARMACISTS.ORG

College of Pharmacists of British Columbia

| General Comments |
| --- |
| |

| Comments submitted by: | |
| --- | --- |
| **Name of individual** | Darren Kopetsky |
| **Name of organization** | Provincial Health Services Authority |
| **Date** | May 1, 2020 |



tel 604.733.2440 800.663.1940 fax 604.733.2493 800.377.8129 200 / 1765 WEST 8TH AVE VANCOUVER BC V6J 5C6 BCPHARMACISTS.ORG

British Columbia Pharmacy Association

**May 1, 2020**

Director of Policy and Legislation
College of Pharmacists of British Columbia
200 – 1765 W. 8th Avenue
Vancouver, BC V6J 5C6

**BY EMAIL**: legislation@bcpharmacists.org

And To:

Director of Regulatory Initiatives,
Professional Regulation and Oversight,
Clinical Integration, Regulation and Education
Ministry of Health
1515 Blanshard Street
PO Box 9649 STN PROV GOVT
Victoria, BC V8W 9P4

**BY Email**: PROREGADMIN@gov.bc.ca

Dear Madam/Sir:

**Re: Bylaw amendment - Temporary changes for dispensing drugs for the purposes of Medical Assistance in Dying (MAiD)**

The BCPhA wishes to thank you for the opportunity to comment on the proposed bylaw. We note the urgency of this matter and agree with the shortened timelines.

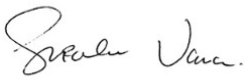
Many of the drugs that are used in MAiD are also used to treat patients with COVID-19 who require critical care. The increased use of these drugs for critical care is leading to shortages of these drugs for use in MAiD. As a result, community pharmacy is facing challenges securing sufficient supply and maintaining adequate inventory levels.

The BCPhA supports the College Board's decision to approve temporary amendments to the *Health Professions Act* Bylaws Schedule F Part 5 – *Dispensing Drugs for the Purposes of MAiD Standards, Limits and Conditions* to temporarily allow injectable drugs that have been dispensed for MAiD purposes to be returned to inventory rather than being disposed of, provided certain conditions are met.

To ensure that pharmacists can lawfully returns such drugs to stock or reuse any drug previously dispensed for the purposes of MAiD, section 22 of the *Pharmacy Operations and Drug Scheduling Act (PODSA)* Bylaw needed to be amended to include a reference to the MAiD Standards, Limits and Conditions.

The BCPhA believes this temporary change is in the interests of patients, and supports this amendment.

Sincerely,



Geraldine Vance
CEO
BC Pharmacy Association

cc: Bob Nakagawa

***Pharmacy Operations and Drug Scheduling Act - BYLAWS***

***Table of Contents***

3B. Application for Pharmacy Licence Reinstatement – Telepharmacy
3C. Application for Pharmacy Licence Reinstatement – Hospital
3F. Application for Pharmacy Licence Reinstatement – Pharmacy Education Site
4A. Application for Pharmacy Closure
4B. Application for Unanticipated Temporary Pharmacy Closure
4C. Closure for Suspended Pharmacy
5. Manager/Direct Owner/Indirect Owner – Proof of Eligibility
6. Manager/Direct Owner/Indirect Owner – Notice of Ineligibility
7. Indirect Owner – Email Contacts
8A. Application for Change of Direct Owner
8B. Application for Change of Indirect Owner(s)
8C. Application for Change of Manager
8D. Application for Change of Corporation Name
8E. Application for Change of Operating Name
8F. Application for Change of Location
8G. Application for Change of Layout
10A. Pharmacy Pre-Opening Inspection Report – Community
10B. Pharmacy Pre-Opening Inspection Report – Community Telepharmacy

**Definitions**

1 In these bylaws:

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

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

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

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

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

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

**"community pharmacy"** means a pharmacy licensed to sell or dispense drugs to the public, but does not include a telepharmacy;

**"*Community Pharmacy Standards of Practice*"** means the standards, limits and conditions for practice established under section 19(1)(k) of the *Health Professions Act* respecting community pharmacies;

**"controlled drug substances"** means a drug which includes a substance listed in the Schedules in the regulations made pursuant to the *Controlled Drugs and Substances Act* (Canada), and Part G of the *Food and Drug Regulations* (Canada);

**"controlled prescription program"** means a program approved by the board, to prevent prescription forgery and reduce inappropriate prescribing of drugs;

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

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

**"direct supervision"** means real time audio and visual observation by a full pharmacist of pharmacy services performed at a telepharmacy consistent with a pharmacy manager's responsibilities as set out in section 18(2);

**"dispensary"** means the area of a community pharmacy or a telepharmacy that contains Schedule I and II drugs;

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

**"electronic signature"** means

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

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

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

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

**"health authority"** includes

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

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

**"hospital pharmacy"** means a pharmacy licensed to operate in or for a hospital;

**"hospital pharmacy satellite"** means a physically separate area on or outside the hospital premises used for the provision of pharmacy services which is dependent upon support and administrative services from the hospital pharmacy;

**"*Hospital Pharmacy Standards of Practice*"** means the standards, limits and conditions for practice established under section 19(1)(k) of the *Health Professions Act* respecting hospital pharmacies;

**"incentive"** has the same meaning as in Part 1 of Schedule "F" of the bylaws of the College under the *Health Professions Act;*

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

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

**"outsource prescription processing"** means to request another community pharmacy to prepare or process a prescription drug order;

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

**"personal health information"** has the same meaning as in section 25.8 of the *Health Professions Act*;

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

**"pharmacy education site"** means a pharmacy

(a) that has Schedule I, II and III drugs, but no controlled drug substances,
(b) that is licensed solely for the purpose of pharmacy education, and
(c) from which pharmacy services are not provided to any person;

**"pharmacy security"** means

(a) measures to prevent unauthorized access and loss of Schedule I, IA, II and III drugs, and controlled drug substances,
(b) measures providing for periodic and post-incident review of pharmacy security,
(c) measures to protect against unauthorized access, collection, use, disclosure or disposal of personal health information;

**"pharmacy services"** has the same meaning as in section 1 of the bylaws of the College under the *Health Professions Act*;

**"pharmacy technician"** has the same meaning as in section 1 of the bylaws of the College under the *Health Professions Act*;

**"prescription drug"** means a drug referred to in a prescription;

**"professional products area"** means the area of a community pharmacy that contains Schedule III drugs;

**"professional service area"** means the area of a community pharmacy that contains Schedule II drugs;

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

**"*Residential Care Facilities and Homes Standards of Practice*"** means the standards, limits and conditions for practice established under section 19(1)(k) of the *Health Professions Act* respecting residential care facilities and homes;

**"rural and remote community"** means a community set out in Schedule "H";

**"Schedule I, Schedule IA, Schedule II, or Schedule III"**, as the case may be, refers to the drugs listed in Schedule I, IA, II or III of the *Drug Schedules Regulation*;

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

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

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

**"*Telepharmacy Standards of Practice*"** means the standards, limits and conditions for practice established under section 19(1)(k) of the *Health Professions Act* respecting the operation of telepharmacies.

## PART I – Pharmacy Licences

### Licence Types

2 (1) The registrar may issue a licence for any of the following:

(a) a community pharmacy;

(b) a hospital pharmacy;

(c) a pharmacy education site; or

(d) a telepharmacy.

### New Community Pharmacy Licence

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

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

(a) an application in Form 1A;

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

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

(d) Form 10A;

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

(f) a copy of the pharmacy's valid business licence issued by the jurisdiction to the direct owner, if applicable.

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

(a) an email contact of each indirect owner;

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

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

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

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

(a) an email contact of each indirect owner;

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

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

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

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

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

(b) indirect owner(s); and

(c) the manager.

**Community Pharmacy Licence Renewal**

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

(a) an application in Form 2A;

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

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

(d) a copy of the current British Columbia Company Summary or the most recently filed BC Annual Report, if a direct owner is or includes a corporation.

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

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

(b) indirect owner(s); and

(c) the manager.

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

**Community Pharmacy Licence Reinstatement**

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

(a) an application in Form 3A;

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

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

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

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

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

(b) indirect owner(s); and

(c) the manager.

**New Hospital Pharmacy Licence**

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

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

(a) an application in Form 1C;

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

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

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

(4) A pharmacy located in a hospital which dispenses drugs to staff, out-patients or the public and which is not owned or operated by a health authority, must be licensed as a community pharmacy or telepharmacy.

**Hospital Pharmacy Licence Renewal**

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

(a) an application in Form 2C; and

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

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

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

**Hospital Pharmacy Licence Reinstatement**

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

(a) an application in Form 3C; and

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

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

**New Pharmacy Education Site Licence**

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

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

(a) an application in Form 1F; and

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

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

**Pharmacy Education Site Licence Renewal**

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

(a) an application in Form 2F; and

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

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

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

**Pharmacy Education Site Licence Reinstatement**

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

(a) an application in Form 3F; and

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

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

**New Telepharmacy Licence**

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

(a) an application in Form 1B;

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

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

(d) Form 10B;

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

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

**Conditions for Telepharmacy Licence**

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

(a) the proposed telepharmacy will be the only telepharmacy or community pharmacy located in the rural and remote community,

(b) the proposed telepharmacy is located at least 25 kilometers away from any other telepharmacy or community pharmacy,

(c) the proposed name on the external signage of the telepharmacy described in section 18(2)(r) includes the word "telepharmacy",

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

(e) the central pharmacy applicant and the telepharmacy will have the same direct owner, and

(f) the central pharmacy is in compliance, and the telepharmacy will be in compliance, with the *Telepharmacy Standards of Practice*.

(2) A telepharmacy licence issued under subsection (1) is valid only for the location stated on the telepharmacy licence.

**Telepharmacy Licence Renewal**

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

(a) an application in Form 2B;

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

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

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

**Telepharmacy Licence Reinstatement**

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

(a) an application in Form 3B;

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

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

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

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

**Unlawful Operation**

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

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

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

## PART II - All Pharmacies

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

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

(a) Form 8A;

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

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

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

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

(a) Form 8B;

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

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

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

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

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

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

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

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

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

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

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

**Changes to the Pharmacy Premises and Name**

17 (1) If there is a change in the name of a corporation that is a direct owner, the registrar may amend the pharmacy licence, and telepharmacy licence if applicable, upon receipt of the following from the direct owner:

(a) Form 8D;

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

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

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

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

(a) Form 8D;

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

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

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

(a) Form 8E;

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

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

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

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

(a) Form 8F;

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

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

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

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

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

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

(a) Form 8G;

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

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

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

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

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

(a) an application in Form 4A;

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

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

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

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

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

18 (1) A full pharmacist may not act as manager of more than one pharmacy location, unless the pharmacy of which the full pharmacist is manager includes

(a) a telepharmacy,

(b) a hospital pharmacy,

(c) a hospital pharmacy satellite, or

(d) a pharmacy education site.

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

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

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

(c) establish policies and procedures

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

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

(iii) for pharmacy security,

(iv) for emergency preparedness, and

(v) for drug recall of pharmacy inventory;

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

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

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

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

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

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

(j) ensure that

(i) registrant and support persons staff levels are commensurate with workload volumes and patient care requirements are met at all times in accordance with the bylaws, Code of Ethics and standards of practice, and

(ii) meeting quotas, targets or similar measures do not compromise patient safety or compliance with the bylaws, Code of Ethics or standards of practice;

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

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

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

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

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

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

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

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

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

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

(u) advise the registrar if the pharmacy is providing pharmacy services over the internet, and provide to the registrar the internet address of every website operated or used by the pharmacy;

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

(w) require anyone who will access the in-pharmacy computer system to sign an undertaking in a form approved by the registrar to maintain the confidentiality of patient personal health information;

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

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

(z) ensure that no incentive is provided to a patient or patient's representative for the purpose of inducing the patient or patient's representative to

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) advise the registrar in writing of the disposition of all drugs and prescription records at the time of a closure, in accordance with policies approved by the board,

(iii) provide the registrar with a copy of the return invoice and any other documentation sent to Health Canada in respect of the destruction of all controlled drug substances,

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

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

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

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

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

(4) Subsection (2)(z) does not prevent a manager, direct owner or indirect owner(s) from

(a) providing free or discounted parking to patients or patient's representatives,

(b) providing free or discounted delivery services to patients or patient's representatives, or

(c) accepting payment for a drug or device by a credit or debit card that is linked to an incentive.

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

(6) A pharmacy education site's manager must ensure that only registrants and instructors are present in the pharmacy education site and must also comply with subsections (2)(a), (b), (c)(ii), (d), (e), (i), (p), (ee)(i) and (ee)(ii).

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

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

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

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

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

**Sale and Disposal of Drugs**

19 (1) Schedule I, II, and III drugs and controlled drug substances must only be sold or dispensed from a pharmacy.

(2) A registrant must not sell or dispense a quantity of drug that will not be used completely prior to the manufacturer's expiry date, if used according to the directions on the label.

(3) If the manufacturer's expiry date states the month and year but not the date, the expiry date is the last day of the month indicated.

(4) Every registrant practising in a pharmacy is responsible for the protection from loss, theft or unlawful sale or dispensing of all Schedule I, II, and III drugs and controlled drug substances in or from the pharmacy.

(5) A registrant must not sell, dispense, dispose of or transfer a Schedule I drug except

(a) on the prescription or order of a practitioner,

(b) for an inventory transfer to a pharmacy by order of a registrant in accordance with the policies approved by the board,

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

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

(6) Drugs included in the controlled prescription program must not be sold or dispensed unless

(a) the registrant has received the prescription on the prescription form approved by both the board and the College of Physicians and Surgeons of British Columbia, and

(b) the prescription form is signed by the patient or the patient's representative upon receipt of the dispensed drug.

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

(7) A new prescription from a practitioner is required each time a drug is dispensed, except for

(a) a part-fill,

(b) a prescription authorizing repeats,

(c) a full pharmacist-initiated renewal or adaptation, or

(d) an emergency supply for continuity of care.

(8) Subsection (6) does not apply to prescriptions written for

(a) residents of a facility or home subject to the requirements of the *Residential Care Facilities and Homes Standards of Practice*, or

(b) patients admitted to a hospital.

**Drug Procurement/Inventory Management**

20 (1) In this section:

**"premises"** means:

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

(2) A full pharmacist may authorize the purchase of Schedule I, II, or III drugs or controlled drug substances only from

(a) a wholesaler or manufacturer licensed to operate in Canada, or

(b) another pharmacy in accordance with the policies approved by the board.

(3) A registrant must record a transfer of drugs that occurs for any reason other than for the purpose of dispensing in accordance with a practitioner's prescription.

(4) All drug shipments must be delivered unopened to

(a) the pharmacy, or

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

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

(6) A full pharmacist must not purchase Schedule I, II and III drugs and controlled drug substances unless they are for sale or dispensing in or from a pharmacy.

**Interchangeable Drugs**

21 When acting under section 25.91 of the *Health Professions Act,* a full pharmacist must determine interchangeability of drugs by reference to Health Canada's Declaration of Equivalence, indicated by the identification of a Canadian Reference Product in a Notice of Compliance for a generic drug.

**Returned Drugs**

22 No registrant may accept for return to stock or reuse any drug previously dispensed except in accordance with section 11(3) of the *Residential Care Facilities and Homes*

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

**Records**

23 (1) All prescriptions, patient records, invoices and documentation in respect of the purchase, receipt or transfer of Schedule I, II and III drugs and controlled drug substances must be retained for a period of not less than three years from the date

(a) a drug referred to in a prescription was last dispensed, or

(b) an invoice was received for pharmacy stock.

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

(3) Registrants, support persons, managers, direct owners, and indirect owners must not, for commercial purposes, disclose or permit the disclosure of information or an abstract of information obtained from a prescription or patient record which would permit the identity of the patient or practitioner to be determined.

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

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

(3) For purposes of subsection (2):

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## PART III – Community Pharmacies

### Community Pharmacy's Manager – Quality Management

24 (1) A community pharmacy's manager must establish and maintain written quality management policies and procedures that

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

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

(c) include a process for reporting, documenting and following up on known, alleged and suspected errors, incidents and discrepancies.

(2) If a community pharmacy is a central pharmacy, the quality management policies and procedures in subsection (1) must include all telepharmacies associated with the central pharmacy and must comply with the *Telepharmacy Standards of Practice.*

### Community Pharmacy and Telepharmacy Premises

25 (1) In locations where a community pharmacy or telepharmacy does not comprise 100 per cent of the total area of the premises, the community pharmacy manager or the central pharmacy manager in the case of a telepharmacy, must ensure that

(a) the professional products area extends not more than 25 feet from the perimeter of the dispensary and is visually distinctive from the remaining areas of the premises by signage, and

(b) a sign reading "Medication Information" is clearly displayed to identify a consultation area or counter at which a member of the public can obtain a full pharmacist's advice.

(2) Subject to subsection (3), the dispensary area of a community pharmacy or a telepharmacy must

(a) be at least 160 square feet,

(b) be inaccessible to the public by means of gates or doors across all entrances,

(c) include a dispensing counter with at least 30 square feet of clear working space, in addition to service counters,

(d) contain adequate shelf and storage space that is clean and organized,

(e) contain a double stainless steel sink with hot and cold running water,

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

(g) contain a refrigerator.

(3) A telepharmacy that was authorized by the registrar to provide pharmacy services as a telepharmacy remote site as of January 1, 2017 is exempt from the requirements in subsections (2)(a) and (c) until such time as it commences a renovation of all or part of the premises.

(4) In all new and renovated community pharmacies or telepharmacies, an appropriate area must be provided for patient consultation that

(a) ensures privacy and is conducive to confidential communication, and

(b) includes, but is not limited to, one of the following:

(i) a private consultation room, or

(ii) a semiprivate area with suitable barriers.

**Community Pharmacy and Telepharmacy Security**

26 (1) A community pharmacy or telepharmacy must:

(a) keep Schedule IA drugs in a locked metal safe inside the dispensary that is secured in place and equipped with a time delay lock set at a minimum of five minutes;

(b) install and maintain a security camera system that:

(i) has date/time stamp images that are archived and available for no less than 30 days; and

(ii) is checked daily for proper operation; and

(c) install and maintain motion sensors in the dispensary.

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

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

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

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

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

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

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

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

(2.1) A community pharmacy or telepharmacy that exists on the date this provision comes into force and is not renovated during the period must comply with sections 26(2)(a)(ii) and (b)(ii) no later than three years after the date that provision comes into force.

(2.2) For the purposes of subsection (2), a full pharmacist is deemed to be present at a telepharmacy when he or she is engaged in direct supervision of the telepharmacy.

(3) Subject to subsection (5), a community pharmacy or a telepharmacy must clearly display at all external entrances that identify the premises as a pharmacy, and at the dispensary counter signage provided by the College.

(4) The manager, direct owner or indirect owner(s) of a community pharmacy or telepharmacy that does not stock IA drugs must complete a declaration attesting that Schedule IA drugs are never stocked on the premises.

(5) A pharmacy that is never open to the public and has no external signage identifying it as a pharmacy is exempt from the requirements in subsection (3).

**Permitted Activities of a Community Pharmacy without a Full Pharmacist Present**

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

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

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

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

(c) the hours when a full pharmacist is on duty are posted.

(3) Subject to subsection (2) if a full pharmacist is not present, only the following activities may be carried out:

(a) pharmacy technicians may access the dispensary to perform activities outlined in section 4 of the *Community Pharmacy Standards of Practice*, that do not require pharmacist supervision, except if any such activity involves patient interaction; and

(b) receive drug shipments under section 20(4).

(3) Nothing contained in this section relieves a pharmacy manager of their responsibilities under section 18(2)(a).

**Outsource Prescription Processing**

28 (1) A community pharmacy may outsource prescription processing if

(a) all locations involved in the outsourcing are community pharmacies,

(b) all prescriptions dispensed are labeled and include an identifiable code that provides a complete audit trail for the dispensed drug, and

(c) a notice is posted informing patients that the preparation of their prescriptions may be outsourced to another pharmacy.

(2) The manager of an outsourcing community pharmacy must ensure that all applicable standards of practice are met in processing prescriptions at all locations involved in the outsourcing.

(3) In this section, “community pharmacy” includes a hospital pharmacy.

## PART IV – Hospital Pharmacies

**Hospital Pharmacy’s Manager – Quality Management**

29 (1) A hospital pharmacy’s manager must establish and maintain written quality management policies and procedures that

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

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

(c) include a process for reporting, documenting and following up on known, alleged and suspected errors, incidents and discrepancies,

(d) document periodic audits of the drug distribution process,

(e) include a process to review patient-oriented recommendations,

(f) include a process that reviews a full pharmacist's documentation notes in the hospital's medical records,

(g) include a process to evaluate drug use, and

(h) regularly update policies and procedures for drug use control and patient-oriented pharmacy services in collaboration with the medical and nursing staff and appropriate committees.

(2) If sample drugs are used within a hospital, the hospital pharmacy's manager must ensure that the pharmacy oversees the procurement, storage and distribution of all sample drugs.

**After Hours Service**

30 (1) If continuous pharmacy services are not provided in a hospital, the hospital pharmacy's manager must ensure that urgently needed drugs and patient-oriented pharmacy services are available at all times by

(a) providing a cabinet which must

(i) be a locked cabinet or other secure enclosure located outside of the hospital pharmacy, to which only authorized persons may obtain access,

(ii) be stocked with a minimum supply of drugs most commonly required for urgent use,

(iii) not contain controlled drug substances unless they are provided by an automated dispensing system,

(iv) contain drugs that are packaged to ensure integrity of the drug and labeled with the drug name, strength, quantity, expiry date and lot number, and

(v) include a log in which drug withdrawals are documented, and

(b) arranging for a full pharmacist to be available for consultation on an on-call basis.

(2) When a hospital pharmacy or hospital pharmacy satellite is closed, the premises must be equipped with a security system that will detect unauthorized entry.

## PART V – Telepharmacies

**Telepharmacy Operation**

31 (1) A telepharmacy must not remain open and prescriptions must not be dispensed

without a full pharmacist physically present on duty at the telepharmacy, unless

(a) a full pharmacist at the central pharmacy is engaged in direct supervision of the telepharmacy in accordance with the *Telepharmacy Standards of Practice*, and

(b) subject to subsection (2), a pharmacy technician is physically present on duty at the telepharmacy.

(2) A telepharmacy located at an address listed in Schedule "G" is exempt from the requirements in subsection (1)(b).

(3) A telepharmacy must have a security system that prevents the public and non-pharmacy staff from accessing the professional services area and the dispensary area, including any area where personal health information is stored.

(4) Prescriptions and labels relating to prescriptions dispensed at a telepharmacy must identify the prescription as having been dispensed at that telepharmacy.

(4.1) Prescriptions and labels relating to prescriptions dispensed at a pharmacy listed in Schedule "F" must distinguish between those dispensed when it is operating as a telepharmacy from when it is operating as a community pharmacy.

(5) The manager of a central pharmacy, or a full pharmacist designated by the manager, must

(a) inspect and audit its telepharmacy at least 4 times each year, at intervals of not less than 2 months,

(b) record each inspection and audit in the prescribed form, and

(c) provide the inspection and audit records to the registrar immediately upon request.

(6) A telepharmacy located at an address listed in Schedule "G" must perform a monthly count of narcotics at the telepharmacy and retain a record of each monthly count signed by the supervising pharmacist for three years at both the central pharmacy and the telepharmacy location, and provide the signed record to the registrar immediately upon request.

(7) A telepharmacy must not continue to provide pharmacy services for more than 30 days after

(a) its location ceases to be a rural and remote community,

(b) a community pharmacy is established within the community, or

(c) a community pharmacy is established within 25 kilometers of the location of the telepharmacy.

(8) In accordance with sections 18(2)(c) and (d), a telepharmacy must have policies and procedures on site that outline the methods for ensuring the safe and

effective distribution of pharmacy products and delivery of pharmaceutical care by the telepharmacy.

(9) All transactions in PharmaNet must be distinguishable between the central pharmacy and telepharmacy.

## PART VI – PharmaNet

### Application of Part

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

### Definitions

33 In this Part:

**"patient record"** means the patient record described in section 11(2) of the *Community Pharmacy Standards of Practice* and in the *British Columbia Professional and Software Conformance Standards, Electronic Health Information Exchange* as the "patient record (pharmacy)".

"**PharmaNet**" means "PharmaNet" as defined in section 1 of the *Information Management Regulation*, B.C. Reg. 74/2015;

### Operation of PharmaNet

34 A pharmacy must connect to PharmaNet.

### Data Collection, Transmission of and Access to PharmaNet Data

35 (1) A registrant must enter the prescription information and record it in PharmaNet at the time of dispensing and keep the patient record current.

(2) A registrant may collect and record patient information in PharmaNet, or access, use and disclose a patient's PharmaNet record only for the purposes of:

(a) dispensing a drug;

(b) providing patient consultation;

(c) evaluating a patient's drug usage;

(d) claims adjudication and payment by an insurer; or

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

(3) A registrant must revise information in PharmaNet pertaining to corrected billings for prescriptions billed to the patient or a payment agency other than PharmaCare and record the reason for the revision within 120 days of the original entry in PharmaNet.

(4) A registrant must reverse information in PharmaNet, for any drug that is not released to the patient or the patient's representative, and record the reason for

the reversal no later than 30 days from the date of the original entry of the prescription information in PharmaNet.

(5) If a registrant is unable to comply with the deadlines in subsection (3) or (4), he or she must provide the information required to make the correction to the Ministry of Health as soon as possible thereafter.

## PART VII – Confidentiality

### Confidentiality

36 A registrant must take reasonable steps to confirm the identity of a patient, patient's representative, registrant or practitioner before providing any pharmacy service that requires accessing, using or disclosing of patient personal health information.

## PART VIII – College

### Forms

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

### Use, Disclosure and Retention of Criminal Record History Information

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

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

## SCHEDULE OF AMENDMENTS

The bylaws of the College of Pharmacists of British Columbia made under the authority of the *Pharmacy Operations and Drug Scheduling Act* are amended in light of COVID-19 related drug shortages to temporarily allow return to inventory, injectable drugs previously dispensed for the purpose of providing Medical Assistance in Dying, as follows:

1. Section 22 is repealed and replaced by the following:

| | |
|---|---|
| 22 | No registrant may accept for return to stock or reuse any drug previously dispensed except in accordance with section 11(3) of the *Residential Care Facilities and Homes Standards of Practice*, section 5(2) of the *Hospital Pharmacy Standards of Practice*, or section 5 of the *Dispensing Drugs for the Purposes of Medical Assistance in Dying Standards, Limits and Conditions*. |

# Temporary Exemption for Dispensing Drugs for the Purposes of Medical Assistance in Dying (MAiD) Now in Effect

*A temporary exemption allowing injectable drugs, previously dispensed for the purpose of providing Medical Assistance in Dying (MAiD), to be returned to inventory, is now in effect.*

This means that during the COVID-19 public health emergency in British Columbia, if there is a shortage for any injectable drug dispensed for the purpose of MAiD, all unused injectable MAiD drugs **dispensed and returned within the same, original sealed tamper-proof kit** may be returned to inventory.

*Shortages may include manufacturer reported shortages (i.e. those listed on Drug Shortages Canada), or those proactively assigned by Health Canada, such as a Tier 3 Drug Shortage.*

Prior to returning unused medications to inventory, the pharmacist must be satisfied that the following conditions have been met:

1. The medication has not left the possession of the prescribing medical practitioner or nurse practitioner, or a licensed health care professional assigned by the physician or nurse practitioner; and the integrity of the medication can be verified.
2. Each dose is unused and in the original sealed tamper proof kit; and
3. The medication has been maintained in accordance with the manufacturers requirements and any other applicable requirements.

## Temporary Exemption

Recently, a number of the drugs used in the MAiD intravenous drug protocol have been included in Health Canada's 'Tier 3 Drug Shortages' list, which lists shortages that have the greatest impact on Canada's drug supply and health care system.

Many of these drugs are also used in the treatment of patients with COVID-19, who require critical care.

In response to these shortages of drugs used for MAiD, the Board approved amendments to the *Health Professions Act* Bylaws Schedule F Part 5 – *Dispensing Drugs for the Purposes of MAiD Standards, Limits and Conditions* to temporarily allow injectable drugs, previously dispensed for the purpose of providing MAiD, to be returned to inventory.

***Health Professions Act* Bylaws Schedule F Part 5 – *Dispensing Drugs for the Purposes of MAiD Standards, Limits and Conditions***

*If there is a shortage of medication for medical assistance in dying, a pharmacist may accept for return to inventory, injectable medication previously dispensed for the purpose of providing medical assistance in dying if they are satisfied that:*

*a) The medication has not left the possession of the prescribing medical practitioner or nurse practitioner, or a licensed health care professional assigned by the physician or nurse practitioner and the integrity of the medications can be verified;*

*b) Each dose is unused and in the original sealed tamper proof kit; and,*

c) *The medication has been maintained in accordance with the manufacturer's requirements and any other applicable requirements.*

**The temporary exemption will be in effect during the COVID-19 public health emergency in British Columbia.**

To support this exemption, consequential amendments to Section 22 of the *Pharmacy Operations and Drug Scheduling Act* (PODSA) Bylaws have also been implemented.

Registrants may now accept for return to stock or reuse, any drug previously dispensed in accordance with the temporary amendments to the *Dispensing Drugs for the Purposes of MAiD Standards Limits and Conditions*, as noted above.

***Pharmacy Operations and Drug Scheduling Act (PODSA)* Bylaws**

**Returned Drugs**

22. No registrant may accept for return to stock or reuse any drug previously dispensed except in accordance with section 11(3) of the *Residential Care Facilities and Homes Standards of Practice,* section 5(2) of the *Hospital Pharmacy Standards of Practice,* **or section 5 of the *Dispensing Drugs for the Purpose of Medical Assistance in Dying Standards, Limits and Conditions.***

## Proper Storage of Injectable MAiD Drugs

When dispensing drugs for the purpose of MAiD, the pharmacist should ensure the prescribing medical practitioner or nurse practitioner knows how to appropriately store the medications. Pharmacists may consult the **Medical Assistance in Dying British Columbia Pharmacy Protocols** (available on e-Services) and other sources (e.g. the manufacturer's requirements) for information on how to store injectable MAiD drugs.

College of Pharmacists of British Columbia

# 5. Filing of Consequential Amendments to the *Pharmacy Operations and Drug Scheduling Act* Bylaws to Temporarily Permit Return to Inventory Injectable Drugs Previously Dispensed for the Purpose of Medical Assistance in Dying

**Anu Sharma**

Acting Director of Policy and Legislation

College of Pharmacists of British Columbia

# Background

## April 30, 2020 Board Teleconference

- The Board approved amendments to HPA Bylaws - *Dispensing Drugs for the Purposes of Medical Assistance in Dying Standards, Limits and Conditions* for filing with the Minister of Health. The amendments temporarily permit return to inventory, injectable drugs previously dispensed for the purpose of medical assistance in dying (MAiD).
- The Board also approved a consequential amendment to the *Pharmacy Operations and Drug Scheduling Act* (PODSA) Bylaws for public posting and requested a shortened public posting period from the Minister to bring the amendment into force as soon as possible.

College of Pharmacists of British Columbia

# Public Posting and Filing

## Public Posting

- The consequential amendment to the PODSA Bylaws was publicly posted on April 30, 2020 for a 24 hour shortened period.
- The posting period ended on May 1, 2020 at 6:00pm.
- 4 responses were received, and all were supportive of the consequential amendment.
- No changes to the amendment are proposed.

## Filing

- It is recommended that the amendment proceeds for filing with the Minister of Health, with a request for a shortened filing period.

College of Pharmacists of British Columbia

# 5. Filing of Consequential Amendments to the Pharmacy Operations and Drug Scheduling Act Bylaws to Temporarily Permit Return to Inventory Injectable Drugs Previously Dispensed for the Purpose of Medical Assistance in Dying

**MOTION:**

Approve the following resolution to amend the *Pharmacy Operations and Drug Scheduling Act* Bylaws consequentially:

"RESOLVED THAT, in accordance with the authority established in section 21(1) of the *Pharmacy Operations and Drug Scheduling Act* and subject to the requirements in section 21(4) of the *Pharmacy Operations and Drug Scheduling Act*, the Board of the College of Pharmacists of British Columbia approves the proposed bylaws, as circulated, for filing with the Minister of Health."

College of Pharmacists of British Columbia

# BOARD MEETING
# May 7, 2020

## 6. Amendments to *Professional Practice Policy-58 Medication Management (Adapting a Prescription)*

## DECISION REQUIRED

### Recommended Board Motion:

1. Approve amendments to *Professional Practice Policy 58 - Amendment to Orientation Guide – Medication Management (Adapting a Prescription)* in light of COVID-19, to be effective immediately.

2. Approve amendments to *Professional Practice Policy 58 - Orientation Guide – Medication Management (Adapting a Prescription)* in light of COVID-19, to be effective immediately.

### Purpose

To provide information and recommendations on proposed amendments to *Professional Practice Policy-58 Medication Management (Adapting a Prescription)* (PPP-58).

### Background

PPP-58 provides the framework to guide pharmacists in the safe and effective adaptation of existing prescriptions (see Appendix 1).

As outlined in the Orientation Guide to PPP-58 (see Appendix 2), the three primary activities considered under the notion of adapting a prescription include:

1. **Change**: changing the dose, formulation, or regimen of a prescription to enhance patient outcomes;
2. **Renew**: renewing a prescription for continuity of care; and
3. **Substitution**: making a therapeutic drug substitution within the same therapeutic class for a prescription to best suit the needs of the patient.

PPP-58 does not apply to controlled drug substances or cancer chemotherapy agents. If a change to a prescription for one of these categories of drugs is warranted, the pharmacist must contact the original prescriber to discuss modifying the original prescription. In addition, PPP-58 does not allow for the adaptation of a prescription if the original prescription has expired.

Additional limitations on adaptation are described in the Amendments to the Orientation Guide (see Appendix 3). Dose or regimen changes are not permitted for prescriptions for cancer, cardiovascular disease, asthma, seizures or psychiatric conditions, unless in practice settings such as a hospital, long-term care facilities or multi-disciplinary environments where collaborative relationships or appropriate protocols are established. Pharmacists may only renew psychiatric medications if they work in a multidisciplinary team.
Therapeutic substitutions are limited to those categories under the Ministry of Health's Reference Drug Program (RDP), unless in practice settings such as a hospital, long-term care facilities or multi-disciplinary environments where collaborative relationships or appropriate protocols are established.

A fulsome review of PPP-58 is included as part of the Policy and Legislation Department's five year operational plan for policy and legislative changes. However, in light of the COVID-19 public health emergency, members of the Board had expressed interest in reviewing the following aspects of PPP-58 to support patient care during the pandemic:

- prescriber notification requirements of renewals;
- adaptation of transferred prescriptions; and
- the limitation on drug categories for therapeutic substitution.

It is noted that given the short timeline, an opportunity for fulsome consultation which would typically occur for any proposed amendments to a policy, did not occur.

## Discussion

On March 11, 2020, the World Health Organization declared the novel coronavirus, COVID-19, a pandemic, citing concern over alarming levels of spread and severity across the globe. The novel coronavirus has caused a global outbreak of respiratory infections since its discovery in December 2019.

When considering amendments in light of the COVID-19 pandemic, it is noted that in recent weeks, BC has experienced a reduction in the number of confirmed new cases of COVID-19 in the province. Additionally, there has been a steady decline in cases currently in hospital and Intensive Care Units since mid-April.[1]

**1. Prescriber Notification Requirement of Renewals**
In accordance with PPP-58, in order to adapt a prescription, a pharmacist must notify the original prescriber (and the general practitioner if appropriate) as soon as reasonably possible (preferably within 24 hours of dispensing). Notification must be recorded in the client's record or directly on the prescription. This is outlined further within the PPP-58 Orientation Guide, which stipulates that notification must include:

[1] See BC COVID-19 Daily Situation Repot, April 27, 2020 from the BC Centre for Disease Control

1. Patient (including PHN number) and Pharmacist (including signature and name of Pharmacy) information
2. Original prescription information (including prescribers name and contact information)
3. A description of the adaptation (including all relevant prescription details)
4. The rationale for the decision to adapt the prescription (including pertinent details of your assessment and patient history along with any instructions to the patient and relevant follow-up plan)
5. Acknowledgment of informed consent
6. The date and name of practitioner notified

At the onset of the COVID-19 pandemic, a joint statement was issued by the Minister of Health and BC's provincial health officer, which advised pharmacies to provide patients with a prescription refill or an emergency supply of their medications if needed in order to provide physicians more time to care for patients with acute care needs.[2] This recommendation was expected to result in an increase in the use of PPP-58 to provide medication renewals for patients, along with an increase in renewal notifications being sent to prescribers by pharmacists.

***Jurisdictional Scan***

A jurisdictional scan was conducted to determine the notification requirements of other Pharmacy Regulatory Authorities (PRAs). Particular attention was paid to any amendments made due to the COVID-19 pandemic. Information was collected from Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Yukon (see Appendix 4).

The majority of PRAs require the pharmacist to notify the original prescriber when renewing a prescription.[3] As a result of the COVID-19 pandemic, four PRAs (Alberta, Saskatchewan, Yukon and Nova Scotia) have removed the requirement for the pharmacist to notify the original prescriber when renewing a prescription. All four PRAs removed this requirement by the beginning of April.

***Prescriber's Feedback***

In considering a change to the current prescriber notification requirement in PPP-58, discussion occurred with the College of Physicians and Surgeons of BC and the Doctors of BC to determine potential impacts that may result from the possible removal of this requirement for renewals for the duration of the COVID-19 pandemic. Although neither organization was able to provide a detailed response from their membership due to time constraints, on a general level, it was acknowledged that physicians benefit from the current notification requirements and any perceived administrative burden of receiving a notification is largely outweighed by the benefits of staying informed. Based on previous survey results, Doctors of BC was able to confirm that from the physician perspective, the overall benefits of requiring notification for prescription

[2] https://news.gov.bc.ca/releases/2020HLTH0086-000499

[3] Only one PRA, (New Brunswick) requires that the pharmacist inform the original prescriber when the change to the prescription is "clinically significant".

renewal are justified to support continuity of patient care. This could also be true during the COVID-19 pandemic, as many physicians may have seen a drop in the number of patient visits due to physical distancing measures.

***Options for the Board's Consideration***
There are two options for the Board's consideration.

*Option 1: Maintain the Notification Requirement for Renewals*

The first option for the Board's consideration is to maintain the current notification requirements within PPP-58, which require the notification of the original prescriber as soon as reasonably possible (preferably within 24 hours of dispensing).

Pros

- Requiring notification maintains an informed circle of care and provides enhanced opportunity for collaboration amongst healthcare professionals.
- Discussion with the College of Physicians and Surgeons of BC as well the Doctors of BC revealed that prescribers appreciate notification upon renewal.
- Maintaining notification aligns with the current requirements of the majority of PRAs.
- Maintaining notification aligns with the current requirements of *Professional Practice Policy-31 Emergency Supply for Continuity of Care* (PPP-31) which specifies that a pharmacist, where possible and appropriate, should notify the patient's practitioner in a timely fashion and should make a record of this in the patient's record.

Cons

- Pharmacies may be experiencing higher-than-normal volumes of prescription renewals, which would subsequently increase the volume of notifications that must be prepared and sent to prescribers.
- The increased time required to prepare and send notifications may reduce the time pharmacists have to perform other patient care activities.

*Option 2: Remove the Notification Requirement for Renewals for the duration of the COVID-19 public health emergency in British Columbia*

The second option for the Board's consideration is to remove the notification requirement for renewals during the COVID-19 public health emergency in British Columbia.

Pros

- Removing the notification requirement could help ensure the health-care system is best positioned to respond to the pandemic by reducing a perceived administrative burden for both pharmacists and physicians.

Cons

- Removing the notification requirement could result in an uninformed circle of care and reduce the opportunity for collaboration amongst healthcare professionals.
- Discussions with the College of Physicians and Surgeons of BC and the Doctors of BC identified that generally, prescribers are appreciative of renewal notifications to maintain continuity of care.
- Only a minority of PRAs have waived this requirement during the COVID-19 public health emergency.
- Removing the notification requirement would be incongruent with PPP-31, which specifies that the pharmacist should notify the patient's practitioner in a timely fashion.
- Lack of consultation and potential for unintended consequences.

Staff recommend that the Board proceed with Option 1, which is to maintain the current notification requirement within PPP-58. Requiring notification maintains an informed circle of care and provides enhanced opportunity for collaboration amongst health professionals. Maintaining the notification requirements also aligns with feedback received from the College of Physicians and Surgeons of BC as well as the Doctors of BC, and aligns with notification requirements of PPP-31. Additionally, although public health orders and physical distancing measures remain in place, BC has experienced a reduction in the number of confirmed cases of COVID-19 in the province and it is understood from discussion with prescribers that the notification is manageable and appreciated.

**2. Permitting Adaptation of Transferred Prescriptions**

In accordance with PPP-58, in order to adapt a prescription a pharmacist must have a prescription that is current, authentic, and appropriate. As outlined in the Orientation Guide to PPP-58, a pharmacist must have the original prescription (an authorization from a practitioner to dispense a specified drug for use by a designated individual). A pharmacist may not adapt if the original prescription has expired. Further, as stipulated in the Amendments to the Orientation Guide, original prescriptions do not include transferred prescriptions, previously adapted prescriptions, or emergency refills. Although adapting a transferred prescription is currently not permitted under PPP-58 requirements, during the COVID-19 public health emergency it may be beneficial for a pharmacist to adapt transferred prescriptions due to drug shortages or physical distancing measures and travel restrictions in place.

***Jurisdictional Scan***

A jurisdictional scan was conducted to determine original prescription requirements of other PRAs. Particular attention was paid to any amendments made because of the COVID-19 pandemic. Information was collected from Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland, and the Yukon (see Appendix 5). Four of nine PRAs (Alberta, Saskatchewan, Manitoba and Yukon) require a pharmacist to have the original prescription when adapting a prescription. The remaining five PRAs (Ontario, New Brunswick, Nova Scotia, PEI and Newfoundland & Labrador) do not require an original

prescription when adapting a prescription. In these provinces, pharmacists are permitted to adapt a prescription that has been transferred.

Two provinces have amended original prescription requirements for adapting a prescription during the COVID-19 pandemic. Ontario (which already allows adaptation without the original prescription if they have access to the information contained in the original prescription) has further relaxed requirements during the COVID-19 pandemic to allow adaptation if the pharmacist has a prescription label, prescription receipt or photograph of the prescription. PEI has removed the requirement for the original prescription to be at the dispensing pharmacy (i.e. a transferred prescription could be adapted).

***Options for the Board's Consideration***

There are two options for the Board's consideration.

*Option 1: Permitting Transferred Prescriptions to be Adapted for the duration of the COVID-19 public health emergency in British Columbia*

The first option for the Board's consideration is to amend PPP-58 to permit transferred prescriptions to be adapted during the COVID-19 public health emergency in British Columbia. Amendments to the Amendments to the Orientation Guide would be required (see Appendix 6).

Pros

- Transferred prescriptions may be more common during the COVID-19 public health emergency (due to travel restrictions, pharmacy closures, drug shortages etc.) and permitting a pharmacist to adapt a transferred prescription may improve patient health outcomes
- Minimizes delays in initiating or changing drug therapy
- Allows a pharmacist to use their professional judgement to determine whether to adapt a transferred prescription

Cons

- The pharmacy that receives the original prescription has all of the information necessary to determine whether to adapt the prescription (such as the prescription date, any prescriber notations/instructions, etc.), which is not required to be communicated to the receiving pharmacist when a prescription transfer occurs[4]
- Where a patient is known to the pharmacy that received the original prescription, there is an opportunity to optimize drug therapy leading to improved patient health outcomes
- Lack of consultation and potential for unintended consequences.

[4] A prescription transfer does not include all of the information required of a prescription as outlined in section 6(2) of the *Community Pharmacy Standards of Practice*. For example, the date of the first and last dispensing of the medication must be communicated at the time of transfer, but the date the prescription was written is not required.

*Option 2: Maintain the Original Prescription Requirement for Adaptations*

The second option for the Board's consideration is to maintain the current original prescription requirement within PPP-58, which require the pharmacist to have the original prescription when adapting a prescription. Under this current requirement, the adaptation of a transferred prescription is not permitted.

Pros

- The pharmacy that receives the original prescription has all of the information necessary to determine whether to adapt the prescription (such as the prescription date, any prescriber notations/instructions, etc.)
- Where a patient is known to the pharmacy that received the original prescription, there is an opportunity to optimize drug therapy leading to improved patient health outcomes

Cons

- Transferred prescriptions may be more common during the COVID-19 public health emergency (due to travel restrictions, drug shortages etc.) and limiting the pharmacist's ability to adapt a transferred prescription may negatively impact patient health outcomes
- If a transferred prescription requires adaptation, the pharmacist would need to contact the prescriber to discuss the prescription, leading to a potential for a delay in initiating or changing drug therapy

Staff recommend that the Board proceed with Option 1, which is to permit transferred prescriptions to be adapted during the COVID-19 public health emergency. Transferred prescriptions may be more common during the COVID-19 public health emergency, and permitting the pharmacist to adapt a transferred prescription may increase patient outcomes. It allows a pharmacist to use their professional judgement to determine whether to adapt a transferred prescription, and alleviates the potential of a delay in patient therapy as the pharmacist would not need to contact the prescriber.

It is noted that the above recommendation would permit transferred prescriptions to be adapted for the duration of the COVID-19 public health emergency in British Columbia. As previously indicated, a more fulsome review of PPP-58 is included as part of the Policy and Legislation Department's five year operational plan for policy and legislative changes, and would include considering whether to allow transferred prescriptions to be adapted in ordinary circumstances.

**3. Remove Limitation on Drug Categories for Therapeutic Substitution where Drug Shortages Exist**

Under PPP-58, therapeutic substitutions are limited to those categories under the Ministry of Health's Reference Drug Program (RDP)[5], unless in practice settings such as hospital, long-term care facilities or multi-disciplinary environments where collaborative relationships or appropriate protocols are established. The RDP includes the following categories:

- Angiotensin converting enzyme inhibitors (ACE inhibitors)
- Angiotensin receptor blockers (ARBs)
- Dihydropyridine calcium channel blockers (DHP CCBs)
- Histamine 2 receptor blockers (H2RAs)
- Proton pump inhibitors (PPIs)
- Nitrates
- Non-steroidal anti-inflammatory drugs (NSAIDS)
- Statins

***Drug Shortages***

A drug shortage occurs when a manufacturer is unable to meet demand for a drug, and while drug shortages have been increasing in recent years, additional drug shortages are occurring, or are expected to occur, as a result of the COVID-19 pandemic. Drug shortages occur for a variety of reasons, including unanticipated increases in demand, shortages of the active ingredients, and supply chain disruptions, and can be impacted by events occurring around the globe.
In recent years, drug shortages of drugs within RDP classes have occurred, including ARBs and H2RAs. The ability of the pharmacist to provide a therapeutic substitution with another drug in the same class can mitigate some of the impacts of these drug shortages. Expected and actual drug shortages due to COVID-19 will extend beyond the therapeutic categories of the RDP, and consideration to removing this limitation is recommended during these uncertain times.

There are a number of ways to determine if there is a drug shortage. In accordance with the *Food and Drug Regulations*[6], if a drug shortage exists or is likely to occur, manufacturers must report the drug shortage to a third party website, www.drugshortagescanada.ca, within specified timeframes. Manufacturers or wholesalers may also alert pharmacies of these shortages through direct communication.

Health Canada may proactively assign drug shortage status to drugs, even if a manufacturer is currently able to meet demand. PharmaCare also maintains a list of current shortages of drugs that are on the PharmaCare formulary.[7]

---

[5] https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/prescribers/reference-drug-program/reference-drug-program-list-of-full-and-partial-benefits

[6] https://laws-lois.justice.gc.ca/eng/regulations/c.r.c.%2C_c._870/page-97.html#h-575006

[7] https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/pharmacies/drug-shortage-information

***Jurisdictional Scan***

A jurisdictional scan across Canada revealed that most PRAs permit pharmacists to provide therapeutic substitution. These jurisdictions include Alberta, Saskatchewan, Quebec, New Brunswick, Nova Scotia, Newfoundland & Labrador, Prince Edward Island, and the Yukon (see Appendix 7). Saskatchewan and Quebec are not included in the Appendix 7 summary as Saskatchewan's therapeutic substitution policy is subject to a collaborative practice agreement between a pharmacist and a practitioner, and Quebec's information was only available in French.

Of the six jurisdictions included in the scan, all had therapeutic substitution policies similar to PPP-58, though unlike PPP-58, none had restrictions on which therapeutic classes could be substituted (controlled substances are excluded from all PRA's therapeutic substitution policies). Additionally, four PRAs (New Brunswick, Prince Edward Island, Newfoundland & Labrador and Yukon) don't require therapeutic substitutions to be within the same therapeutic class, as long as the substituted drug is expected to have a therapeutically equivalent effect.

***Ministry of Health Considerations***

The Ministry of Health, at present, pays clinical service fees to pharmacies for adaptations that are consistent with the definition of adaptation in PPP-58.[8] As such, College staff discussed the possible amendments to the therapeutic substitution component of PPP-58 with staff from the Pharmaceutical Services Division and the Professional Regulation Branch the Ministry of Health. Staff from the Ministry of Health have indicated that changes to PPP-58 to address shortage-based therapeutic substitutions in light of COVID-19 would be supported by the Ministry of Health.

***Other Considerations***

Some of the existing restrictions on adaptations were created in consultation with prescribers when PPP-58 was first implemented. Consultation with prescribers on changes to therapeutic substitution restrictions was not possible due to the expedited timeline of this policy change. There is a different, existing limit on changing the dose or regimen of a prescription that does not permit pharmacists to change the dose or regimen of prescriptions for cancer, cardiovascular disease, asthma, seizures or psychiatric conditions. *Changes* are a different adaptation activity than *therapeutic substitutions*, and amendments to the limits on changes have not been proposed or considered at this time.

***Options for the Board's Consideration***

There are two options for the Board's consideration.

*Option 1: Remove the limitation on drug categories for therapeutic substitution for the duration of the COVID-19 public health emergency in British Columbia*

[8] https://www2.gov.bc.ca/assets/gov/health/health-drug-coverage/pharmacare/8-4to8-6.pdf

The first option for the Board's consideration is to allow pharmacists to adapt prescriptions for drugs not in the RDP by therapeutic substitution, where there is an actual drug shortage for a prescribed drug, and where no interchangeable drug is available, for the duration of the COVID-19 public health emergency in British Columbia (see Appendix 8). Under this option evidence of the drug shortage (e.g. report from drugshortagescanada.ca or a "no alternative available" listing on PharmaCare's Current Drug Shortages List) must be included with the adaptation documentation.

Pros

- Drug shortages in classes beyond the RDP are anticipated in the context of COVID-19, and this option would allow pharmacists to ensure timely continuity of care for patients impacted by these drug shortages
- PPP-58 already outlines the elements pharmacists must follow to ensure substitution optimizes therapeutic treatment and will not put the patient at increased risk
- This option aligns with the other PRAs included in the jurisdictional scan, as none place limits on therapeutic classes that can be substituted
- Improved efficacy and efficiency of the health care system

Cons

- There may be unanticipated consequences that we have not identified as consultation with the public and prescribers was not possible
- Misalignment in level of restrictions on different adaptation activities, as pharmacists would still not be permitted to change the dose or regimen for prescriptions for cancer, cardiovascular disease, asthma, seizures or psychiatric conditions, but may be permitted to substitute prescribed drugs for these conditions where a drug shortage exists (therapeutic substitution of controlled substances and cancer chemotherapy will remain excluded)

*Option 2: Maintain existing limitation on therapeutic substitution to only those categories under the Ministry of Health RDP.*

The second option for the Board's consideration is to maintain the existing limitation on therapeutic substitution to only those categories under the Ministry of Health RDP.

Pros

- No risk of unanticipated consequences due to policy change
- Level of restrictions on adaptations by *change* of dose or regimen, and by *therapeutic substitution* remain similar

Cons

- There may be delays in initiating drug therapy if the prescriber cannot be contacted in a timely manner to authorize substitutions for drugs that are short

- None of the PRAs identified in the jurisdictional scan place limits on therapeutic classes that can be substituted

Option 1 is recommended to allow pharmacists to adapt prescriptions for drugs not in the RDP by therapeutic substitution, where there is an actual drug shortage and no interchangeable drug is available. Drug shortages have been increasing over time, and global events in the midst of the COVID-19 pandemic may further impact drug shortages in British Columbia. Allowing pharmacists to substitute where drug shortages exist will support continuity of care for patients and minimize delays in initiating or changing drug therapy. The potential unanticipated consequences of the proposed policy change may be lessened by only allowing therapeutic substitution outside of the RDP where there is an actual drug shortage, and only during the COVID-19 public health emergency in British Columbia.

**4. Minor Updates to Orientation Guide**
Minor updates to the Orientation Guide are recommended to align with the recent changes to *Professional Practice Policy 31 – Emergency Supply for Continuity of Care*, as approved by the Board in November 2019. Proposed updates can be found in Appendix 8.

## Guiding Questions

When reviewing the options and considering the recommended options for amendments to PPP-58, the Board is asked to consider:

- Do the amendments to PPP-58 support patient care during the COVID-19 public health emergency?
- Is there anything unclear, ambiguous, or unnecessary in the amendments?

## Recommendation

Staff recommend the following amendments to PPP-58 during the COVID-19 public health emergency:

- Permitting transferred prescriptions to be adapted; and,
- Removing the limitation on therapeutic substitution to within RDP categories allowing pharmacists to adapt prescriptions for drugs not in the RDP by therapeutic substitution, where there is an actual drug shortage for a prescribed drug, and where no interchangeable drug is available.

| **Appendix** | |
|---|---|
| 1 | *Professional Practice Policy 58 – Medication Management (Adapting a Prescription)* |
| 2 | Orientation Guide – Medication Management (Adapting a Prescription) |
| 3 | Amendments to Orientation Guide – Medication Management (Adapting a Prescription) (December 2008 – revised February 2011/April 2016/October 2016) |
| 4 | Prescriber Notification Jurisdictional Scan Summary |
| 5 | Original Prescription Jurisdictional Scan Summary |
| 6 | Amendments to Amendments to the Orientation Guide – Medication Management (Adapting a Prescription) (December 2008 – revised February 2011/April 2016/October 2016) (track changes and clean) |
| 7 | Therapeutic Substitution Jurisdictional Scan Summary |
| 8 | Amendments to Orientation Guide – Professional Practice Policy #58 – Medication Management (Adapting a Prescription) (track changes and clean) |

**POLICY CATEGORY:** **PROFESSIONAL PRACTICE POLICY-58**
**POLICY FOCUS:** **Medication Management (Adapting a Prescription)**

## POLICY STATEMENT(S):

A pharmacist may dispense a drug contrary to the terms of a prescription (adapt a prescription) if the action is intended to optimize the therapeutic outcome of treatment with the prescribed drug and meets **all** of the following elements of a protocol to adapt a prescription:

1. **Individual competence**
   a. Pharmacist has appropriate knowledge and understanding of the condition and the drug being dispensed in order to adapt the prescription.

2. **Appropriate information**
   a. Pharmacist has sufficient information about the specific client's health status to ensure that adapting the prescription will maintain or enhance the effectiveness of the drug therapy and will not put the client at increased risk.

3. **Prescription**
   a. Pharmacist has a prescription that is current, authentic, and appropriate.

4. **Appropriateness**
   a. Pharmacist determines whether adapting the prescription is appropriate in the circumstances.

5. **Informed consent**
   a. Pharmacist must obtain the informed consent of the client or client's representative before undertaking any adapting activity.

6. **Documentation**
   a. Pharmacist must document in the client's record any adaptation of the prescription, the rationale for the decision, and any appropriate follow-up plan.

7. **Notification of other health professionals**
   a. Pharmacist must notify the original prescriber (and the general practitioner if appropriate) as soon as reasonably possible (preferably within 24 hours of dispensing) and this must be recorded in the client's record or directly on the prescription.

**Note: PPP-58 is not a stand-alone document and must be read with the Orientation Manual and the Amendment to the Orientation Manual. For a pharmacist to use PPP-58 they will be required to sign the PPP-58 Declaration Form.**

**POLICY CATEGORY:** **PROFESSIONAL PRACTICE POLICY-58**
**POLICY FOCUS:** **Medication Management (Adapting a Prescription)**

## BACKGROUND:

### Protocol for medication management (adapting a prescription)

This professional practice policy enables pharmacists to maximize their full educational and professional competencies by providing authorization to adapt existing prescriptions. This policy is not mandatory and the decision whether to adapt a prescription is at the discretion of the individual pharmacist.

To guide decisions with respect to adapting a prescription, where a specific hospital board - or College of Pharmacists of BC - Board approved protocol does not exist, the pharmacist must refer to all applicable legislation and standards. This includes, but is not limited to, the Health Professions Act, Pharmacy Operations and Drug Scheduling Act, the Regulation and Bylaws of the College of Pharmacists of BC made pursuant to these Acts, the Health Care (Consent) and Care Facility (Admission) Act, the Framework of Professional Practice, the Code of Ethics and Professional Practice Policies. This specific policy (PPP-58) does not apply to controlled drug substances and cancer chemotherapy agents.

The Framework of Professional Practice (FPP) is the standards of pharmacy practice in British Columbia. In adapting a prescription the pharmacist must follow the FPP Role 1 *Provide pharmaceutical care.* Role 1 elements include:

- Function A – Assess the client's health status and needs
- Function B – Develop a care plan with the client
- Function C – Support the client to implement the care plan
- Function D – Support and monitor the client's progress with the care plan
- Function E – Document findings, follow-ups recommendations, information provided and client's outcomes

### Benefits of professional practice policy

The benefits to clients are to:

a) Optimize drug therapy leading to improved client health outcomes
   1) Better therapeutic responses.
   2) Reduced drug errors.
   3) Fewer adverse drug reactions/interactions.

b) Have an effective and efficient health care system
   1) Minimize delays in initiating and changing drug therapy.
   2) Make the best use of human resources in the health care system.

c) Expand the opportunities to identify people with significant risk factors.

d) Encourage collaboration among health care providers.

### Supporting documents

- Amendment to PPP-58
- Orientation Guide – Declaration FormPPP-58 Orientation Guide
- Pharmacist Prescription Adaptation Documentation and Notification Form
- Sample letter/fax introducing PPP-58
- Quick Reference Guide

# APPENDIX 1

Revised: 14 Sep 2018
Reaffirmed: 27 Mar 2009

APPENDIX 2

College of Pharmacists
of British Columbia

# Orientation Guide

## Professional Practice Policy #58 - Medication Management (Adapting a Prescription)

# Foreword

Medication Management is an umbrella term that encompasses all professional activities that a pharmacist undertakes, as the medication experts, to optimize safe and effective drug therapy outcomes for patients. Pharmacists' involvement in medication management activities will continue to expand as the needs of patients and the demands of the healthcare system continue to increase.

This point was reinforced throughout the February 2008 'Throne Speech' where the provincial government acknowledged the challenges of sustaining the current healthcare system and called on all healthcare professionals to practice to their full scope as a means of helping to alleviate pressure from the system. This led to the introduction of – *Bill 25 – The Health Professions (Regulatory Reform) Amendment Act, 2008* which, specific to the pharmacy profession, formalizes a pharmacist's authority to 'renew existing prescriptions'.

The College of Pharmacists of BC's Professional Practice Policy #58 (PPP-58) entitled *"Protocol for Medication Management – Adapting a Prescription"*, approved by College council in September 2007, provides the framework to guide pharmacists in the safe and effective adaptation, including renewal, of existing prescriptions. PPP-58 is applicable to pharmacists in all practice settings, including community, long-term care, hospital and other institutional pharmacy settings.

This policy, which provides the opportunity for pharmacists to maximize their full educational and professional competencies, also provides structure to, and refines the process of, exercising professional judgment in clinical practice. This becomes increasingly important as pharmacists evolve their role as medication experts and assume accountability for their drug therapy decisions.

Although it is **not mandatory that a pharmacist adapt a prescription**, given that PPP-58 enhances pharmacist's scope of practice, it is mandatory that all registrants:

- Acknowledge that they have read and understood PPP-58 (by signing the Declaration Form included in this Guide)

Should a pharmacist choose to adapt a prescription, in addition to having read and understood the Orientation Guide, a pharmacist must:

- Possess personal professional liability insurance (minimum $2 million) and must adhere to all of the seven fundamentals for adapting a prescription as outlined in PPP-58

# How to Use This Guide

This Orientation Guide (the Guide) is a companion to the actual policy PPP-58 which can be found in Appendix A. The intention of the Guide is to provide further detail and clarity (including practical examples) to assist pharmacists in the implementation of the policy into practice and ensure that adaptations are done safely and effectively. For clarity, a Glossary of Terms specific to PPP-58 can be found in Appendix B. It is important to note that this document is a guide only and is not intended to cover all possible practice scenarios. As with all professional activities, pharmacists must use sound professional judgment when adapting a prescription.

It will take you about 2 hours to read through this Guide. Assuming that after reading the Guide you are confident that you understand the content you need to sign the Declaration Form (final page of Guide) and retain it in your files. Should you require further clarification, you may contact the College at **practicesupport@bcpharmacists.org**.

# Disclaimer

This Guide provides interpretation of PPP-58 under the statutes that govern the pharmacy profession in British Columbia. As a professional health practitioner in a self-regulated profession, you – the pharmacist – are responsible for understanding and practicing according to all relevant requirements and laws. You have a responsibility as a professional for interpreting and applying PPP-58 and the contents of this Guide within the context of your own practice.

# Acknowledgement

Thank you to the Alberta College of Pharmacists for sharing their materials and experiences from their work on implementing practice standards for adapting a prescription in Alberta. Thank you to the BC Pharmacy Association for their participation in the Working Group that created this Orientation Guide.

# Feedback

Questions and comments about this Orientation Guide are welcome and can be sent to:

Bob Nakagawa, Registrar
College of Pharmacists of BC
200–1765 West 8th Avenue Vancouver, BC V6J 5C6
Phone: 604.733.2440 or 800.663.1940
Fax: 604.733.2493 or 800.377.8129
E-mail: info@bcpharmacists.org

# Table of Contents

# 1.0 Introduction

## 1.1 Overview

The Framework of Professional Practice (FPP) provides the framework for good pharmacy practice in British Columbia. It describes what BC pharmacists do in daily practice and how they know they are doing it well. The FPP is designed to help pharmacists enhance their practice and patient outcomes, and to guide their professional development.

Within the current provincial legislative structure, pharmacists have the authority to perform certain professional activities to help people achieve their desired health outcomes. The College develops Professional Practice Policies to more clearly articulate a pharmacist's professional practice authorities and responsibilities. Professional Practice Policy #58 (PPP- 58) entitled *Protocol for Medication Management (Adapting a Prescription) is one such policy and falls under FPP Role 1 – Provide Pharmaceutical Care*.

In adapting a prescription however, in addition to PPP-58, the pharmacist must refer to all applicable legislation and standards. This includes, but is not limited to, the *Health Professions Act* (HPA)*, the Pharmacy Operations and Drug Scheduling Act (PODSA), the Pharmaceutical Services Act (PSA)* and related regulations and bylaws, the *Health Care (Consent) and Care Facility (Admission) Act*, the FPP, and other Professional Practice Policies.

Although it is mandatory to know this policy, it is not mandatory that a pharmacist adapt a prescription. The decision to adapt a prescription or not is at the discretion of the individual pharmacist. Whenever a pharmacist chooses to adapt a prescription however, the adaptation must be done in accordance with PPP-58 and within the limits of the pharmacist's own competencies.

This policy is designed to enable continued high quality, safe and effective pharmacy care by BC pharmacists and to serve as a foundation for new professional pharmacist activities in the future.

## 1.2 Important Facts

Although the Guide will go into specific detail regarding the parameters and application requirements of *Medication Management – Adapting a Prescription (PPP-58)* the following is a list of key facts:

- PPP-58 applies to adapting an **existing** prescription only and does not include initiating a prescription nor activities requiring diagnosis
- Excludes narcotics, controlled drugs and targeted substances
- Does not replace a patient's need to see their physician
- For a pharmacist to adapt a prescription they must have completed the Orientation process and must possess personal professional liability insurance (minimum $2 million)
- Pharmacist authorization to adapt prescriptions **does not** mean obligation

- Once a pharmacist adapts a prescription they take **full responsibility** for and **assume liability** for that adapted prescription
- Although notification to the prescriber is the **final step** in the adaptation process, **prior approval** from the prescriber is not required

## 1.3 Bottom-line

The implementation of PPP-58 provides pharmacists the opportunity to utilize their professional judgment and practice to the full extent of their knowledge, skills and abilities to optimize health outcomes for their patients.

The evolutionary change in pharmacy practice through the implementation of PPP-58 is that it gives pharmacists independent authority and accountability for the adaptation of a prescription. In doing this, the pharmacist is making the decision, based on their professional judgment, that the prescription is the 'right' prescription for their patient.

Although this additional authority comes with added responsibility and ultimately liability, it allows pharmacists to demonstrate their value, as medication experts, in an evolving patient-centered, clinical care environment.

## 1.4 Objectives

After reviewing the material in this Guide, you will be able to:

1. Understand the elements of *Medication Management (Adapting a Prescription)*;
2. Understand the professional requirements and expectations when you undertake *Medication Management (Adapting a Prescription)*;
3. Understand the specific consent, documentation and notification requirements of implementing this policy in your practice;
4. Implement specifically defined Medication Management activities; and
5. Optimize the services you provide to patients within your enhanced scope of practice.

# 2.0 About PPP-58 Medication Management (Adapting a Prescription)

This section provides a detailed description of the following:

2.1 The fundamentals of adapting a prescription

2.2 The categories of adapting a prescription that you are authorized to engage in; and

2.3 Determining when you are NOT adapting a prescription.

## 2.1 Seven Fundamentals of Adapting a Prescription

PPP-58 outlines that you may dispense a drug contrary to the terms of an existing prescription (adapt a prescription) if the action is intended to optimize the therapeutic outcome of treatment with the prescription drug **and** you have addressed ***all*** of the following seven fundamental elements:

1. **Individual competence;**
2. **Appropriate information;**
3. **Prescription;**
4. **Appropriateness of adaptation;**
5. **Informed consent;**
6. **Documentation; and**
7. **Notification of other health professionals.**

Each of these elements provides structure to, and refines the process for, exercising professional judgment in your practice. When considering an adaptation you must consider the seven fundamentals in sequential order beginning with number 1 – Individual competence. If you are uncomfortable or unsure about any aspect along the way, **do not** adapt the prescription.

### 2.1.1 Individual Competence (Fundamental 1)

You must practice within your area of competency only. Do not adapt a prescription for any patient unless you have 'appropriate knowledge and understanding' of the condition being treated and the drug being prescribed.

It is not possible to establish parameters to define what is meant by 'appropriate knowledge and understanding', each situation like each patient, is unique. Therefore, in order for a pharmacist to determine if they feel that they have 'appropriate knowledge and information' they must rely on their own professional judgment.

In doing this, it is helpful to answer the following questions:

1. If someone asks why I made this decision, can I justify it?

2. Would this decision withstand a test of reasonableness (i.e., would another pharmacist make the same decision in this situation)?

## 2.1.2 Appropriate Information (Fundamental 2)

You must have 'sufficient information' about the patient's health status to be satisfied that adapting the prescription will maintain or enhance the effectiveness of the drug therapy, patient outcomes and will not put the patient at increased risk.

In doing this you must respect and consider all relevant information available to you. This would include, but is not limited to: a review of the patient's health record on local and PharmaNet data bases, the acknowledgement of any hand-written notations on the prescription by the prescriber, and any information obtained directly from the patient or their representative. You may also need to obtain additional information from an appropriate source such as relevant medical literature or other colleagues.

Again, it is not possible to establish parameters to define what is meant by 'sufficient information' as each situation, like each patient, is unique. Therefore, in order for a pharmacist to determine if they feel that they have 'sufficient information' they must rely on their own professional judgment.

In doing this, it is helpful to consider the following questions:

1. If someone asks why I made this decision, can I justify it?
2. Would this decision withstand a test of reasonableness (i.e., would another pharmacist make the same decision in this situation)?

## 2.1.3 Prescription (Fundamental 3)

You must have an **original prescription (an authorization from a practitioner to dispense a specified drug for use by a designated individual)** and it must be current, authentic, and otherwise appropriate for the patient. Pharmacists may not adapt a prescription if the original prescription has expired. All prescriptions have an expiry of one year from the date the **original prescription is written**. The exception is oral contraceptives, which have a two year expiry date.

***Reminder:***
*Irrespective of PPP-58, if, upon review of relevant information, your professional judgment is that a drug-related problem exists and the prescription should not be filled or the drug should not be sold, you must refuse to dispense or sell the drug.*

***Example(s) of Prescription Expiry:***
**If a prescription is written on January 1, it is valid until December 31 of that same year even though the prescriber may only authorize an initial quantity of 100 days (with no authorized refills).**

*continued on next page*

**If after the initial 100 days the pharmacist felt, based on following the Seven Fundamentals laid out in PPP-58 that it was appropriate for the patient, they could adapt (renew) the prescription for any portion of the days remaining – in this case to a maximum of 265 days.** ***(Note: while the decision to renew can be up to 265 days, it may also be significantly less and the duration is based on the professional judgement of the pharmacist)***

**It is never possible, however, for a pharmacist to adapt (renew) the prescription beyond its' validity date – in this case December 31. Therefore, if the patient requested that the pharmacist adapt (renew) the prescription on Dec 1, the pharmacist could only dispense a 30 day supply and must refer the patient back to their prescriber for a new prescription.** ***(Note: if the patient were to present to the pharmacist after the Dec 31 expiry date, the pharmacist could not adapt (renew) the prescription at all but could, for continuity of care purposes, extend an emergency refill under PPP-31)***

**It is also important to remember that the validity of a prescription is based on a period of time – in this example Jan 1 to Dec 31 – not on the overall quantity that could potentially be dispensed over that period of time.**

**To illustrate this point, let's assume that the patient has the initial 100 days dispensed on Jan 1 but then does nothing until Dec 1 of that same year. At that point he presents to the pharmacist requesting a renewal for another 100 days. Although there is enough undispensed quantity to accommodate this request the prescription is only valid for 30 more days so the pharmacist could only provide a renewal for up to 30 days and must refer the patient back to their prescriber for a new prescription.**

## 2.1.4 Appropriateness of Adaptation (Fundamental 4)

You must be sure that adapting the prescription is appropriate for the patient under the current circumstances, and will, in your professional judgment, optimize the therapeutic outcome of treatment.

You must maintain your professional independence at all times when making any adaptation and particularly when making therapeutic substitution decisions. You must critically evaluate evidence, clinical practice guidelines, information from pharmaceutical manufacturers, and approved indications. You may also be required to take into account formulary restrictions and other patient-related considerations. To be consistent with general practices and the College's Code of Ethics it is not appropriate to adapt a prescription for yourself or family members.

All decisions must be in the best interest of the patient and must focus on addressing the health needs of that patient. Any indication that a decision is based on benefit to the pharmacist or pharmacy rather than the patient will be considered professional misconduct.

# 2.1.5 Informed Consent (Fundamental 5)

## 2.1.5.1 General

In British Columbia, the obligation to obtain informed consent to healthcare from an adult patient, the criteria for consent and how to obtain consent, is defined in the *Health Care (Consent) and Care Facility (Admission) Act*.

The Act, states that every adult patient has the right to give, refuse or withdraw consent to treatment. Adaptation of a prescription in accordance with PPP-58 is a treatment that requires you to obtain consent from a particular patient.

The Act also sets out the criteria and process for obtaining valid consent. You must ensure that the consent has been **voluntarily** given to the proposed treatment by a capable adult patient.

You must also provide the patient with enough information to enable that patient to make an informed decision. Although this may sometimes be difficult to determine, you are required to decide:

*What the average prudent and reasonable person in the patient's particular position would agree to or not agree to, if all material and special risks of going ahead (with the treatment) or foregoing it were made known to him.*[1]

When advising a patient of risks, you must be familiar with the patient's circumstances, and take into account any special considerations that apply.

Informed consent is specific to the current treatment under consideration and not a blanket consent for any possible treatment. You **must** bring the following matter to the patient's attention:

- The specific condition for which the prescription adaptation is proposed;
- The nature of the proposed adaptation; and
- The risks and benefits of the adaptation that a reasonable patient would expect to be told about.

This list is not inclusive. Other matters may exist that need to be discussed with the patient, depending on the circumstances.

You must also provide an opportunity for the patient to ask questions and receive answers about the adaptation.

## 2.1.5.2 Substitute Consent - Adult Patients

Pharmacists frequently obtain consent from someone other than the patient being treated. This usually happens when an adult patient is no longer capable of providing an informed consent. In this situation, based upon the information that you have been provided, you must determine whether the patient has demonstrated that he or she is not able to give a valid consent.

[1] Reibl v Hughes, (1980) 14 C.C.L.T. 1 at paragraph 21

When this happens, the Act provides that you may obtain consent from a recognized representative from one of the following three categories:

- A committee appointed by the Supreme Court of British Columbia pursuant to the *Patients Property Act*;
- A representative named in a Representation Agreement validly made pursuant to the *Representation Agreement Act*; or
- A substitute decision maker pursuant to Section 16 of the *Health Care (Consent) and Care Facility (Admission) Act* where there is no committee or representative. The ranked list of acceptable substitute decision makers is:
  1. The patient's spouse;
  2. The patient's child;
  3. The patient's parents;
  4. The patient's brother or sister; or
  5. Any one else related by birth or adoption to the patient.

In order to give substitute consent, substitute decision makers must meet the following criteria. They must:

- Be at least 19 years old;
- Have had contact with the patient in the preceding twelve months;
- Have no dispute with the patient;
- Be capable themselves; and
- Be willing to comply with the duties in Section 19 of the *Health Care (Consent) and Care Facility (Admission) Act*.

If there is no one available to act as a substitute decision maker, you should contact the Health Care Decisions Consultant at the Public Guardian and Trustee for assistance. The Public Guardian and Trustee is authorized to provide consent in appropriate cases.

### 2.1.5.3 Consent of Minors

In British Columbia, the age of majority is 19 years. Normally a parent or guardian provides consent to healthcare on behalf of the minor. However, this is not always the case. The *Infants Act* provides that a minor may consent to treatment (adaptation of a prescription) if you have explained to and are satisfied that the minor understands the nature, consequences and can reasonably foresee risks and benefits of the treatment; and you have decided that in the circumstances the treatment is in the infant's best interest. A parent or guardian cannot overrule the decision made by the minor and is not entitled to disclosure of the information.

If a parent or a guardian is unavailable to provide consent and the infant is not mature enough to provide his or her own consent, it is customary for you to obtain the consent of grandparents, aunts, uncles, or other relatives as appropriate in the circumstances.

### 2.1.5.4 Recording of Consent

*The Health Care (Consent) and Care Facility (Admission) Act* provides that consent may be expressed orally, in writing or may be inferred from the patient's conduct. Therefore, it is not strictly necessary for you to document that you have obtained consent. However, the recommended documentation/notification template form (Appendix D) includes an area to acknowledge, by a tick mark, that consent was obtained and if by a representative, their name.

Such documentation is a useful risk management tool. In fact, written evidence that informed consent has been obtained in a particular situation can have a significant influence on the outcome of a negligence case brought against a healthcare professional for failure to obtain informed consent.

## 2.1.6 Documentation (Fundamental 6)

You must document all adaptations of all prescriptions in a way that creates an accurate record of the circumstances and details of the adaptation. The documentation must always relate back to the original prescription and include (if applicable) reference to any and all previous adaptations. Attached to this Guide as Appendix D is a recommended documentation and notification template form (an electronic version of this form is available on the college website **www.bcpharmcists.org**). The intention of the form is that once complete it can easily be faxed to the prescriber for notification purposes and then attached to the adapted prescription and maintained in the pharmacy records.

Pharmacists can develop their own documentation process as long as they ensure that the method of record-keeping is consistent with College auditing policies and procedures. In other words, all original prescription hard copies must always be retained, including new prescription hard copies generated as part of the adaptation process. All of the required documentation information, listed below, must be captured and retained with the adapted prescription.

Documentation must include:

1. Patient (including PHN number) and Pharmacist (including signature and name of Pharmacy) information
2. Original prescription information (including prescribers name and contact information)
3. A description of the adaptation (including all relevant prescription details)
4. The rationale for the decision to adapt the prescription (including pertinent details of your assessment and patient history along with any instructions to the patient and relevant follow-up plan)
5. Acknowledgment of informed consent
6. The date and name of practitioner(s) notified

When adapting an existing prescription, during the prescription filling process on PharmaNet, you must input your pharmacist identification number in the prescriber field. This will confirm, within the system, that you have adapted the initial prescription and are now responsible for the adapted prescription.

Documentation establishes accountability and responsibility for your professional activities. It is a key component in demonstrating how you exercised your professional judgment and will be the primary tool used to communicate the rationale for your decision. It is also important to remember that every time you document you are creating a health care record. Following are some points to be considered:

- Complete your documentation as soon as possible (preferably immediately) after the activity;
- Use a standard format (preferably the template included with this Guide) for documenting that includes the information outlined above;
- Include all information deemed necessary to support the identification of drug-related problems, recommendations and decisions;
- Use clear, logical and precise language;
- Ensure all documentation is legible and non-erasable; and
- Do not delete, remove or rewrite from any part of the record. If you make an error, cross out the error with a single line and initial it.
- Remember that documentation must always relate back to the original prescription and include, if applicable, reference to any and all adaptations.

## 2.1.7 Notification of Other Health Professionals (Fundamental 7)

***Note:***
*The College of Pharmacists of BC developed this form with input from the College of Physicians and Surgeon of BC.*

At all times, when you adapt a prescription you must notify the **original prescriber**[2]. Notification must take place as soon as reasonably possible, preferably within 24 hours. **You must also notify the patient's most responsible clinician** if you are aware that the original prescriber is not your patient's usual practitioner. Although a requirement of PPP-58, one of the benefits of notification is that it provides enhanced opportunity for collaboration between you, the prescriber and the patient.

As introduced in Fundamental 6 and attached to this Guide as Appendix D is a recommended documentation and notification template form (an electronic version of this form is available on the college website **www.bcpharmcists.org**). The intention of the form is that once complete it can easily be faxed to the prescriber for notification purposes and then attached to the adapted prescription and maintained in the pharmacy records.

[2] For purposes of PPP-58, and included in the Glossary of Terms (Appendix B) the 'original prescriber' refers to the prescriber who authorized the first fill.

Pharmacists can develop their own notification process as long as all of the required notification information, listed below, is included.

Notification must include:

1. Patient (including PHN number) and Pharmacist (including signature and name of Pharmacy) information
2. Original prescription information (including prescribers name and contact information)
3. A description of the adaptation (including all relevant prescription details)
4. The rationale for the decision to adapt the prescription (including pertinent details of your assessment and patient history along with any instructions to the patient and relevant follow-up plan)
5. Acknowledgment of informed consent
6. The date and name of practitioner notified

Experience in other jurisdictions has shown that fax notification is a preferred method for notification of other health professionals. You will need to determine the most suitable notification method for your practice based on what works best for you and the practitioners you usually communicate with. Fax or written notification is the preferred method, however, in certain circumstances, verbal notification may be sufficient, but may lead to extra transcribing work at the receiver's end and introduces a margin of error if the information is transcribed incorrectly.

This Guide also includes, in Appendix E, a sample letter &/or fax directed to prescribers introducing them to PPP-58. You may choose to utilize this document as a means of preparing and informing your prescribers that you will be exercising your authority to adapt prescriptions, starting January 1, 2009, and introduce them to the type of documentation they can expect to see from you.

## 2.2 Activities considered Adapting a Prescription

Three professional activities are considered to be adapting a prescription within the current scope of pharmacy practice in BC:

***Remember:*** *Authorization does not mean obligation.*

1. **Change**: Changing the dose, formulation, or regimen of a prescription to enhance patient outcomes;
2. **Renew**: Renewing a prescription for continuity of care; and
3. **Substitution**: Making a therapeutic drug substitution within the same therapeutic class for a prescription to best suit the needs of the patient.

Exceptions:

- PPP-58 **does not** include adapting a prescription for narcotic, controlled drugs or targeted substances. If a change to a prescription for one of these categories of drugs is warranted, the pharmacist must contact the original prescriber to discuss modifying the original prescription.

- PPP-58 **does not** allow for the adaptation of a prescription if the original prescription has expired. All prescriptions have an expiry of one year from the date the original prescription is written. The exception is oral contraceptives, which have a two year expiry date.

You must use professional judgment to evaluate each situation and have addressed all of the seven fundamentals of adapting a prescription as described in Section 2.1 of this Guide.

## 2.2.1 Changing the Dose, Formulation, or Regimen of a New Prescription

Under PPP-58 you can change the dose, quantity, formulation, or regimen of a drug presented on a prescription without prior authorization from the prescriber if, in your professional judgment, the change will enhance the patient's outcome. This includes adding missing information.

**Changing the dose**

You can change the dose:

- If the strength of the drug prescribed is not commercially available;
- If the patient's age, weight or kidney or liver function requires you to change the dose; or
- If, in your professional judgment, you are satisfied the changed dose would otherwise benefit the patient.

**Changing the formulation or regimen**

You can change the formulation or the regimen of the medication to improve the ability of the patient to effectively take the medication.

**Miscellaneous**

You can also adapt a prescription dose, quantity, formulation or regimen if the information provided is incomplete but you determine what the intended treatment is through consultation with the patient and a review of your records (locally or on PharmaNet).

## 2.2.2 Renewing a Previously Filled Prescription for Continuity of Care

PPP-31 – Emergency Prescription Refills state pharmacists may exercise professional judgment in in the provision of emergency prescription refill supplies of a medication. This practice is the exception to the rule and not the normal practice (see Appendix C). The intention of PPP-31 is to ensure continuity of care by allowing pharmacists to extend a prescription, for a short period of time, to enable the patient to get back to their prescriber for authorization.

Now under PPP-58 pharmacists, by adhering to *the Seven Fundamentals of Adapting a Prescription*, are able to adapt (renew) the prescription themselves on behalf of the patient without prior authorization from the prescriber for whatever period of time felt appropriate as long as it does not exceed the expiry of the prescription (refer to 2.1.3 of this Guide).

By doing this the pharmacist is utilizing their professional judgment and demonstrating that they have enough competence and information about the patient and their condition to determine that the prescription will maintain or enhance the patient's health outcome. PPP-58 provides pharmacists with the opportunity to practice to the full extent of their knowledge, skills and ability and demonstrate their value as medication experts.

Given the authority available to pharmacists under PPP-58, when faced with a situation requiring or requesting the renewal of a prescription for continuity of care, it is recommended that a pharmacist first consider the opportunity to fully adapt the prescription under PPP-58 before deferring to PPP-31.

It is important to remember that unlike PPP-31, where a pharmacist can provide an emergency refill without access to a prescription (evidence such as; an empty prescription vial, a label or a copy of a prescription receipt will suffice), PPP-58 requires that a pharmacist has the original prescription and that it is current, authentic and has not expired.

***Illustration:***
When a pharmacist is presented with a situation in which a patient has run out of a valid prescription (i.e.; it is current, authentic, appropriate and has not expired) and there are no authorized refills the pharmacist should:

- Step One: Consider adapting the prescription by referring to the first two of the seven fundamentals of PPP-58 and ask:
  a. Do I have 'appropriate knowledge and understanding' of the condition being treated and the drug being prescribed? If yes, then ask,
  b. Do I have 'sufficient information' about the patient's health status to be satisfied that adapting the prescription will maintain or enhance the effectiveness of the drug therapy, patient outcomes and will not put the patient at increased risk? If yes, then the pharmacist should consider adapting the prescription

- Step Two: If on the other hand the pharmacist answers no to either of the questions in step one they should not adapt the prescription but could either try to contact the prescriber to seek approval for a refill or defer to PPP-31 and provide an emergency supply

## 2.2.3 Making a Therapeutic Drug Substitution within the Same Therapeutic Class

You may adapt a prescription by making a therapeutic substitution. You are making a therapeutic substitution when you substitute the drug prescribed with a different drug that is expected to have a similar therapeutic effect, as long as that drug is from within the same therapeutic class. When making a therapeutic drug substitution, you must be satisfied that the dose and the dosing regimen of the new drug you select will have an equivalent therapeutic effect.

You must be satisfied that the following conditions are met when making a therapeutic substitution decision:

1. The decision is in the best interest of the patient by:
    a. Addressing the health needs of that patient,
    b. Maintaining or enhancing the safety or effectiveness of drug therapy,
    c. Not placing the patient at increased risk,
    d. Considering formulary or payer restrictions and other patient-related information, and
    e. Ensuring the drug is approved for the intended indication by Health Canada or strong evidence supports using the drug for the intended indication (e.g., clinical practice guidelines);
2. Your professional independence has been maintained and you avoid conflict of interest. If a decision is based on benefit to the pharmacist or pharmacy rather than the patient, this will be considered professional misconduct;
3. You have considered all relevant information about the patient, the condition and the drug, and you have effectively communicated this to the patient to ensure they agree with the decision; and
4. You take full responsibility for your decision.

# 2.3 Determining When You Are Not Adapting a Prescription

## 2.3.1 When You Call the Original Prescriber to Make a Change

When you identify a drug-related problem during the process of filling a prescription or discussing medication needs with a patient, you may choose to do what you have always done and contact the prescriber to discuss your concerns about the prescription. If, as a result of that conversation, the original prescriber directs you to make a change to the prescription, you may make the change and sign or initial it as you always have. In this case you are not adapting the prescription.

In fact, in any circumstance where you obtain prior authorization from the prescriber to make a change, provide a substitution or refill a prescription you are not adapting a prescription.

## 2.3.2 When You Dispense an Interchangeable Drug Product

Dispensing an interchangeable drug product, including generic substitution, is not adapting a prescription. .

## 2.3.3 When an Approved Protocol Exists

If you practice in environments where a specific hospital board – or College Council – approved protocol exists and applies in that situation, you may be required to make changes to the prescription. In these circumstances, where you are simply applying the policy or treatment protocol (e.g. automatic substitution), and you are not using your professional judgment, you are not adapting a prescription.

## 2.3.4 When You Are Continuing Therapy by Advancing a Few Doses

As described in PPP-31 – Emergency Prescription Refills (see Appendix C), you are already authorized to assist patients in maintaining continuity of their drug therapy by advancing them a few doses or a few days supply if they run out of medication and an appointment with the prescribing physician is imminent. Advance supplies are not technically prescription renewals and do not fall under PPP-58, but you must evaluate the patient's need for the medication and be satisfied that providing any additional doses will not cause or worsen a drug-related problem for the patient.

# 3.0 Implementing PPP-58 in Your Practice

In addition to information posted on the College's website (www.bcpharmacists.org) and/or communicated in ongoing College publications such as ReadLinks, there are a number of resources available to support you in the effective implementation of PPP-58 in your practice.

## 3.1 Support is Available

### 3.1.1 Practical Resources

The following resources are provided in the appendix of this Guide:

- Appendix B – Glossary of Terms
- Appendix D – Documentation and Notification Template (an electronic version is also available on the College website - www.bcpharmacists.org)
- Appendix E – Sample letter/fax introducing PPP-58 to your prescribers
- Appendix F – Practical Examples

### 3.1.2 Need more support?

If you still have questions or concerns and want to implement the policy in your practice, please contact Practice Support through the College office at 604-733-2440 or by email at practicesupport@bcpharmacists.org.

# 4.0 Other Considerations

## 4.1 Liability and Insurance

Adapting a prescription is one activity within a pharmacist's current scope of practice that expands the potential for liability. Although a pharmacist is not obligated to adapt a prescription, should they choose to adapt a prescription, they are required to possess personal professional liability insurance – minimum $2 million.

## 4.2 Consequences for Failure to Follow PPP-58

Any pharmacist who adapts a prescription contrary to the requirements of PPP-58 will be forwarded to the Inquiry Committee process as per current College procedures.

All pharmacists are expected to abide by all aspects of professional practice as described in the College's Framework of Professional Practice, federal legislation (*the Food and Drug Act (FDA) and Regulations and the Controlled Drug and Substances Act*), provincial legislation (*the HPA, PODSA, and PSA along with related regulations and bylaws*), and the College's *Professional Practice Policies*.

## 4.3 Conflict of Interest

The implementation of PPP-58 may put pharmacists in a position of real or perceived conflict of interest with their patients. The adaptation of a prescription may lead to increased revenue thereby enhancing a pharmacist's financial interests.

Pharmacists must consider first and foremost the interest and well-being of their patients. Prescriptions must not be adapted unless it is in the best interest of a patient to do so.

Any indication that the decision was based on benefit to the pharmacist or pharmacy, rather than the patient, will be considered professional misconduct and reviewed through the Inquiry Committee process.

## 4.4 Conclusion

These are indeed exciting times for the profession of pharmacy in British Columbia as pharmacist's involvement in medication management activities continues to expand. PPP-58 creates the framework to guide pharmacists in the safe and effective adaptation of prescriptions allowing you to maximize your full educational and professional competencies to optimize therapeutic outcomes for your patients. In addition this policy provides a structure to the process of using professional judgment in practice and establishes a foundation for the further expansion of pharmacy practice in the future.
Take time to consider your competencies, your work environment, and your current and potential relationships with patients and other health professionals. And the next time you have the opportunity to adapt a prescription – use the seven fundamentals to help determine if it is the 'right' thing to do for your patient.

# 5.0 Declaration Form

## Medication Management
## (Adapting a Prescription)
## Professional Practice Policy #58 (PPP-58)

### Declaration of completion and understanding

I,_____ a registrant on the Register of Pharmacists of the College of Pharmacists of British Columbia, declare that I have thoroughly read and understood the PPP-58 Orientation Guide Medication Management (Adapting a Prescription).

I also declare and understand that although it is not mandatory that I adapt a prescription, should I choose to adapt a prescription in addition to having read and understood the Orientation Guide I must:

- Adhere to all of the seven fundamentals for adapting a prescription as outlined in PPP-58 and possess personal professional liability insurance (minimum $2 million).

Signature:_____ Date:_____

***Note:***
*You should retain this signed Declaration Form in your personal records.*

# Appendix A: Professional Practice Policy #58 Protocol for Medication Management (Adapting a Prescription)

**POLICY STATEMENT(S):**

A pharmacist may dispense a drug contrary to the terms of a prescription (adapt a prescription) if the action is intended to optimize the therapeutic outcome of treatment with the prescribed drug and meets **all** of the following elements of a protocol to adapt a prescription:

1. **Individual competence**
   a. Pharmacist has appropriate knowledge and understanding of the condition and the drug being dispensed in order to adapt the prescription.

2. **Appropriate information**
   a. Pharmacist has sufficient information about the specific client's health status to ensure that adapting the prescription will maintain or enhance the effectiveness of the drug therapy and will not put the client at increased risk.

3. **Prescription**
   a. Pharmacist has a prescription that is current, authentic, and appropriate.

4. **Appropriateness**
   a. Pharmacist determines whether adapting the prescription is appropriate in the circumstances.

5. **Informed consent**
   a. Pharmacist must obtain the informed consent of the client or client's representative before undertaking any adapting activity.

6. **Documentation**
   a. Pharmacist must document in the client's record any adaptation of the prescription, the rationale for the decision, and any appropriate follow-up plan.

7. **Notification of other health professionals**
   a. Pharmacist must notify the original prescriber (and the general practitioner if appropriate) as soon as reasonably possible (preferably within 24 hours of dispensing) and this must be recorded in the client's record or directly on the prescription hard copy.

**Note: PPP-58 is not a stand-alone document and must be read with the Orientation Manual and the Amendment to the Orientation Manual. For a pharmacist to use PPP-58 they will be required to sign the PPP-58 Declaration Form.**

BACKGROUND:

**Protocol for medication management (adapting a prescription)**

This professional practice policy enables pharmacists to maximize their full educational and professional competencies by providing authorization to adapt existing prescriptions. This policy is not mandatory and the decision whether to adapt a prescription is at the discretion of the individual pharmacist.

To guide decisions with respect to adapting a prescription, where a specific hospital board - or College of Pharmacists of BC - Board approved protocol does not exist, the pharmacist must refer to all applicable legislation and standards. This includes, but is not limited to, the *Health Professions Act, Pharmacy Operations and Drug Scheduling Act*, the Regulation and Bylaws of the College of Pharmacists of BC made pursuant to these Acts, the *Health Care (Consent) and Care Facility (Admission) Act*, the Framework of Professional Practice (FPP), the Code of Ethics and Professional Practice Policies. This specific policy (PPP-58) does not apply to controlled drug substances and cancer chemotherapy agents.

The FPP is the standards of pharmacy practice in British Columbia. In adapting a prescription the pharmacist must follow the FPP Role 1 *Provide pharmaceutical care.* Role 1 elements include:

- Function A – Assess the client's health status and needs
- Function B – Develop a care plan with the client
- Function C – Support the client to implement the care plan
- Function D – Support and monitor the client's progress with the care plan
- Function E – Document findings, follow-ups recommendations, information provided and client's outcomes

**Benefits of professional practice policy**

The benefits to clients are to:

a) Optimize drug therapy leading to improved client health outcomes
   1) Better therapeutic responses.
   2) Reduced drug errors.
   3) Fewer adverse drug reactions/interactions.

b) Have an effective and efficient health care system
   1) Minimize delays in initiating and changing drug therapy.
   2) Make the best use of human resources in the health care system.

c) Expand the opportunities to identify people with significant risk factors.

d) Encourage collaboration among health care providers.

First approved: 21 Sep 2007 **PPP-58**
Revised:
Reaffirmed: 27 Mar 2009

# Appendix B: Glossary of Terms

For the purposes of Professional Practice Policy #58 *Protocol for Medication Management – Adapting a Prescription* – the terms below have the following meaning:

| | |
|---|---|
| **Adaptation** | • term used to describe the pharmacists' authority under PPP-58 to adapt an existing prescription when, in their professional judgment, the action is intended to optimize the therapeutic outcome of treatment |
| **Conflict of Interest** | • at all times pharmacists must maintain professional independence and adaptation decisions must first and foremost be made in the best interest of the patient with the intention of optimizing the therapeutic outcome of treatment<br>• any indication that a decision is based on benefit to the pharmacist or pharmacy, rather than the patient, will be considered professional misconduct |
| **Continuity of Care** (for medication management) | • the assurance of uninterrupted drug therapy for the best health outcome of the patient |
| **Liability** | • pharmacist assumes legal responsibility for the adapted prescription and as a mandatory condition of their authority to adapt possesses personal professional liability insurance (minimum coverage $2 million) |
| **Original Prescriber** | • refers to the prescriber who authorized the first fill |
| **Prescription Expiry** | • all prescriptions have an expiry of one year from the date the prescription is written (the exception is oral contraceptives, which is two years)<br>• a pharmacist may not adapt a prescription if the original prescription has expired<br>• a pharmacist may not adapt components of a prescription beyond its' expiry date (ie: quantity cannot exceed the time remaining) |

| | |
|---|---|
| **Refill** | • term used by the prescriber to indicate their authorization to provide a refill(s) to the original prescription |
| **Renew** | • term used to describe the extension of a prescription (not beyond its' expiry date) by a pharmacist; the act of renewing a prescription constitutes adaptation and thereby transfers liability to the adaptor |
| **Responsible Clinician** | • most responsible physician/provider who manages the patient's care on an ongoing basis (ie: family physician, nurse practitioner) |
| **Therapeutic Drug Substitution** | • substitution of the prescribed drug with a different drug, from the same therapeutic class, that is expected to have a similar therapeutic effect<br>• pharmacist must be satisfied that the dose and dosing regimen of the new drug will have an equivalent therapeutic effect |

# Appendix C: Other Relevant Professional Practice Policies

## 1 – PPP-31 – Emergency Prescription Refills

Pharmacists may exercise professional judgment in the provision of emergency prescription refill supplies of a medication. This practice is *the exception to the rule and not the normal practice*.

A pharmacist may dispense an emergency refill in the following situations;
- where a patient's medication supply has been exhausted, a refill may be dispensed to ensure continuity of care. OR
- where a patient attends the pharmacy for an authorized refill of a valid prescription but PharmaNet returns the message, '101 Prescriber not found' or 'D3 Prescriber is not authorized' and the pharmacist ensures that the patient is not on Pharmacare's *Restricted Claimants Program*, a refill may be dispensed to ensure continuity of care and to allow time for the patient to find a new prescriber.

The pharmacist must comply with each of the following practice fundamentals;

**1. Individual competence**

a. Pharmacist has appropriate knowledge and understanding of the condition and the drug being dispensed in order to adapt the prescription.

**2. Appropriate information**

a. Pharmacist has sufficient information about the specific patient's health status to ensure that dispensing an emergency refill of the prescription will ensure continuity of care and will not put the patient at increased risk.

**3. Appropriateness**

a. Pharmacist must use their professional judgment to determine whether provision of an emergency refill is appropriate in the circumstances, and must determine an appropriate days supply based on the drug involved and how long it will take the patient to see a prescriber.

**4. Informed consent**

a. Pharmacist must obtain the informed consent of the patient or patient's representative before undertaking an emergency refill.

**5. Documentation**

a. Pharmacists must use their CPBC pharmacist registration numbers in the PharmaNet practitioner ID field to identify the responsible decision-maker when providing an emergency supply of a drug to a patient.
b. 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.

First Approved: 29 January 1999
Revised: 20 June 2003/15 Feb 2013
Reaffirmed: 27 Mar 2009

# Appendix C: Prescription Adaptation Documentation and Notification Template

(an electronic version of this template is available on the College website www.bcpharmacists.org)

## Patient Information

Name: _____

PHN: _____

## Prescriber Information

Name: _____

Phone: _____

Fax: _____

## Pharmacist Information

Name: _____

Pharmacy: _____

_____

Phone: _____

Fax: _____

Signature: _____

## Original Prescription Information

Date of Prescription: _____

Prescription Details: _____

_____

## Adaptation Information

Date of Adaptation: _____

Adaptation Details: _____

_____

## Rationale for Adaptation (including instructions to patient and follow-up plan)

Rationale

_____

_____

_____

_____

_____

_____

_____

Instructions to Patient

_____

Follow-up Plan

_____

_____

## Informed Consent

The patient and/or their representative (name: _____) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent. ☐

## Notification Information

Date of Notification: _____ Name of Practitioner(s) Notified: _____

Method of Notification (fax preferred): _____

☐ Fax # _____ ☐ Phone # _____ ☐ Other _____

The information contained in this fax communication is confidential and is intended only for the use of the recipient named above If the reader of this fax memo is not the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this fax memo is strictly prohibited. If you have received this fax memo in error, please destroy the memo and notify the sender.

# Appendix E: Sample letter/fax introducing PPP-58

[drugstore letterhead]

Date

Doctor name
Address

Re: Introduction to Pharmacists enhanced scope of practice

Dear Dr. _____,

The purpose of this letter is to ensure that you are aware of some recent changes that have evolved the scope of practice for pharmacists in BC. Earlier this year the government introduced Bill 25 which, specific to the profession of pharmacy, formalized pharmacists' authority to 'renew' existing prescriptions.

In conjunction with this the College of Pharmacists of BC (CPBC) has introduced *Professional Practice Policy #58 (PPP-58) Medication Management – Adapting a Prescription* which provides the framework to guide pharmacists in the safe and effective adaptation, including renewal, of existing prescriptions.

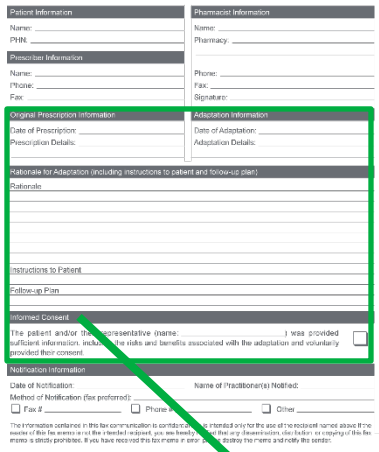
Although it is not mandatory that a pharmacist adapt a prescription, it is mandatory that should a pharmacist choose to adapt a prescription they adhere to the guidelines laid out in the PPP-58 Orientation Guide, which includes notification to the original prescriber (a copy of the PPP-58 Orientation Guide is available on the CPBC website www.bcpharmacists.org).

This means that from time to time you may receive a fax notification (sample attached) from a member of our pharmacy team to inform you of a prescription adaptation that has occurred. Pharmacists' authorization to implement this policy and thereby adapt prescriptions is effective January 1, 2009.

We value our professional relationship with you. Please feel free to contact (insert: pharmacy manager name) with any questions or comments you may have.

Sincerely,

# Appendix F: Practical Examples


Patient Information
Name:
PHN:
Pharmacist Information
Name:
Pharmacy:
Prescriber Information
Name:
Phone:
Fax:
Phone:
Fax:
Signature:
Original Prescription Information
Date of Prescription:
Prescription Details:
Adaptation Information
Date of Adaptation:
Adaptation Details:
Rationale for Adaptation (including instructions to patient and follow-up plan)
Rationale
Instructions to Patient
Follow-up Plan
Informed Consent
The patient and/or their representative (name: ) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent.
Notification Information
Date of Notification:
Name of Practitioner(s) Notified:
Method of Notification (fax preferred):
Fax #
Phone #
Other

***Example 1 – Changing the Dose:***

You receive a new prescription for alendronate 10mg once weekly for an elderly female patient. The PharmaNet record indicates the patient was previously taking alendronate 10mg once daily for the past year. You have a discussion with the patient and determine the following:

- The patient has been having difficulty with compliance of the once daily regimen.
- The physician discussed with her that she was changing the prescription to the once weekly formulation to make it easier for her to remember her dose.

**Original Prescription Information**

Date of Prescription: January 15, 2009

Prescription Details: Alendronate 10mg once weekly x 6 months

**Adaptation Information**

Date of Adaptation: January 16, 2009

Adaptation Details: changed Alendronate 10mg once weekly to 70mg once weekly x 3 months with 1 refill

**Rationale for Adaptation (including instructions to patient and follow-up plan)**

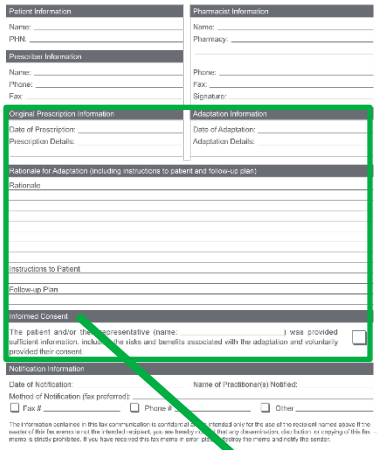
Rationale
- usual dose alendronate 10mg once daily or 70 mg once weekly
– product monograph indicates no dosage adjustment necessary for the elderly or for patients with mild to moderate renal insufficiency
– confirmed with patient that no impaired renal function
– patient confirmed doctor discussed change to weekly formulation for compliance reasons

Instructions to Patient: Instructed the patient to take 1 tablet once/week on the same day each week with plenty of water.

Follow-up Plan: contact her physician if any GI upset or unusual symptoms.

**Informed Consent**

The patient and/or their representative (name: _____) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent. ✓




***Example 2 – Incomplete Information:***

You receive a new prescription for an adult female patient for Betaderm 0.1% Cream; Apply TID. The patient indicated that her skin is really dry and scaly and that she would prefer a product with more of a moisturizing effect.

You have a discussion with the patient and determine the following:

- She had used Betaderm 0.1% Cream for one month and was getting results with the cream.
- You visually confirm that her skin is dry and scaly.

**Original Prescription Information**

Date of Prescription: January 15, 2009

Prescription Details: Betaderm 0.1% Cream; Apply TID

**Adaptation Information**

Date of Adaptation: January 15, 2009

Adaptation Details: changed Betaderm 0.1% Cream to etaderm 0.1% Ointment; Apply TID

**Rationale for Adaptation (including instructions to patient and follow-up plan)**

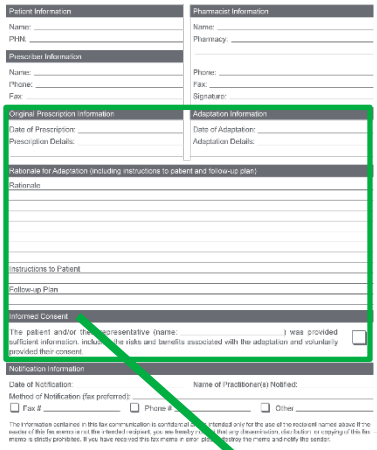
Rationale
- reviewed PharmaNet profile which indicates patient has been using Betaderm 0.1% Cream for one month
- patient indicated that the cream is helping her condition except that the affected area on her skin is dry and scaly
- change in formulation will still provide the same result with a more emollient effect

Instructions to Patient: Apply sparingly to affected area three times a day. If skin condition worsens, contact your doctor.

Follow-up Plan: See your doctor at your regular interval in one month.

**Informed Consent**

The patient and/or their representative (name: _____) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent. ☑


Patient Information
Name:
PHN:
Pharmacist Information
Name:
Pharmacy:
Prescriber Information
Name:
Phone:
Fax:
Phone:
Fax:
Signature:
Original Prescription Information
Date of Prescription:
Prescription Details:
Adaptation Information
Date of Adaptation:
Adaptation Details:
Rationale for Adaptation (including instructions to patient and follow-up plan):
Rationale
Instructions to Patient
Follow-up Plan
Informed Consent
The patient and/or their representative (name: ) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent.
Notification Information
Date of Notification:
Name of Practitioner(s) Notified:
Method of Notification (fax preferred):
Fax #
Phone #
Other

***Example 3 – Incomplete Information:***

You receive a new prescription for Ramipril – take one tablet daily. No strength is indicated on the prescription. The PharmaNet record indicates the patient has been getting the 10mg strength for the past 6 months.

You have a discussion with the patient and determine the following:

- The patient confirms that the prescription was intended for the same dose (10mg) as before and that the medication is being used for blood pressure control.

**Original Prescription Information**

Date of Prescription: January 4, 2009

Prescription Details: Ramipril
take 1 tablet daily, Mitte 90, no refills

**Adaptation Information**

Date of Adaptation: January 4, 2009

Adaptation Details: Ramipril 10mg
once daily Mitte 90, no refills.

**Rationale for Adaptation (including instructions to patient and follow-up plan)**

Rationale - PharmaNet record indicates patient has been on Ramipril 10mg once daily for 6 months
– Patient confirmed that his regular doctor is on holiday and the locum prescribed his regular medication (he was not expecting any changes)
– Patient confirms his blood pressure is on target (130/75)

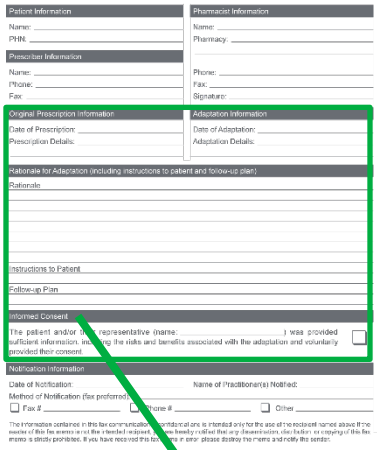
Instructions to Patient Take one Ramipril 10mg daily for blood pressure control.

Follow-up Plan Instructed to continue to check blood pressure regularly.

**Informed Consent**

The patient and/or their representative (name: ) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent. ✓

**Notification Information**


Patient Information
Name:
PHN:
Prescriber Information
Name:
Phone:
Fax:
Pharmacist Information
Name:
Pharmacy:
Phone:
Fax:
Signature:
Original Prescription Information
Date of Prescription:
Prescription Details:
Adaptation Information
Date of Adaptation:
Adaptation Details:
Rationale for Adaptation (including instructions to patient and follow-up plan):
Rationale
Instructions to Patient
Follow-up Plan
Informed Consent
The patient and/or their representative (name: ) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent.
Notification Information
Date of Notification:
Name of Practitioner(s) Notified:
Method of Notification (fax preferred)
Fax #
Phone #
Other

***Example 4 – Renew a Prescription:***

A long standing patient of your pharmacy takes a thyroid supplement and diuretic every day. She comes to the pharmacy and requests a renewal of her prescriptions. You notice in your records that 3 months ago she received the same prescriptions but no refills were authorized. You review the PharmaNet record and determine she has been on the same dose of the same medications for 2 years.

You have a discussion with the patient and determine the following:

- She confirms that her TSH levels are being regularly monitored as well as her blood pressure.
- She confirms that she sees her physician every 6 months and that she is due for her follow-up in 3 months.

**Original Prescription Information**

Date of Prescription: October 4, 2008

Prescription Details: Hydrochlorthiazide 50mg OD
Synthroid 100mcg 1 OD, no refills

**Adaptation Information**

Date of Adaptation: January 16, 2009

Adaptation Details: Hydrochlorthiazide 50mg OD
Synthroid 100mcg 1 OD, renewed x 3mth supply

**Rationale for Adaptation (including instructions to patient and follow-up plan)**

Rationale
- PharmaNet record indicates patient has been on same dosage of both medications for 2 years
- Patient confirmed TSH and blood pressure are regularly monitored
- Patient confirmed she has follow-up with physician every 6 months and is seeing doctor in 3 months
- Most recent original prescription was 3 months ago (Oct. 4/08) therefore prescription is still a valid prescription

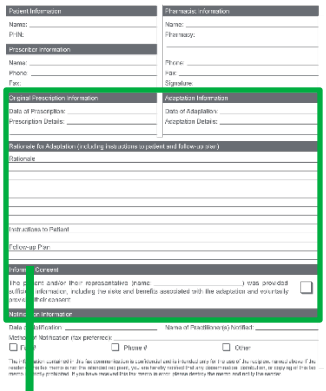
Instructions to Patient: Take 1 tablet of each medication daily, in the morning, on an empty stomach and continue monitoring your blood pressure regularly.

Follow-up Plan: Return for follow-up with your physician in 3 months as scheduled.

**Informed Consent**

The patient and/or their representative (name: _____) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent. ☑

Notification Information



***Note:***
*In the 'Notification' section of the form you would indicate that both physicians were notified of this adaptation.*

***Example 5 – Therapeutic Substitution:***

Patient arrives at your pharmacy with a prescription for Prevacid 30mg once daily x 3 months for GERD. You notice the prescription is from the local walk-in clinic physician. You check the PharmaNet profile and determine that the patient has previously been on Rabeprazole 20mg once daily x 6 months and has had Pharmacare coverage through special authorization for the Rabeprazole. You process the prescription for Prevacid 30mg once daily and notice that the patient does not have special authorization for the Prevacid.

You have a discussion with the patient and determine the following:

- The patient receives social assistance and cannot afford the prescription cost for the Prevacid.
- The patient had run out of the Rabeprazole prescription last week and couldn't get to her regular doctor, so went to the walk-in clinic.
- The patient wanted a renewal of the prescription she was previously on for her heartburn, but she couldn't remember the name of it when she went to the clinic and she didn't have her empty vial with her.
- Her previous prescription had been controlling her symptoms very well and she had not had any side effects.
- Patient is anxious to get her Rabeprazole medication as her symptoms have increased over the past week since she has been out of her medication.

**Original Prescription Information**

Date of Prescription: January 15, 2009
Prescription Details: Prevacid 30mg OD x 3 months

**Adaptation Information**

Date of Adaptation: January 16, 2009
Adaptation Details: changed to Rabeprazole 20mg OD x 3 months

**Rationale for Adaptation (including instructions to patient and follow-up plan)**

Rationale
- Patient previously on Rabeprazole 20mg OD over last 6 months
– Patient has Pharmacare special authority coverage for Rabeprazole
- Patient cannot afford cost of Prevacid (no SA for Prevacid)
– Product monograph for GERD Rabeprazole 20mg OD
– Patient confirms she has had good control of symptoms and no side effects on Rabeprazole 20mg
- Patient confirmed she had run out of medication 1 week ago and needed refill ASAP but couldn't remember the name of her Rx when she saw the walk-in clinic physician

Instructions to Patient: Take one tablet daily ½ hour before food. Try non-drug measures to help control symptoms. Elevate the head of the bed, eat smaller more frequent meals. Avoid spicy food and alcohol.

Follow-up Plan: Do a diary of food intake to see what foods make you feel worse or better. Review in 1 month.

**Informed Consent**

The patient and/or their representative (name: _____) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent. ☑

# Patient Inquiries About Renewals

*Over the coming months the public will become more aware of the expanded scope pharmacists have been given which will likely lead to a little confusion and a lot of questions.*

*The scenario below is an example of a potential conversation between a patient and pharmacist and is intended to help guide you in answering some of the questions which will likely arise.*

**Patient asks...**
"I heard somewhere that you can now renew my prescription – is that true?"

**Pharmacist responds…**
"Maybe. It is true that pharmacists now have the authority to renew prescriptions however each situation has to be considered independently. What it really depends on is how well I know your condition and your drug therapy. Let's take a look..."

**Patient asks...**
"How can I trust that you know what you are doing?"

**Pharmacist responds...**
"Pharmacists really are medication experts and we have more training in drug therapy than almost any other health care provider. But more importantly, I won't renew a prescription unless I'm confident that it will optimize your treatment and you are comfortable with the decision. Once I renew the prescription, I take responsibility for it, so you can be sure that I will be confident in my decision."

**Patient asks…**
"What about my doctor? Is he going to be upset by this? Does this mean I never have to go back to see him?"

**Pharmacist responds...**
"My renewal of your prescription in no way replaces the role your physician plays. First of all, as part of the process of renewing your prescription I will be notifying your doctor of what we have done and why. In the unlikely event that your doctor has any concerns about this they will contact one of us. Secondly, I cannot renew your prescription beyond the life of the prescription, which is one year, so at some point I will be referring you back to your doctor."

# IMPORTANT INFORMATION

## Amendments to
## Orientation Guide – Medication Management (Adapting a Prescription)
## (December 2008 – revised February 2011/April 2016/October 2016)

| Topic | Current wording in Orientation Guide | Reference in Orientation Guide | Clarification / Update |
|---|---|---|---|
| Prescription (Fundamental 3) | You must have an original prescription (an authorization from a practitioner to dispense a specified drug for use by a designated individual) and it must be current, authentic, and otherwise appropriate for the patient. | Section 2.1.3; page 7. | **October 2016:**<br>• Pharmacists may adapt an original prescription, including the first and subsequent refills of that prescription, in accordance with PPP-58.<br>• The adaptation does not need to be the beginning of a new drug therapy.<br>• Original prescriptions do not include transferred prescriptions, previously adapted prescriptions, or emergency refills. |
| Liability Insurance | Minimum requirements for liability insurance:<br>• Personal professional liability insurance (minimum $2 million) | Section 4.1; Page 19 | **December 2008:**<br>Minimum requirements for liability insurance are:<br>• The policy provides a minimum of $2 million coverage, and<br>• The policy provides occurrence-based coverage or claims-made coverage with an extended reporting period of at least three years, and<br>If not issued in the pharmacist's name, the group policy covers the pharmacist as an individual. |
| Handwritten notation from prescriber "Do Not Renew / Adapt" (or similar) | "review . . . the acknowledgement of any hand-written notations on the prescription by the prescriber." | Section 2.1.2; Page 7 | **December 2008:**<br>• Pharmacists will honour hand-written (not pre-stamped) "Do Not Renew / Adapt" notification on prescriptions<br>• If a prescriber electronically produces their prescriptions they must sign or initial beside the notation. |

| Topic | Current wording in Orientation Guide | Reference in Orientation Guide | Clarification / Update |
|---|---|---|---|
| Renewals – specific conditions &/or drugs | No limits and/or conditions stated | n/a | **February 2011:**<br>• Renewals apply to stable, chronic conditions (same medication, with no change) *Note: 'no change' is defined as usually a minimum of six months*<br>• For psychiatric medications renewals are reserved for pharmacists working in multidisciplinary teams |
| Renewals – length of time | "for whatever period of time felt appropriate as long as it does not exceed the expiry of the prescription" | Section 2.2.2; Page 15 and Section 2.1.3; Page 7 | **February 2011:**<br>• For whatever period of time felt appropriate as long as it does not exceed the expiry of the prescription<br><br>*Note: All prescriptions have an expiry of one year from the date the original prescription is written; oral contraceptives have a 2 year expiry date* |
| Change: dose or regimen | No limits and/or conditions stated | Section 2.2.1; Page 14 | **December 2008:**<br>Unless in practice settings such as hospital, long-term care facilities or multi-disciplinary environments where collaborative relationships or appropriate protocols are established, pharmacists:<br>• Will not change the dose or regimen of prescriptions for: cancer, cardio-vascular disease, asthma, seizures or psychiatric conditions<br>• Pharmacists can complete missing information on a prescriptions if there is historical evidence to support it |

| Topic | Current wording in Orientation Guide | Reference in Orientation Guide | Clarification / Update |
|---|---|---|---|
| Therapeutic Substitution | No limits and/or conditions stated | Section 2.2.3; Page 16 | **April 2016:**<br>Unless in practice settings such as hospital, long-term care facilities or multi-disciplinary environments where collaborative relationships or appropriate protocols are established, pharmacists:<br>Will limit therapeutic substitution to those categories under the Ministry of Health's Reference Drug Program, the updated list can be accessed here: http://www2.gov.bc.ca/gov/content/health/health-drug-coverage/pharmacare-for-bc-residents/what-we-cover/general-coverage-policies#rdp |

# Prescriber Notification Jurisdictional Scan Summary

A jurisdictional scan was completed to determine prescriber notification requirements at other Pharmacy Regulatory Authorities (PRAs). The chart below provides an overview of these requirements when renewing a prescription.

| Policy Component | BC | AB | SK | MB | ON | NB | NS | PEI | N&L | YK |
|---|---|---|---|---|---|---|---|---|---|---|
| **Prescriber Notification** | | | | | | | | | | |
| The pharmacist must notify the original prescriber when **renewing a prescription.** | ✓ | ✓[i] * | ✓ * | ✓ | ✓ | ✓[ii] | ✓ * | ✓ | ✓ | ✓* |

**Note:** An asterisk (*) indicates the removal of this requirement during the coronavirus pandemic.

[i] A pharmacist who renews a prescription must also notify a pharmacist at the original dispensing pharmacy and document that notification.

[ii] A pharmacist who adapts an existing prescription must inform the original prescriber (where such exists) when the change to the prescription the pharmacist is adapting is clinically significant.

# Appendix 5

## Requirement for Original Prescription when Adapting – Jurisdictional Scan Summary

| | BC | AB | SK | MB | ON | NB | NS | PEI | N&L | YK |
|---|---|---|---|---|---|---|---|---|---|---|
| The pharmacist must have the original prescription when adapting[i] a prescription. | ✓ | ✓[ii] | ✓[iii] | ✓ | ×* | × | × | ×*[iv] | × | ✓[v] |

* indicates additional change due to COVID-19

[i] Each PRA defines adaptation slightly differently

[ii] A pharmacist who does not have an original prescription may **renew** a prescription to ensure continuity of care IF they are satisfied that:

a) the patient has presented evidence of current ongoing therapy based on a prescription (such as an empty prescription vial),
b) there is immediate need for drug therapy, and
c) it is not reasonably possible for the patient to attend the original dispensing pharmacy or to have the prescription transferred from the original dispensing pharmacy.

[iii] When **renewing** a prescription previously initiated by a practitioner, a pharmacist may do so without the original prescription if the pharmacist confirms in the Pharmaceutical Information Program (PIP) that the medication is safe (i.e. the condition is chronic and stabilized) to renew. If the patient is from out of province and the pharmacist is unable to check the PIP, then they must take reasonable steps (e.g. contact originating pharmacy) to obtain medication history.

[iv] An original prescription is not required for adaptation or therapeutic substitution. There was previously a requirement to have the original prescription in order to prescribe for continuity of care (similar to renewal), but this requirement was removed.

[v] A pharmacist who does not have an original prescription may **renew** a prescription to ensure continuity of care IF they are satisfied that:

a) the patient has presented evidence of current ongoing therapy based on a prescription (such as an empty prescription vial),
b) there is immediate need for drug therapy, and
c) it is not reasonably possible for the patient to attend the original dispensing pharmacy or to have the prescription transferred from the original dispensing pharmacy.

# IMPORTANT INFORMATION

## Amendments to
## Orientation Guide – Medication Management (Adapting a Prescription)
## (December 2008 – revised February 2011/April 2016/October 2016)

| Topic | Current wording in Orientation Guide | Reference in Orientation Guide | Clarification / Update |
|---|---|---|---|
| Prescription (Fundamental 3) | You must have an original prescription (an authorization from a practitioner to dispense a specified drug for use by a designated individual) and it must be current, authentic, and otherwise appropriate for the patient. | Section 2.1.3; page 7. | **October 2016:**<br>• Pharmacists may adapt an original prescription, including the first and subsequent refills of that prescription, in accordance with PPP-58.<br>• The adaptation does not need to be the beginning of a new drug therapy.<br>• Original prescriptions do not include transferred prescriptions*, previously adapted prescriptions, or emergency refills.<br><br>***COVID-19 Update May 2020:**<br>The following temporary amendment is in effect during the COVID-19 public health emergency in British Columbia:<br>A pharmacist may adapt a transferred prescription. |
| Liability Insurance | Minimum requirements for liability insurance:<br>• Personal professional liability insurance (minimum $2 million) | Section 4.1; Page 19 | **December 2008:**<br>Minimum requirements for liability insurance are:<br>• The policy provides a minimum of $2 million coverage, and<br>• The policy provides occurrence-based coverage or claims-made coverage with an extended reporting period of at least three years, and<br>If not issued in the pharmacist's name, the group policy covers the pharmacist as an individual. |

| | | | |
|---|---|---|---|
| Handwritten notation from prescriber "Do Not Renew / Adapt" (or similar) | "review . . . the acknowledgement of any hand-written notations on the prescription by the prescriber." | Section 2.1.2; Page 7 | **December 2008:**<br>• Pharmacists will honour hand-written (not pre-stamped) "Do Not Renew / Adapt" notification on prescriptions<br>• If a prescriber electronically produces their prescriptions they must sign or initial beside the notation. |
| **Topic** | **Current wording in Orientation Guide** | **Reference in Orientation Guide** | **Clarification / Update** |
| Renewals – specific conditions &/or drugs | No limits and/or conditions stated | n/a | **February 2011:**<br>• Renewals apply to stable, chronic conditions (same medication, with no change) *Note: 'no change' is defined as usually a minimum of six months*<br>• For psychiatric medications renewals are reserved for pharmacists working in multidisciplinary teams |
| Renewals – length of time | "for whatever period of time felt appropriate as long as it does not exceed the expiry of the prescription" | Section 2.2.2; Page 15 and Section 2.1.3; Page 7 | **February 2011:**<br>• For whatever period of time felt appropriate as long as it does not exceed the expiry of the prescription<br><br>*Note: All prescriptions have an expiry of one year from the date the original prescription is written; oral contraceptives have a 2 year expiry date* |
| Change: dose or regimen | No limits and/or conditions stated | Section 2.2.1; Page 14 | **December 2008:**<br>Unless in practice settings such as hospital, long-term care facilities or multi-disciplinary environments where collaborative relationships or appropriate protocols are established, pharmacists:<br>• Will not change the dose or regimen of prescriptions for: cancer, cardio-vascular disease, asthma, seizures or psychiatric conditions<br>• Pharmacists can complete missing information on a prescriptions if there is historical evidence to support it |

| Topic | Current wording in Orientation Guide | Reference in Orientation Guide | Clarification / Update |
|---|---|---|---|
| Therapeutic Substitution | No limits and/or conditions stated | Section 2.2.3; Page 16 | **April 2016:**<br>Unless in practice settings such as hospital, long-term care facilities or multi-disciplinary environments where collaborative relationships or appropriate protocols are established, pharmacists:<br>Will limit therapeutic substitution to those categories under the Ministry of Health's Reference Drug Program, the updated list can be accessed here: http://www2.gov.bc.ca/gov/content/health/health-drug-coverage/pharmacare-for-bc-residents/what-we-cover/general-coverage-policies#rdp<br><br>**COVID-19 Update May 2020:**<br>The following temporary amendment is in effect during the COVID-19 public health emergency in British Columbia:<br>Where there is an actual drug shortage for a prescribed drug that is not included in a category under the Ministry of Health's Reference Drug Program, and where no interchangeable drug is available, therapeutic substitution of that drug is permitted in accordance with this policy. Evidence of the actual drug shortage (e.g., report from drugshortagescanada.ca or a "no alternative available" listing on PharmaCare's Current Drug Shortages List) must be included with the adaptation documentation.<br>When making a therapeutic drug substitution, you must be satisfied that the dose and the dosing regimen of the new drug you select will have an equivalent therapeutic effect, and that the substituted drug is within the same therapeutic class as the prescribed drug. Therapeutic substitution is not permitted for controlled drug substances and cancer chemotherapy agents. |

# IMPORTANT INFORMATION

## Amendments to
## Orientation Guide – Medication Management (Adapting a Prescription)
## (December 2008 – revised February 2011/April 2016/October 2016)

| Topic | Current wording in Orientation Guide | Reference in Orientation Guide | Clarification / Update |
|---|---|---|---|
| Prescription (Fundamental 3) | You must have an original prescription (an authorization from a practitioner to dispense a specified drug for use by a designated individual) and it must be current, authentic, and otherwise appropriate for the patient. | Section 2.1.3; page 7. | **October 2016:**<br>• Pharmacists may adapt an original prescription, including the first and subsequent refills of that prescription, in accordance with PPP-58.<br>• The adaptation does not need to be the beginning of a new drug therapy.<br>• Original prescriptions do not include transferred prescriptions*, previously adapted prescriptions, or emergency refills.<br><br>***COVID-19 Update May 2020:**<br>The following temporary amendment is in effect during the COVID-19 public health emergency in British Columbia:<br>A pharmacist may adapt a transferred prescription. |
| Liability Insurance | Minimum requirements for liability insurance:<br>• Personal professional liability insurance (minimum $2 million) | Section 4.1; Page 19 | **December 2008:**<br>Minimum requirements for liability insurance are:<br>• The policy provides a minimum of $2 million coverage, and<br>• The policy provides occurrence-based coverage or claims-made coverage with an extended reporting period of at least three years, and<br>If not issued in the pharmacist's name, the group policy covers the pharmacist as an individual. |

| | | | |
|---|---|---|---|
| Handwritten notation from prescriber "Do Not Renew / Adapt" (or similar) | "review . . . the acknowledgement of any hand-written notations on the prescription by the prescriber." | Section 2.1.2; Page 7 | **December 2008:**<br>• Pharmacists will honour hand-written (not pre-stamped) "Do Not Renew / Adapt" notification on prescriptions<br>• If a prescriber electronically produces their prescriptions they must sign or initial beside the notation. |
| **Topic** | **Current wording in Orientation Guide** | **Reference in Orientation Guide** | **Clarification / Update** |
| Renewals – specific conditions &/or drugs | No limits and/or conditions stated | n/a | **February 2011:**<br>• Renewals apply to stable, chronic conditions (same medication, with no change) *Note: 'no change' is defined as usually a minimum of six months*<br>• For psychiatric medications renewals are reserved for pharmacists working in multidisciplinary teams |
| Renewals – length of time | "for whatever period of time felt appropriate as long as it does not exceed the expiry of the prescription" | Section 2.2.2; Page 15 and Section 2.1.3; Page 7 | **February 2011:**<br>• For whatever period of time felt appropriate as long as it does not exceed the expiry of the prescription<br><br>*Note: All prescriptions have an expiry of one year from the date the original prescription is written; oral contraceptives have a 2 year expiry date* |
| Change: dose or regimen | No limits and/or conditions stated | Section 2.2.1; Page 14 | **December 2008:**<br>Unless in practice settings such as hospital, long-term care facilities or multi-disciplinary environments where collaborative relationships or appropriate protocols are established, pharmacists:<br>• Will not change the dose or regimen of prescriptions for: cancer, cardio-vascular disease, asthma, seizures or psychiatric conditions<br>• Pharmacists can complete missing information on a prescriptions if there is historical evidence to support it |

| Topic | Current wording in Orientation Guide | Reference in Orientation Guide | Clarification / Update |
|---|---|---|---|
| Therapeutic Substitution | No limits and/or conditions stated | Section 2.2.3; Page 16 | **April 2016:**<br>Unless in practice settings such as hospital, long-term care facilities or multi-disciplinary environments where collaborative relationships or appropriate protocols are established, pharmacists:<br>Will limit therapeutic substitution to those categories under the Ministry of Health's Reference Drug Program, the updated list can be accessed here: http://www2.gov.bc.ca/gov/content/health/health-drug-coverage/pharmacare-for-bc-residents/what-we-cover/general-coverage-policies#rdp<br><br>**COVID-19 Update May 2020:**<br>The following temporary amendment is in effect during the COVID-19 public health emergency in British Columbia:<br>Where there is an actual drug shortage for a prescribed drug that is not included in a category under the Ministry of Health's Reference Drug Program, and where no interchangeable drug is available, therapeutic substitution of that drug is permitted in accordance with this policy. Evidence of the actual drug shortage (e.g., report from drugshortagescanada.ca or a "no alternative available" listing on PharmaCare's Current Drug Shortages List) must be included with the adaptation documentation.<br>When making a therapeutic drug substitution, you must be satisfied that the dose and the dosing regimen of the new drug you select will have an equivalent therapeutic effect, and that the substituted drug is within the same therapeutic class as the prescribed drug. Therapeutic substitution is not permitted for controlled drug substances and cancer chemotherapy agents. |

APPENDIX 7

## Therapeutic Substitution Jurisdictional Scan Summary

Note: Manitoba, Ontario, Northwest Territories and Nunavut do not permit therapeutic substitution. Quebec does permit substitution, and further information on their policy has been sought but has not yet been received. Saskatchewan only permits therapeutic substitution if pharmacists have level II prescribing authorization, and have a collaborative practice agreement with a practitioner.

| Policy Component | BC | AB | NB | NS | PEI | N&L | YK |
|---|---|---|---|---|---|---|---|
| **Therapeutic substitution definition** | | | | | | | |
| Substitution of drug prescribed with a different drug that is expected to have a similar therapeutic effect, as long as that drug is from the same therapeutic class | ✓ | ✓ | ✓[i] | ✓ | ✓[ii] | ✓[iii] | ✓[iv] |
| No limits on therapeutic classes that can be substituted (excluding drugs listed in the *Controlled Drugs and Substances Act* and Regulations) | ✗[v] | ✓ | ✓ | ✓[vi] | ✓ | ✓[vii] | ✓ |
| Therapeutic substitution is considered a type of prescribing | ✗ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| **Additional Training or Experiential Requirements for Therapeutic Substitution** | | | | | | | |
| Orientation or training requirement | ✓ | ✗ | ✗ | ✗ | ✗ | ✓ | ✗ |

[i] Therapeutic substitution is not limited to within therapeutic class
[ii] Therapeutic substitution is not limited to within therapeutic class
[iii] Therapeutic substitution is not limited to within therapeutic class
[iv] Therapeutic substitution is not limited to within therapeutic class
[v] Limited to practice settings such as hospital, long-term care facilities or multi-disciplinary environments where collaborative relationships or appropriate protocols are established; or, where these don't exist, limited to categories under MoH Reference Drug Program (angiotensin converting enzyme inhibitors, angiotensin receptor blockers, dihydropyridine calcium channel blockers, histamine2 receptor blockers, nitrates, non-steroidal anti-inflammatory drugs, proton pump inhibitors, statins)
[vi] Standards of Practice note that prescribing for veterinary indications it outside the scope of practice of pharmacy
[vii] Pharmacists must not prescribe for an animals; pharmacists must not prescribe drugs that must be written on a tamper-proof prescription pad

APPENDIX 8

College of Pharmacists of British Columbia

# Orientation Guide

## Professional Practice Policy #58 - Medication Management (Adapting a Prescription)

# Foreword

Medication Management is an umbrella term that encompasses all professional activities that a pharmacist undertakes, as the medication experts, to optimize safe and effective drug therapy outcomes for patients. Pharmacists' involvement in medication management activities will continue to expand as the needs of patients and the demands of the healthcare system continue to increase.

This point was reinforced throughout the February 2008 'Throne Speech' where the provincial government acknowledged the challenges of sustaining the current healthcare system and called on all healthcare professionals to practice to their full scope as a means of helping to alleviate pressure from the system. This led to the introduction of – *Bill 25 – The Health Professions (Regulatory Reform) Amendment Act, 2008* which, specific to the pharmacy profession, formalizes a pharmacist's authority to 'renew existing prescriptions'.

The College of Pharmacists of BC's Professional Practice Policy #58 (PPP-58) entitled *"Protocol for Medication Management – Adapting a Prescription"*, approved by College council in September 2007, provides the framework to guide pharmacists in the safe and effective adaptation, including renewal, of existing prescriptions. PPP-58 is applicable to pharmacists in all practice settings, including community, long-term care, hospital and other institutional pharmacy settings.

This policy, which provides the opportunity for pharmacists to maximize their full educational and professional competencies, also provides structure to, and refines the process of, exercising professional judgment in clinical practice. This becomes increasingly important as pharmacists evolve their role as medication experts and assume accountability for their drug therapy decisions.

Although it is **not mandatory that a pharmacist adapt a prescription**, given that PPP-58 enhances pharmacist's scope of practice, it is mandatory that all registrants:

- Acknowledge that they have read and understood PPP-58 (by signing the Declaration Form included in this Guide)

Should a pharmacist choose to adapt a prescription, in addition to having read and understood the Orientation Guide, a pharmacist must:

- Possess personal professional liability insurance (minimum $2 million) and must adhere to all of the seven fundamentals for adapting a prescription as outlined in PPP-58

# How to Use This Guide

This Orientation Guide (the Guide) is a companion to the actual policy PPP-58 which can be found in Appendix A. The intention of the Guide is to provide further detail and clarity (including practical examples) to assist pharmacists in the implementation of the policy into practice and ensure that adaptations are done safely and effectively. For clarity, a Glossary of Terms specific to PPP-58 can be found in Appendix B. It is important to note that this document is a guide only and is not intended to cover all possible practice scenarios. As with all professional activities, pharmacists must use sound professional judgment when adapting a prescription.

It will take you about 2 hours to read through this Guide. Assuming that after reading the Guide you are confident that you understand the content you need to sign the Declaration Form (final page of Guide) and retain it in your files. Should you require further clarification, you may contact the College at **practicesupport@bcpharmacists.org**.

# Disclaimer

This Guide provides interpretation of PPP-58 under the statutes that govern the pharmacy profession in British Columbia. As a professional health practitioner in a self-regulated profession, you – the pharmacist – are responsible for understanding and practicing according to all relevant requirements and laws. You have a responsibility as a professional for interpreting and applying PPP-58 and the contents of this Guide within the context of your own practice.

# Acknowledgement

Thank you to the Alberta College of Pharmacists for sharing their materials and experiences from their work on implementing practice standards for adapting a prescription in Alberta. Thank you to the BC Pharmacy Association for their participation in the Working Group that created this Orientation Guide.

# Feedback

Questions and comments about this Orientation Guide are welcome and can be sent to:

Bob Nakagawa, Registrar
College of Pharmacists of BC
200–1765 West 8th Avenue Vancouver, BC V6J 5C6
Phone: 604.733.2440 or 800.663.1940
Fax: 604.733.2493 or 800.377.8129
E-mail: info@bcpharmacists.org

# Table of Contents

# 1.0 Introduction

## 1.1 Overview

The Framework of Professional Practice (FPP) provides the framework for good pharmacy practice in British Columbia. It describes what BC pharmacists do in daily practice and how they know they are doing it well. The FPP is designed to help pharmacists enhance their practice and patient outcomes, and to guide their professional development.

Within the current provincial legislative structure, pharmacists have the authority to perform certain professional activities to help people achieve their desired health outcomes. The College develops Professional Practice Policies to more clearly articulate a pharmacist's professional practice authorities and responsibilities. Professional Practice Policy #58 (PPP- 58) entitled *Protocol for Medication Management (Adapting a Prescription) is one such policy and falls under FPP Role 1 – Provide Pharmaceutical Care*.

In adapting a prescription however, in addition to PPP-58, the pharmacist must refer to all applicable legislation and standards. This includes, but is not limited to, the *Health Professions Act* (HPA)*, the Pharmacy Operations and Drug Scheduling Act (PODSA), the Pharmaceutical Services Act (PSA)* and related regulations and bylaws, the *Health Care (Consent) and Care Facility (Admission) Act*, the FPP, and other Professional Practice Policies.

Although it is mandatory to know this policy, it is not mandatory that a pharmacist adapt a prescription. The decision to adapt a prescription or not is at the discretion of the individual pharmacist. Whenever a pharmacist chooses to adapt a prescription however, the adaptation must be done in accordance with PPP-58 and within the limits of the pharmacist's own competencies.

This policy is designed to enable continued high quality, safe and effective pharmacy care by BC pharmacists and to serve as a foundation for new professional pharmacist activities in the future.

## 1.2 Important Facts

Although the Guide will go into specific detail regarding the parameters and application requirements of *Medication Management – Adapting a Prescription (PPP-58)* the following is a list of key facts:

- PPP-58 applies to adapting an **existing** prescription only and does not include initiating a prescription nor activities requiring diagnosis
- Excludes narcotics, controlled drugs and targeted substances
- Does not replace a patient's need to see their physician
- For a pharmacist to adapt a prescription they must have completed the Orientation process and must possess personal professional liability insurance (minimum $2 million)
- Pharmacist authorization to adapt prescriptions **does not** mean obligation

- Once a pharmacist adapts a prescription they take **full responsibility** for and **assume liability** for that adapted prescription
- Although notification to the prescriber is the **final step** in the adaptation process, **prior approval** from the prescriber is not required

## 1.3 Bottom-line

The implementation of PPP-58 provides pharmacists the opportunity to utilize their professional judgment and practice to the full extent of their knowledge, skills and abilities to optimize health outcomes for their patients.

The evolutionary change in pharmacy practice through the implementation of PPP-58 is that it gives pharmacists independent authority and accountability for the adaptation of a prescription. In doing this, the pharmacist is making the decision, based on their professional judgment, that the prescription is the 'right' prescription for their patient.

Although this additional authority comes with added responsibility and ultimately liability, it allows pharmacists to demonstrate their value, as medication experts, in an evolving patient-centered, clinical care environment.

## 1.4 Objectives

After reviewing the material in this Guide, you will be able to:

1. Understand the elements of *Medication Management (Adapting a Prescription)*;
2. Understand the professional requirements and expectations when you undertake *Medication Management (Adapting a Prescription)*;
3. Understand the specific consent, documentation and notification requirements of implementing this policy in your practice;
4. Implement specifically defined Medication Management activities; and
5. Optimize the services you provide to patients within your enhanced scope of practice.

# 2.0 About PPP-58 Medication Management (Adapting a Prescription)

This section provides a detailed description of the following:

2.1 The fundamentals of adapting a prescription

2.2 The categories of adapting a prescription that you are authorized to engage in; and

2.3 Determining when you are NOT adapting a prescription.

## 2.1 Seven Fundamentals of Adapting a Prescription

PPP-58 outlines that you may dispense a drug contrary to the terms of an existing prescription (adapt a prescription) if the action is intended to optimize the therapeutic outcome of treatment with the prescription drug **and** you have addressed ***all*** of the following seven fundamental elements:

1. **Individual competence;**
2. **Appropriate information;**
3. **Prescription;**
4. **Appropriateness of adaptation;**
5. **Informed consent;**
6. **Documentation; and**
7. **Notification of other health professionals.**

Each of these elements provides structure to, and refines the process for, exercising professional judgment in your practice. When considering an adaptation you must consider the seven fundamentals in sequential order beginning with number 1 – Individual competence. If you are uncomfortable or unsure about any aspect along the way, **do not** adapt the prescription.

### 2.1.1 Individual Competence (Fundamental 1)

You must practice within your area of competency only. Do not adapt a prescription for any patient unless you have 'appropriate knowledge and understanding' of the condition being treated and the drug being prescribed.

It is not possible to establish parameters to define what is meant by 'appropriate knowledge and understanding', each situation like each patient, is unique. Therefore, in order for a pharmacist to determine if they feel that they have 'appropriate knowledge and information' they must rely on their own professional judgment.

In doing this, it is helpful to answer the following questions:

1. If someone asks why I made this decision, can I justify it?

2. Would this decision withstand a test of reasonableness (i.e., would another pharmacist make the same decision in this situation)?

## 2.1.2 Appropriate Information (Fundamental 2)

You must have 'sufficient information' about the patient's health status to be satisfied that adapting the prescription will maintain or enhance the effectiveness of the drug therapy, patient outcomes and will not put the patient at increased risk.

In doing this you must respect and consider all relevant information available to you. This would include, but is not limited to: a review of the patient's health record on local and PharmaNet data bases, the acknowledgement of any hand-written notations on the prescription by the prescriber, and any information obtained directly from the patient or their representative. You may also need to obtain additional information from an appropriate source such as relevant medical literature or other colleagues.

Again, it is not possible to establish parameters to define what is meant by 'sufficient information' as each situation, like each patient, is unique. Therefore, in order for a pharmacist to determine if they feel that they have 'sufficient information' they must rely on their own professional judgment.

In doing this, it is helpful to consider the following questions:

1. If someone asks why I made this decision, can I justify it?
2. Would this decision withstand a test of reasonableness (i.e., would another pharmacist make the same decision in this situation)?

## 2.1.3 Prescription (Fundamental 3)

You must have an **original prescription (an authorization from a practitioner to dispense a specified drug for use by a designated individual)** and it must be current, authentic, and otherwise appropriate for the patient. Pharmacists may not adapt a prescription if the original prescription has expired. All prescriptions have an expiry of one year from the date the **original prescription is written**. The exception is oral contraceptives, which have a two year expiry date.

***Reminder:***
*Irrespective of PPP-58, if, upon review of relevant information, your professional judgment is that a drug-related problem exists and the prescription should not be filled or the drug should not be sold, you must refuse to dispense or sell the drug.*

***Example(s) of Prescription Expiry:***
**If a prescription is written on January 1, it is valid until December 31 of that same year even though the prescriber may only authorize an initial quantity of 100 days (with no authorized refills).**

*continued on next page*

**If after the initial 100 days the pharmacist felt, based on following the Seven Fundamentals laid out in PPP-58 that it was appropriate for the patient, they could adapt (renew) the prescription for any portion of the days remaining – in this case to a maximum of 265 days.** ***(Note: while the decision to renew can be up to 265 days, it may also be significantly less and the duration is based on the professional judgement of the pharmacist)***

**It is never possible, however, for a pharmacist to adapt (renew) the prescription beyond its' validity date – in this case December 31. Therefore, if the patient requested that the pharmacist adapt (renew) the prescription on Dec 1, the pharmacist could only dispense a 30 day supply and must refer the patient back to their prescriber for a new prescription.** ***(Note: if the patient were to present to the pharmacist after the Dec 31 expiry date, the pharmacist could not adapt (renew) the prescription at all but could, for continuity of care purposes, ~~extend~~ provide an emergency ~~refill~~ supply under PPP-31)***

**It is also important to remember that the validity of a prescription is based on a period of time – in this example Jan 1 to Dec 31 – not on the overall quantity that could potentially be dispensed over that period of time.**

**To illustrate this point, let's assume that the patient has the initial 100 days dispensed on Jan 1 but then does nothing until Dec 1 of that same year. At that point he presents to the pharmacist requesting a renewal for another 100 days. Although there is enough undispensed quantity to accommodate this request the prescription is only valid for 30 more days so the pharmacist could only provide a renewal for up to 30 days and must refer the patient back to their prescriber for a new prescription.**

## 2.1.4 Appropriateness of Adaptation (Fundamental 4)

You must be sure that adapting the prescription is appropriate for the patient under the current circumstances, and will, in your professional judgment, optimize the therapeutic outcome of treatment.

You must maintain your professional independence at all times when making any adaptation and particularly when making therapeutic substitution decisions. You must critically evaluate evidence, clinical practice guidelines, information from pharmaceutical manufacturers, and approved indications. You may also be required to take into account formulary restrictions and other patient-related considerations. To be consistent with general practices and the College's Code of Ethics it is not appropriate to adapt a prescription for yourself or family members.

All decisions must be in the best interest of the patient and must focus on addressing the health needs of that patient. Any indication that a decision is based on benefit to the pharmacist or pharmacy rather than the patient will be considered professional misconduct.

# 2.1.5 Informed Consent (Fundamental 5)

## 2.1.5.1 General

In British Columbia, the obligation to obtain informed consent to healthcare from an adult patient, the criteria for consent and how to obtain consent, is defined in the *Health Care (Consent) and Care Facility (Admission) Act*.

The Act, states that every adult patient has the right to give, refuse or withdraw consent to treatment. Adaptation of a prescription in accordance with PPP-58 is a treatment that requires you to obtain consent from a particular patient.

The Act also sets out the criteria and process for obtaining valid consent. You must ensure that the consent has been **voluntarily** given to the proposed treatment by a capable adult patient.

You must also provide the patient with enough information to enable that patient to make an informed decision. Although this may sometimes be difficult to determine, you are required to decide:

*What the average prudent and reasonable person in the patient's particular position would agree to or not agree to, if all material and special risks of going ahead (with the treatment) or foregoing it were made known to him.*[1]

When advising a patient of risks, you must be familiar with the patient's circumstances, and take into account any special considerations that apply.

Informed consent is specific to the current treatment under consideration and not a blanket consent for any possible treatment. You **must** bring the following matter to the patient's attention:

- The specific condition for which the prescription adaptation is proposed;
- The nature of the proposed adaptation; and
- The risks and benefits of the adaptation that a reasonable patient would expect to be told about.

This list is not inclusive. Other matters may exist that need to be discussed with the patient, depending on the circumstances.

You must also provide an opportunity for the patient to ask questions and receive answers about the adaptation.

## 2.1.5.2 Substitute Consent - Adult Patients

Pharmacists frequently obtain consent from someone other than the patient being treated. This usually happens when an adult patient is no longer capable of providing an informed consent.

[1] Reibl v Hughes, (1980) 14 C.C.L.T. 1 at paragraph 21

In this situation, based upon the information that you have been provided, you must determine whether the patient has demonstrated that he or she is not able to give a valid consent. When this happens, the Act provides that you may obtain consent from a recognized representative from one of the following three categories:

- A committee appointed by the Supreme Court of British Columbia pursuant to the *Patients Property Act*;
- A representative named in a Representation Agreement validly made pursuant to the *Representation Agreement Act*; or
- A substitute decision maker pursuant to Section 16 of the *Health Care (Consent) and Care Facility (Admission) Act* where there is no committee or representative. The ranked list of acceptable substitute decision makers is:
    1. The patient's spouse;
    2. The patient's child;
    3. The patient's parents;
    4. The patient's brother or sister; or
    5. Any one else related by birth or adoption to the patient.

In order to give substitute consent, substitute decision makers must meet the following criteria. They must:

- Be at least 19 years old;
- Have had contact with the patient in the preceding twelve months;
- Have no dispute with the patient;
- Be capable themselves; and
- Be willing to comply with the duties in Section 19 of the *Health Care (Consent) and Care Facility (Admission) Act*.

If there is no one available to act as a substitute decision maker, you should contact the Health Care Decisions Consultant at the Public Guardian and Trustee for assistance. The Public Guardian and Trustee is authorized to provide consent in appropriate cases.

### 2.1.5.3 Consent of Minors

In British Columbia, the age of majority is 19 years. Normally a parent or guardian provides consent to healthcare on behalf of the minor. However, this is not always the case. The *Infants Act* provides that a minor may consent to treatment (adaptation of a prescription) if you have explained to and are satisfied that the minor understands the nature, consequences and can reasonably foresee risks and benefits of the treatment; and you have decided that in the circumstances the treatment is in the infant's best interest. A parent or guardian cannot overrule the decision made by the minor and is not entitled to disclosure of the information.

If a parent or a guardian is unavailable to provide consent and the infant is not mature enough to provide his or her own consent, it is customary for you to obtain the consent of grandparents, aunts, uncles, or other relatives as appropriate in the circumstances.

### 2.1.5.4 Recording of Consent

*The Health Care (Consent) and Care Facility (Admission) Act* provides that consent may be expressed orally, in writing or may be inferred from the patient's conduct. Therefore, it is not strictly necessary for you to document that you have obtained consent. However, the recommended documentation/notification template form (Appendix D) includes an area to acknowledge, by a tick mark, that consent was obtained and if by a representative, their name.

Such documentation is a useful risk management tool. In fact, written evidence that informed consent has been obtained in a particular situation can have a significant influence on the outcome of a negligence case brought against a healthcare professional for failure to obtain informed consent.

## 2.1.6 Documentation (Fundamental 6)

You must document all adaptations of all prescriptions in a way that creates an accurate record of the circumstances and details of the adaptation. The documentation must always relate back to the original prescription and include (if applicable) reference to any and all previous adaptations. Attached to this Guide as Appendix D is a recommended documentation and notification template form (an electronic version of this form is available on the college website **www.bcpharmcists.org**). The intention of the form is that once complete it can easily be faxed to the prescriber for notification purposes and then attached to the adapted prescription and maintained in the pharmacy records.

Pharmacists can develop their own documentation process as long as they ensure that the method of record-keeping is consistent with College auditing policies and procedures. In other words, all original prescription hard copies must always be retained, including new prescription hard copies generated as part of the adaptation process. All of the required documentation information, listed below, must be captured and retained with the adapted prescription.

Documentation must include:

1. Patient (including PHN number) and Pharmacist (including signature and name of Pharmacy) information
2. Original prescription information (including prescribers name and contact information)
3. A description of the adaptation (including all relevant prescription details)
4. The rationale for the decision to adapt the prescription (including pertinent details of your assessment and patient history along with any instructions to the patient and relevant follow-up plan)
5. Acknowledgment of informed consent
6. The date and name of practitioner(s) notified

When adapting an existing prescription, during the prescription filling process on PharmaNet, you must input your pharmacist identification number in the prescriber field. This will confirm, within the system, that you have adapted the initial prescription and are now responsible for the adapted prescription.

Documentation establishes accountability and responsibility for your professional activities. It is a key component in demonstrating how you exercised your professional judgment and will be the primary tool used to communicate the rationale for your decision. It is also important to remember that every time you document you are creating a health care record. Following are some points to be considered:

- Complete your documentation as soon as possible (preferably immediately) after the activity;
- Use a standard format (preferably the template included with this Guide) for documenting that includes the information outlined above;
- Include all information deemed necessary to support the identification of drug-related problems, recommendations and decisions;
- Use clear, logical and precise language;
- Ensure all documentation is legible and non-erasable; and
- Do not delete, remove or rewrite from any part of the record. If you make an error, cross out the error with a single line and initial it.
- Remember that documentation must always relate back to the original prescription and include, if applicable, reference to any and all adaptations.

## 2.1.7 Notification of Other Health Professionals (Fundamental 7)

***Note:***
*The College of Pharmacists of BC developed this form with input from the College of Physicians and Surgeon of BC.*

At all times, when you adapt a prescription you must notify the **original prescriber**[2]. Notification must take place as soon as reasonably possible, preferably within 24 hours. **You must also notify the patient's most responsible clinician** if you are aware that the original prescriber is not your patient's usual practitioner. Although a requirement of PPP-58, one of the benefits of notification is that it provides enhanced opportunity for collaboration between you, the prescriber and the patient.

As introduced in Fundamental 6 and attached to this Guide as Appendix D is a recommended documentation and notification template form (an electronic version of this form is available on the college website **www.bcpharmcists.org**). The intention of the form is that once complete it can easily be faxed to the prescriber for notification purposes and then attached to the adapted prescription and maintained in the pharmacy records.

[2] For purposes of PPP-58, and included in the Glossary of Terms (Appendix B) the 'original prescriber' refers to the prescriber who authorized the first fill.

Pharmacists can develop their own notification process as long as all of the required notification information, listed below, is included.

Notification must include:

1. Patient (including PHN number) and Pharmacist (including signature and name of Pharmacy) information
2. Original prescription information (including prescribers name and contact information)
3. A description of the adaptation (including all relevant prescription details)
4. The rationale for the decision to adapt the prescription (including pertinent details of your assessment and patient history along with any instructions to the patient and relevant follow-up plan)
5. Acknowledgment of informed consent
6. The date and name of practitioner notified

Experience in other jurisdictions has shown that fax notification is a preferred method for notification of other health professionals. You will need to determine the most suitable notification method for your practice based on what works best for you and the practitioners you usually communicate with. Fax or written notification is the preferred method, however, in certain circumstances, verbal notification may be sufficient, but may lead to extra transcribing work at the receiver's end and introduces a margin of error if the information is transcribed incorrectly.

This Guide also includes, in Appendix E, a sample letter &/or fax directed to prescribers introducing them to PPP-58. You may choose to utilize this document as a means of preparing and informing your prescribers that you will be exercising your authority to adapt prescriptions, starting January 1, 2009, and introduce them to the type of documentation they can expect to see from you.

## 2.2 Activities considered Adapting a Prescription

Three professional activities are considered to be adapting a prescription within the current scope of pharmacy practice in BC:

***Remember:*** *Authorization does not mean obligation.*

1. **Change**: Changing the dose, formulation, or regimen of a prescription to enhance patient outcomes;
2. **Renew**: Renewing a prescription for continuity of care; and
3. **Substitution**: Making a therapeutic drug substitution within the same therapeutic class for a prescription to best suit the needs of the patient.

Exceptions:

- PPP-58 **does not** include adapting a prescription for narcotic, controlled drugs or targeted substances. If a change to a prescription for one of these categories of drugs is warranted, the pharmacist must contact the original prescriber to discuss modifying the original prescription.

- PPP-58 **does not** allow for the adaptation of a prescription if the original prescription has expired. All prescriptions have an expiry of one year from the date the original prescription is written. The exception is oral contraceptives, which have a two year expiry date.

You must use professional judgment to evaluate each situation and have addressed all of the seven fundamentals of adapting a prescription as described in Section 2.1 of this Guide.

## 2.2.1 Changing the Dose, Formulation, or Regimen of a New Prescription

Under PPP-58 you can change the dose, quantity, formulation, or regimen of a drug presented on a prescription without prior authorization from the prescriber if, in your professional judgment, the change will enhance the patient's outcome. This includes adding missing information.

**Changing the dose**

You can change the dose:

- If the strength of the drug prescribed is not commercially available;
- If the patient's age, weight or kidney or liver function requires you to change the dose; or
- If, in your professional judgment, you are satisfied the changed dose would otherwise benefit the patient.

**Changing the formulation or regimen**

You can change the formulation or the regimen of the medication to improve the ability of the patient to effectively take the medication.

**Miscellaneous**

You can also adapt a prescription dose, quantity, formulation or regimen if the information provided is incomplete but you determine what the intended treatment is through consultation with the patient and a review of your records (locally or on PharmaNet).

## 2.2.2 Renewing a Previously Filled Prescription for Continuity of Care

PPP-31 – Emergency ~~Prescription Refills~~Supply for Continuity of Care state~~s~~ pharmacists may exercise professional judgment in in the provision of emergency prescription ~~refill~~ supplies of a medication~~. This practice is the exception to the rule and not the normal practice~~ (see Appendix C). The intention of PPP-31 is to ensure continuity of care by allowing pharmacists to extend a prescription, for a short period of time, to enable the patient to get back to their prescriber for authorization.

Now under PPP-58 pharmacists, by adhering to *the Seven Fundamentals of Adapting a Prescription*, are able to adapt (renew) the prescription themselves on behalf of the patient without prior authorization from the prescriber for whatever period of time felt appropriate as long as it does not exceed the expiry of the prescription (refer to 2.1.3 of this Guide).

By doing this the pharmacist is utilizing their professional judgment and demonstrating that they have enough competence and information about the patient and their condition to determine that the prescription will maintain or enhance the patient's health outcome. PPP-58 provides pharmacists with the opportunity to practice to the full extent of their knowledge, skills and ability and demonstrate their value as medication experts.

Given the authority available to pharmacists under PPP-58, when faced with a situation requiring or requesting the renewal of a prescription for continuity of care, it is recommended that a pharmacist first consider the opportunity to fully adapt the prescription under PPP-58 before deferring to PPP-31.

It is important to remember that unlike PPP-31, where a pharmacist can provide an emergency ~~refill~~ supply without access to a prescription (evidence such as; an empty prescription vial, a label or a copy of a prescription receipt will suffice), PPP-58 requires that a pharmacist has the original prescription and that it is current, authentic and has not expired.

***Illustration:***
When a pharmacist is presented with a situation in which a patient has run out of a valid prescription (i.e.; it is current, authentic, appropriate and has not expired) and there are no authorized refills the pharmacist should:

- Step One: Consider adapting the prescription by referring to the first two of the seven fundamentals of PPP-58 and ask:
  a. Do I have 'appropriate knowledge and understanding' of the condition being treated and the drug being prescribed? If yes, then ask,
  b. Do I have 'sufficient information' about the patient's health status to be satisfied that adapting the prescription will maintain or enhance the effectiveness of the drug therapy, patient outcomes and will not put the patient at increased risk? If yes, then the pharmacist should consider adapting the prescription

- Step Two: If on the other hand the pharmacist answers no to either of the questions in step one they should not adapt the prescription but could either try to contact the prescriber to seek approval for a refill or defer to PPP-31 and provide an emergency supply

## 2.2.3 Making a Therapeutic Drug Substitution within the Same Therapeutic Class

You may adapt a prescription by making a therapeutic substitution. You are making a therapeutic substitution when you substitute the drug prescribed with a different drug that is expected to have a similar therapeutic effect, as long as that drug is from within the same therapeutic class. When making a therapeutic drug substitution, you must be satisfied that the dose and the dosing regimen of the new drug you select will have an equivalent therapeutic effect.

You must be satisfied that the following conditions are met when making a therapeutic substitution decision:

1. The decision is in the best interest of the patient by:
   a. Addressing the health needs of that patient,
   b. Maintaining or enhancing the safety or effectiveness of drug therapy,
   c. Not placing the patient at increased risk,
   d. Considering formulary or payer restrictions and other patient-related information, and
   e. Ensuring the drug is approved for the intended indication by Health Canada or strong evidence supports using the drug for the intended indication (e.g., clinical practice guidelines);
2. Your professional independence has been maintained and you avoid conflict of interest. If a decision is based on benefit to the pharmacist or pharmacy rather than the patient, this will be considered professional misconduct;
3. You have considered all relevant information about the patient, the condition and the drug, and you have effectively communicated this to the patient to ensure they agree with the decision; and
4. You take full responsibility for your decision.

# 2.3 Determining When You Are Not Adapting a Prescription

## 2.3.1 When You Call the Original Prescriber to Make a Change

When you identify a drug-related problem during the process of filling a prescription or discussing medication needs with a patient, you may choose to do what you have always done and contact the prescriber to discuss your concerns about the prescription. If, as a result of that conversation, the original prescriber directs you to make a change to the prescription, you may make the change and sign or initial it as you always have. In this case you are not adapting the prescription.

In fact, in any circumstance where you obtain prior authorization from the prescriber to make a change, provide a substitution or refill a prescription you are not adapting a prescription.

## 2.3.2 When You Dispense an Interchangeable Drug Product

Dispensing an interchangeable drug product, including generic substitution, is not adapting a prescription.~~.~~

## 2.3.3 When an Approved Protocol Exists

If you practice in environments where a specific hospital board – or College ~~Council~~ Board – approved protocol exists and applies in that situation, you may be required to make changes to the prescription. In these circumstances, where you are simply applying the policy or treatment protocol (e.g. automatic substitution), and you are not using your professional judgment, you are not adapting a prescription.

## 2.3.4 When You Are Continuing Therapy by Advancing a Few Doses

As described in PPP-31 – Emergency ~~Prescription Refills~~Supply for Continuity of Care (see Appendix C), you are already authorized to assist patients in maintaining continuity of their drug therapy by advancing them a few doses or a few days supply if they run out of medication and an appointment with the prescribing physician is imminent. Advance supplies are not technically prescription renewals and do not fall under PPP-58, but you must evaluate the patient's need for the medication and be satisfied that providing any additional doses will not cause or worsen a drug-related problem for the patient.

# 3.0 Implementing PPP-58 in Your Practice

In addition to information posted on the College's website (www.bcpharmacists.org) and/or communicated in ongoing College publications such as ReadLinks, there are a number of resources available to support you in the effective implementation of PPP-58 in your practice.

## 3.1 Support is Available

### 3.1.1 Practical Resources

The following resources are provided in the appendix of this Guide:

- Appendix B – Glossary of Terms
- Appendix D – Documentation and Notification Template (an electronic version is also available on the College website - www.bcpharmacists.org)
- Appendix E – Sample letter/fax introducing PPP-58 to your prescribers
- Appendix F – Practical Examples

### 3.1.2 Need more support?

If you still have questions or concerns and want to implement the policy in your practice, please contact Practice Support through the College office at 604-733-2440 or by email at practicesupport@bcpharmacists.org.

# 4.0 Other Considerations

## 4.1 Liability and Insurance

Adapting a prescription is one activity within a pharmacist's current scope of practice that expands the potential for liability. Although a pharmacist is not obligated to adapt a prescription, should they choose to adapt a prescription, they are required to possess personal professional liability insurance – minimum $2 million.

## 4.2 Consequences for Failure to Follow PPP-58

Any pharmacist who adapts a prescription contrary to the requirements of PPP-58 will be forwarded to the Inquiry Committee process as per current College procedures.

All pharmacists are expected to abide by all aspects of professional practice as described in the College's Framework of Professional Practice, federal legislation (*the Food and Drug Act (FDA) and Regulations and the Controlled Drug and Substances Act*), provincial legislation (*the HPA, PODSA, and PSA along with related regulations and bylaws*), and the College's *Professional Practice Policies*.

## 4.3 Conflict of Interest

The implementation of PPP-58 may put pharmacists in a position of real or perceived conflict of interest with their patients. The adaptation of a prescription may lead to increased revenue thereby enhancing a pharmacist's financial interests.

Pharmacists must consider first and foremost the interest and well-being of their patients. Prescriptions must not be adapted unless it is in the best interest of a patient to do so.

Any indication that the decision was based on benefit to the pharmacist or pharmacy, rather than the patient, will be considered professional misconduct and reviewed through the Inquiry Committee process.

## 4.4 Conclusion

These are indeed exciting times for the profession of pharmacy in British Columbia as pharmacist's involvement in medication management activities continues to expand. PPP-58 creates the framework to guide pharmacists in the safe and effective adaptation of prescriptions allowing you to maximize your full educational and professional competencies to optimize therapeutic outcomes for your patients. In addition this policy provides a structure to the process of using professional judgment in practice and establishes a foundation for the further expansion of pharmacy practice in the future.
Take time to consider your competencies, your work environment, and your current and potential relationships with patients and other health professionals. And the next time you have the opportunity to adapt a prescription – use the seven fundamentals to help determine if it is the 'right' thing to do for your patient.

# 5.0 Declaration Form

## Medication Management
## (Adapting a Prescription)
## Professional Practice Policy #58 (PPP-58)

### Declaration of completion and understanding

I,_____ a registrant on the Register of Pharmacists of the College of Pharmacists of British Columbia, declare that I have thoroughly read and understood the PPP-58 Orientation Guide Medication Management (Adapting a Prescription).

I also declare and understand that although it is not mandatory that I adapt a prescription, should I choose to adapt a prescription in addition to having read and understood the Orientation Guide I must:

- Adhere to all of the seven fundamentals for adapting a prescription as outlined in PPP-58 and possess personal professional liability insurance (minimum $2 million).

Signature:_____ Date:_____

***Note:***
*You should retain this signed Declaration Form in your personal records.*

# Appendix A: Professional Practice Policy #58 Protocol for Medication Management (Adapting a Prescription)

**POLICY STATEMENT(S):**

A pharmacist may dispense a drug contrary to the terms of a prescription (adapt a prescription) if the action is intended to optimize the therapeutic outcome of treatment with the prescribed drug and meets **all** of the following elements of a protocol to adapt a prescription:

1. **Individual competence**
   a. Pharmacist has appropriate knowledge and understanding of the condition and the drug being dispensed in order to adapt the prescription.

2. **Appropriate information**
   a. Pharmacist has sufficient information about the specific client's health status to ensure that adapting the prescription will maintain or enhance the effectiveness of the drug therapy and will not put the client at increased risk.

3. **Prescription**
   a. Pharmacist has a prescription that is current, authentic, and appropriate.

4. **Appropriateness**
   a. Pharmacist determines whether adapting the prescription is appropriate in the circumstances.

5. **Informed consent**
   a. Pharmacist must obtain the informed consent of the client or client's representative before undertaking any adapting activity.

6. **Documentation**
   a. Pharmacist must document in the client's record any adaptation of the prescription, the rationale for the decision, and any appropriate follow-up plan.

7. **Notification of other health professionals**
   a. Pharmacist must notify the original prescriber (and the general practitioner if appropriate) as soon as reasonably possible (preferably within 24 hours of dispensing) and this must be recorded in the client's record or directly on the prescription hard copy.

**Note: PPP-58 is not a stand-alone document and must be read with the Orientation Manual and the Amendment to the Orientation Manual. For a pharmacist to use PPP-58 they will be required to sign the PPP-58 Declaration Form.**

BACKGROUND:

**Protocol for medication management (adapting a prescription)**

This professional practice policy enables pharmacists to maximize their full educational and professional competencies by providing authorization to adapt existing prescriptions. This policy is not mandatory and the decision whether to adapt a prescription is at the discretion of the individual pharmacist.

To guide decisions with respect to adapting a prescription, where a specific hospital board - or College of Pharmacists of BC - Board approved protocol does not exist, the pharmacist must refer to all applicable legislation and standards. This includes, but is not limited to, the *Health Professions Act, Pharmacy Operations and Drug Scheduling Act*, the Regulation and Bylaws of the College of Pharmacists of BC made pursuant to these Acts, the *Health Care (Consent) and Care Facility (Admission) Act*, the Framework of Professional Practice (FPP), the Code of Ethics and Professional Practice Policies. This specific policy (PPP-58) does not apply to controlled drug substances and cancer chemotherapy agents.

The FPP is the standards of pharmacy practice in British Columbia. In adapting a prescription the pharmacist must follow the FPP Role 1 *Provide pharmaceutical care.* Role 1 elements include:

- Function A – Assess the client's health status and needs
- Function B – Develop a care plan with the client
- Function C – Support the client to implement the care plan
- Function D – Support and monitor the client's progress with the care plan
- Function E – Document findings, follow-ups recommendations, information provided and client's outcomes

**Benefits of professional practice policy**

The benefits to clients are to:

a) Optimize drug therapy leading to improved client health outcomes
   1) Better therapeutic responses.
   2) Reduced drug errors.
   3) Fewer adverse drug reactions/interactions.

b) Have an effective and efficient health care system
   1) Minimize delays in initiating and changing drug therapy.
   2) Make the best use of human resources in the health care system.

c) Expand the opportunities to identify people with significant risk factors.

d) Encourage collaboration among health care providers.

First approved: 21 Sep 2007 **PPP-58**
Revised:
Reaffirmed: 27 Mar 2009

# Appendix B: Glossary of Terms

For the purposes of Professional Practice Policy #58 *Protocol for Medication Management – Adapting a Prescription* – the terms below have the following meaning:

| | |
|---|---|
| **Adaptation** | • term used to describe the pharmacists' authority under PPP-58 to adapt an existing prescription when, in their professional judgment, the action is intended to optimize the therapeutic outcome of treatment |
| **Conflict of Interest** | • at all times pharmacists must maintain professional independence and adaptation decisions must first and foremost be made in the best interest of the patient with the intention of optimizing the therapeutic outcome of treatment<br>• any indication that a decision is based on benefit to the pharmacist or pharmacy, rather than the patient, will be considered professional misconduct |
| **Continuity of Care** (for medication management) | • the assurance of uninterrupted drug therapy for the best health outcome of the patient |
| **Liability** | • pharmacist assumes legal responsibility for the adapted prescription and as a mandatory condition of their authority to adapt possesses personal professional liability insurance (minimum coverage $2 million) |
| **Original Prescriber** | • refers to the prescriber who authorized the first fill |
| **Prescription Expiry** | • all prescriptions have an expiry of one year from the date the prescription is written (the exception is oral contraceptives, which is two years)<br>• a pharmacist may not adapt a prescription if the original prescription has expired<br>• a pharmacist may not adapt components of a prescription beyond its' expiry date (ie: quantity cannot exceed the time remaining) |

| | |
|---|---|
| **Refill** | • term used by the prescriber to indicate their authorization to provide a refill(s) to the original prescription |
| **Renew** | • term used to describe the extension of a prescription (not beyond its' expiry date) by a pharmacist; the act of renewing a prescription constitutes adaptation and thereby transfers liability to the adaptor |
| **Responsible Clinician** | • most responsible physician/provider who manages the patient's care on an ongoing basis (ie: family physician, nurse practitioner) |
| **Therapeutic Drug Substitution** | • substitution of the prescribed drug with a different drug, from the same therapeutic class, that is expected to have a similar therapeutic effect<br>• pharmacist must be satisfied that the dose and dosing regimen of the new drug will have an equivalent therapeutic effect |

# Appendix C: Other Relevant Professional Practice Policies

## CPBC Professional Practice Policy PPP-31 – Emergency Supply for Continuity of Care

See the most up-to-date Professional Practice Policy – 31 Emergency Supply for Continuity of Care on the CPBC website: http://library.bcpharmacists.org/6_Resources/6-2_PPP/5003-PGP-PPP31.pdf~~1 – PPP-31 – Emergency Prescription Refills~~

~~Pharmacists may exercise professional judgment in the provision of emergency prescription refill supplies of a medication. This practice is *the exception to the rule and not the normal practice*.~~

~~A pharmacist may dispense an emergency refill in the following situations;~~
~~- where a patient's medication supply has been exhausted, a refill may be dispensed to ensure continuity of care. OR~~
~~- where a patient attends the pharmacy for an authorized refill of a valid prescription but PharmaNet returns the message, '101 Prescriber not found' or 'D3 Prescriber is not authorized' and the pharmacist ensures that the patient is not on Pharmacare's *Restricted Claimants Program*, a refill may be dispensed to ensure continuity of care and to allow time for the patient to find a new prescriber.~~

~~The pharmacist must comply with each of the following practice fundamentals;~~
~~**1. Individual competence**~~

~~a. Pharmacist has appropriate knowledge and understanding of the condition and the drug being dispensed in order to adapt the prescription.~~
~~**2. Appropriate information**~~

~~a. Pharmacist has sufficient information about the specific patient's health status to ensure that dispensing an emergency refill of the prescription will ensure continuity of care and will not put the patient at increased risk.~~
~~**3. Appropriateness**~~

~~a. Pharmacist must use their professional judgment to determine whether provision of an emergency refill is appropriate in the circumstances, and must determine an appropriate days supply based on the drug involved and how long it will take the patient to see a prescriber.~~
~~**4. Informed consent**~~

~~a. Pharmacist must obtain the informed consent of the patient or patient's representative before undertaking an emergency refill.~~
~~**5. Documentation**~~

~~a. Pharmacists must use their CPBC pharmacist registration numbers in the PharmaNet practitioner ID field to identify the responsible decision-maker when providing an emergency supply of a drug to a patient.~~
~~b. 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.~~

~~First Approved: 29 January 1999~~

~~Revised: 20 June 2003/15 Feb 2013~~
~~Reaffirmed: 27 Mar 2009~~

# Appendix C: Prescription Adaptation Documentation and Notification Template

(an electronic version of this template is available on the College website www.bcpharmacists.org)

## Patient Information

Name: _____

PHN: _____

## Pharmacist Information

Name: _____

Pharmacy: _____

_____

## Prescriber Information

Name: _____

Phone: _____

Fax: _____

Phone: _____

Fax: _____

Signature: _____

## Original Prescription Information

Date of Prescription: _____

Prescription Details: _____

_____

## Adaptation Information

Date of Adaptation: _____

Adaptation Details: _____

_____

## Rationale for Adaptation (including instructions to patient and follow-up plan)

Rationale

_____

_____

_____

_____

_____

_____

_____

Instructions to Patient

_____

Follow-up Plan

_____

## Informed Consent

The patient and/or their representative (name: _____) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent. ☐

## Notification Information

Date of Notification: _____ Name of Practitioner(s) Notified: _____

Method of Notification (fax preferred): _____

☐ Fax # _____ ☐ Phone # _____ ☐ Other _____

The information contained in this fax communication is confidential and is intended only for the use of the recipient named above If the reader of this fax memo is not the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this fax memo is strictly prohibited. If you have received this fax memo in error, please destroy the memo and notify the sender.

# Appendix E: Sample letter/fax introducing PPP-58

[drugstore letterhead]

Date

Doctor name
Address

Re: Introduction to Pharmacists enhanced scope of practice

Dear Dr. _____,

The purpose of this letter is to ensure that you are aware of some recent changes that have evolved the scope of practice for pharmacists in BC. Earlier this year the government introduced Bill 25 which, specific to the profession of pharmacy, formalized pharmacists' authority to 'renew' existing prescriptions.

In conjunction with this the College of Pharmacists of BC (CPBC) has introduced *Professional Practice Policy #58 (PPP-58) Medication Management – Adapting a Prescription* which provides the framework to guide pharmacists in the safe and effective adaptation, including renewal, of existing prescriptions.

Although it is not mandatory that a pharmacist adapt a prescription, it is mandatory that should a pharmacist choose to adapt a prescription they adhere to the guidelines laid out in the PPP-58 Orientation Guide, which includes notification to the original prescriber (a copy of the PPP-58 Orientation Guide is available on the CPBC website www.bcpharmacists.org).

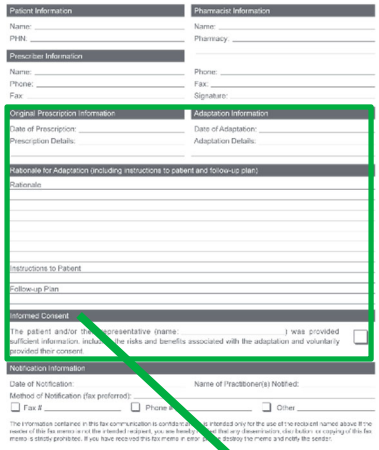
This means that from time to time you may receive a fax notification (sample attached) from a member of our pharmacy team to inform you of a prescription adaptation that has occurred. Pharmacists' authorization to implement this policy and thereby adapt prescriptions is effective January 1, 2009.

We value our professional relationship with you. Please feel free to contact (insert: pharmacy manager name) with any questions or comments you may have.

Sincerely,

The information contained in this fax communication is confidential and is intended only for the use of the recipient named above If the reader of this fax memo is not the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this fax memo is strictly prohibited. If you have received this fax memo in error, please destroy the memo and notify the sender.

# Appendix F: Practical Examples




***Example 1 – Changing the Dose:***

You receive a new prescription for alendronate 10mg once weekly for an elderly female patient. The PharmaNet record indicates the patient was previously taking alendronate 10mg once daily for the past year. You have a discussion with the patient and determine the following:

- The patient has been having difficulty with compliance of the once daily regimen.
- The physician discussed with her that she was changing the prescription to the once weekly formulation to make it easier for her to remember her dose.

**Original Prescription Information**

Date of Prescription: January 15, 2009

Prescription Details: Alendronate 10mg once weekly x 6 months

**Adaptation Information**

Date of Adaptation: January 16, 2009

Adaptation Details: changed Alendronate 10mg once weekly to 70mg once weekly x 3 months with 1 refill

**Rationale for Adaptation (including instructions to patient and follow-up plan)**

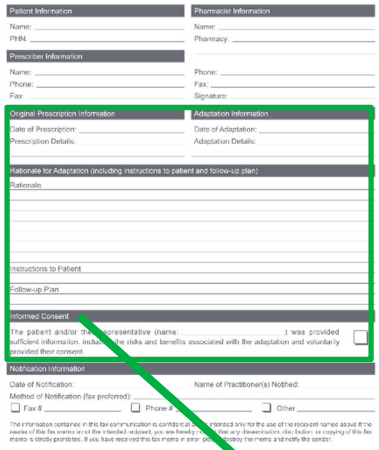
Rationale
- usual dose alendronate 10mg once daily or 70 mg once weekly
– product monograph indicates no dosage adjustment necessary for the elderly or for patients with mild to moderate renal insufficiency
– confirmed with patient that no impaired renal function
– patient confirmed doctor discussed change to weekly formulation for compliance reasons

Instructions to Patient: Instructed the patient to take 1 tablet once/week on the same day each week with plenty of water.

Follow-up Plan: contact her physician if any GI upset or unusual symptoms.

**Informed Consent**

The patient and/or their representative (name: _____) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent. ☑




***Example 2 – Incomplete Information:***

You receive a new prescription for an adult female patient for Betaderm 0.1% Cream; Apply TID. The patient indicated that her skin is really dry and scaly and that she would prefer a product with more of a moisturizing effect.

You have a discussion with the patient and determine the following:

- She had used Betaderm 0.1% Cream for one month and was getting results with the cream.
- You visually confirm that her skin is dry and scaly.

**Original Prescription Information**

Date of Prescription: January 15, 2009

Prescription Details: Betaderm 0.1% Cream; Apply TID

**Adaptation Information**

Date of Adaptation: January 15, 2009

Adaptation Details: changed Betaderm 0.1% Cream to etaderm 0.1% Ointment; Apply TID

**Rationale for Adaptation (including instructions to patient and follow-up plan)**

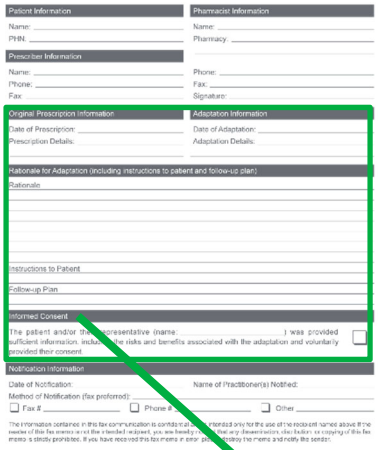
Rationale
- reviewed PharmaNet profile which indicates patient has been using Betaderm 0.1% Cream for one month
- patient indicated that the cream is helping her condition except that the affected area on her skin is dry and scaly
- change in formulation will still provide the same result with a more emollient effect

Instructions to Patient: Apply sparingly to affected area three times a day. If skin condition worsens, contact your doctor.

Follow-up Plan: See your doctor at your regular interval in one month.

**Informed Consent**

The patient and/or their representative (name: _____) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent. ☑




***Example 3 – Incomplete Information:***

You receive a new prescription for Ramipril – take one tablet daily. No strength is indicated on the prescription. The PharmaNet record indicates the patient has been getting the 10mg strength for the past 6 months.

You have a discussion with the patient and determine the following:

- The patient confirms that the prescription was intended for the same dose (10mg) as before and that the medication is being used for blood pressure control.

**Original Prescription Information**

Date of Prescription: January 4, 2009

Prescription Details: Ramipril
take 1 tablet daily, Mitte 90, no refills

**Adaptation Information**

Date of Adaptation: January 4, 2009

Adaptation Details: Ramipril 10mg
once daily Mitte 90, no refills.

**Rationale for Adaptation (including instructions to patient and follow-up plan)**

Rationale - PharmaNet record indicates patient has been on Ramipril 10mg once daily for 6 months
– Patient confirmed that his regular doctor is on holiday and the locum prescribed his regular medication (he was not expecting any changes)
– Patient confirms his blood pressure is on target (130/75)

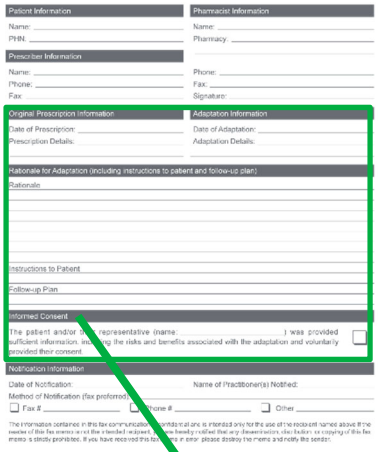
Instructions to Patient Take one Ramipril 10mg daily for blood pressure control.

Follow-up Plan Instructed to continue to check blood pressure regularly.

**Informed Consent**

The patient and/or their representative (name: _____) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent. ✓

**Notification Information**




***Example 4 – Renew a Prescription:***

A long standing patient of your pharmacy takes a thyroid supplement and diuretic every day. She comes to the pharmacy and requests a renewal of her prescriptions. You notice in your records that 3 months ago she received the same prescriptions but no refills were authorized. You review the PharmaNet record and determine she has been on the same dose of the same medications for 2 years.

You have a discussion with the patient and determine the following:

- She confirms that her TSH levels are being regularly monitored as well as her blood pressure.
- She confirms that she sees her physician every 6 months and that she is due for her follow-up in 3 months.

**Original Prescription Information**

Date of Prescription: October 4, 2008

Prescription Details: Hydrochlorthiazide 50mg OD
Synthroid 100mcg 1 OD, no refills

**Adaptation Information**

Date of Adaptation: January 16, 2009

Adaptation Details: Hydrochlorthiazide 50mg OD
Synthroid 100mcg 1 OD, renewed x 3mth supply

**Rationale for Adaptation (including instructions to patient and follow-up plan)**

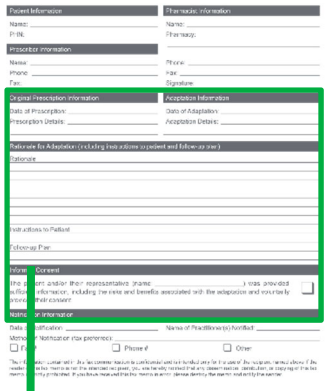
Rationale
- PharmaNet record indicates patient has been on same dosage of both medications for 2 years
- Patient confirmed TSH and blood pressure are regularly monitored
- Patient confirmed she has follow-up with physician every 6 months and is seeing doctor in 3 months
- Most recent original prescription was 3 months ago (Oct. 4/08) therefore prescription is still a valid prescription

Instructions to Patient: Take 1 tablet of each medication daily, in the morning, on an empty stomach and continue monitoring your blood pressure regularly.

Follow-up Plan: Return for follow-up with your physician in 3 months as scheduled.

**Informed Consent**

The patient and/or their representative (name: _____) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent. ☑



**Note:**
*In the 'Notification' section of the form you would indicate that both physicians were notified of this adaptation.*

### *Example 5 – Therapeutic Substitution:*

Patient arrives at your pharmacy with a prescription for Prevacid 30mg once daily x 3 months for GERD. You notice the prescription is from the local walk-in clinic physician. You check the PharmaNet profile and determine that the patient has previously been on Rabeprazole 20mg once daily x 6 months and has had Pharmacare coverage through special authorization for the Rabeprazole. You process the prescription for Prevacid 30mg once daily and notice that the patient does not have special authorization for the Prevacid.

You have a discussion with the patient and determine the following:

- The patient receives social assistance and cannot afford the prescription cost for the Prevacid.
- The patient had run out of the Rabeprazole prescription last week and couldn't get to her regular doctor, so went to the walk-in clinic.
- The patient wanted a renewal of the prescription she was previously on for her heartburn, but she couldn't remember the name of it when she went to the clinic and she didn't have her empty vial with her.
- Her previous prescription had been controlling her symptoms very well and she had not had any side effects.
- Patient is anxious to get her Rabeprazole medication as her symptoms have increased over the past week since she has been out of her medication.

**Original Prescription Information**

Date of Prescription: January 15, 2009
Prescription Details: Prevacid 30mg OD x 3 months

**Adaptation Information**

Date of Adaptation: January 16, 2009
Adaptation Details: changed to Rabeprazole 20mg OD x 3 months

**Rationale for Adaptation (including instructions to patient and follow-up plan)**

Rationale
- Patient previously on Rabeprazole 20mg OD over last 6 months
- Patient has Pharmacare special authority coverage for Rabeprazole
- Patient cannot afford cost of Prevacid (no SA for Prevacid)
- Product monograph for GERD Rabeprazole 20mg OD
- Patient confirms she has had good control of symptoms and no side effects on Rabeprazole 20mg
- Patient confirmed she had run out of medication 1 week ago and needed refill ASAP but couldn't remember the name of her Rx when she saw the walk-in clinic physician

Instructions to Patient: Take one tablet daily ½ hour before food. Try non-drug measures to help control symptoms. Elevate the head of the bed, eat smaller more frequent meals. Avoid spicy food and alcohol.

Follow-up Plan: Do a diary of food intake to see what foods make you feel worse or better. Review in 1 month.

**Informed Consent**

The patient and/or their representative (name: _____) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent. ☑

# Patient Inquiries About Renewals

*Over the coming months the public will become more aware of the expanded scope pharmacists have been given which will likely lead to a little confusion and a lot of questions.*

*The scenario below is an example of a potential conversation between a patient and pharmacist and is intended to help guide you in answering some of the questions which will likely arise.*

**Patient asks...**
"I heard somewhere that you can now renew my prescription – is that true?"

**Pharmacist responds…**
"Maybe. It is true that pharmacists now have the authority to renew prescriptions however each situation has to be considered independently. What it really depends on is how well I know your condition and your drug therapy. Let's take a look..."

**Patient asks...**
"How can I trust that you know what you are doing?"

**Pharmacist responds...**
"Pharmacists really are medication experts and we have more training in drug therapy than almost any other health care provider. But more importantly, I won't renew a prescription unless I'm confident that it will optimize your treatment and you are comfortable with the decision. Once I renew the prescription, I take responsibility for it, so you can be sure that I will be confident in my decision."

**Patient asks…**
"What about my doctor? Is he going to be upset by this? Does this mean I never have to go back to see him?"

**Pharmacist responds...**
"My renewal of your prescription in no way replaces the role your physician plays. First of all, as part of the process of renewing your prescription I will be notifying your doctor of what we have done and why. In the unlikely event that your doctor has any concerns about this they will contact one of us. Secondly, I cannot renew your prescription beyond the life of the prescription, which is one year, so at some point I will be referring you back to your doctor."

APPENDIX 8

College of Pharmacists
of British Columbia

# Orientation Guide

## Professional Practice Policy #58 - Medication Management (Adapting a Prescription)

# Foreword

Medication Management is an umbrella term that encompasses all professional activities that a pharmacist undertakes, as the medication experts, to optimize safe and effective drug therapy outcomes for patients. Pharmacists' involvement in medication management activities will continue to expand as the needs of patients and the demands of the healthcare system continue to increase.

This point was reinforced throughout the February 2008 'Throne Speech' where the provincial government acknowledged the challenges of sustaining the current healthcare system and called on all healthcare professionals to practice to their full scope as a means of helping to alleviate pressure from the system. This led to the introduction of – *Bill 25 – The Health Professions (Regulatory Reform) Amendment Act, 2008* which, specific to the pharmacy profession, formalizes a pharmacist's authority to 'renew existing prescriptions'.

The College of Pharmacists of BC's Professional Practice Policy #58 (PPP-58) entitled *"Protocol for Medication Management – Adapting a Prescription"*, approved by College council in September 2007, provides the framework to guide pharmacists in the safe and effective adaptation, including renewal, of existing prescriptions. PPP-58 is applicable to pharmacists in all practice settings, including community, long-term care, hospital and other institutional pharmacy settings.

This policy, which provides the opportunity for pharmacists to maximize their full educational and professional competencies, also provides structure to, and refines the process of, exercising professional judgment in clinical practice. This becomes increasingly important as pharmacists evolve their role as medication experts and assume accountability for their drug therapy decisions.

Although it is **not mandatory that a pharmacist adapt a prescription**, given that PPP-58 enhances pharmacist's scope of practice, it is mandatory that all registrants:

- Acknowledge that they have read and understood PPP-58 (by signing the Declaration Form included in this Guide)

Should a pharmacist choose to adapt a prescription, in addition to having read and understood the Orientation Guide, a pharmacist must:

- Possess personal professional liability insurance (minimum $2 million) and must adhere to all of the seven fundamentals for adapting a prescription as outlined in PPP-58

# How to Use This Guide

This Orientation Guide (the Guide) is a companion to the actual policy PPP-58 which can be found in Appendix A. The intention of the Guide is to provide further detail and clarity (including practical examples) to assist pharmacists in the implementation of the policy into practice and ensure that adaptations are done safely and effectively. For clarity, a Glossary of Terms specific to PPP-58 can be found in Appendix B. It is important to note that this document is a guide only and is not intended to cover all possible practice scenarios. As with all professional activities, pharmacists must use sound professional judgment when adapting a prescription.

It will take you about 2 hours to read through this Guide. Assuming that after reading the Guide you are confident that you understand the content you need to sign the Declaration Form (final page of Guide) and retain it in your files. Should you require further clarification, you may contact the College at **practicesupport@bcpharmacists.org**.

# Disclaimer

This Guide provides interpretation of PPP-58 under the statutes that govern the pharmacy profession in British Columbia. As a professional health practitioner in a self-regulated profession, you – the pharmacist – are responsible for understanding and practicing according to all relevant requirements and laws. You have a responsibility as a professional for interpreting and applying PPP-58 and the contents of this Guide within the context of your own practice.

# Acknowledgement

Thank you to the Alberta College of Pharmacists for sharing their materials and experiences from their work on implementing practice standards for adapting a prescription in Alberta. Thank you to the BC Pharmacy Association for their participation in the Working Group that created this Orientation Guide.

# Feedback

Questions and comments about this Orientation Guide are welcome and can be sent to:

Bob Nakagawa, Registrar
College of Pharmacists of BC
200–1765 West 8th Avenue Vancouver, BC V6J 5C6
Phone: 604.733.2440 or 800.663.1940
Fax: 604.733.2493 or 800.377.8129
E-mail: info@bcpharmacists.org

# Table of Contents

# 1.0 Introduction

## 1.1 Overview

The Framework of Professional Practice (FPP) provides the framework for good pharmacy practice in British Columbia. It describes what BC pharmacists do in daily practice and how they know they are doing it well. The FPP is designed to help pharmacists enhance their practice and patient outcomes, and to guide their professional development.

Within the current provincial legislative structure, pharmacists have the authority to perform certain professional activities to help people achieve their desired health outcomes. The College develops Professional Practice Policies to more clearly articulate a pharmacist's professional practice authorities and responsibilities. Professional Practice Policy #58 (PPP- 58) entitled *Protocol for Medication Management (Adapting a Prescription) is one such policy and falls under FPP Role 1 – Provide Pharmaceutical Care*.

In adapting a prescription however, in addition to PPP-58, the pharmacist must refer to all applicable legislation and standards. This includes, but is not limited to, the *Health Professions Act* (HPA)*, the Pharmacy Operations and Drug Scheduling Act (PODSA), the Pharmaceutical Services Act (PSA)* and related regulations and bylaws, the *Health Care (Consent) and Care Facility (Admission) Act*, the FPP, and other Professional Practice Policies.

Although it is mandatory to know this policy, it is not mandatory that a pharmacist adapt a prescription. The decision to adapt a prescription or not is at the discretion of the individual pharmacist. Whenever a pharmacist chooses to adapt a prescription however, the adaptation must be done in accordance with PPP-58 and within the limits of the pharmacist's own competencies.

This policy is designed to enable continued high quality, safe and effective pharmacy care by BC pharmacists and to serve as a foundation for new professional pharmacist activities in the future.

## 1.2 Important Facts

Although the Guide will go into specific detail regarding the parameters and application requirements of *Medication Management – Adapting a Prescription (PPP-58)* the following is a list of key facts:

- PPP-58 applies to adapting an **existing** prescription only and does not include initiating a prescription nor activities requiring diagnosis
- Excludes narcotics, controlled drugs and targeted substances
- Does not replace a patient's need to see their physician
- For a pharmacist to adapt a prescription they must have completed the Orientation process and must possess personal professional liability insurance (minimum $2 million)
- Pharmacist authorization to adapt prescriptions **does not** mean obligation

- Once a pharmacist adapts a prescription they take **full responsibility** for and **assume liability** for that adapted prescription
- Although notification to the prescriber is the **final step** in the adaptation process, **prior approval** from the prescriber is not required

## 1.3 Bottom-line

The implementation of PPP-58 provides pharmacists the opportunity to utilize their professional judgment and practice to the full extent of their knowledge, skills and abilities to optimize health outcomes for their patients.

The evolutionary change in pharmacy practice through the implementation of PPP-58 is that it gives pharmacists independent authority and accountability for the adaptation of a prescription. In doing this, the pharmacist is making the decision, based on their professional judgment, that the prescription is the 'right' prescription for their patient.

Although this additional authority comes with added responsibility and ultimately liability, it allows pharmacists to demonstrate their value, as medication experts, in an evolving patient-centered, clinical care environment.

## 1.4 Objectives

After reviewing the material in this Guide, you will be able to:

1. Understand the elements of *Medication Management (Adapting a Prescription)*;
2. Understand the professional requirements and expectations when you undertake *Medication Management (Adapting a Prescription)*;
3. Understand the specific consent, documentation and notification requirements of implementing this policy in your practice;
4. Implement specifically defined Medication Management activities; and
5. Optimize the services you provide to patients within your enhanced scope of practice.

# 2.0 About PPP-58 Medication Management (Adapting a Prescription)

This section provides a detailed description of the following:

2.1 The fundamentals of adapting a prescription

2.2 The categories of adapting a prescription that you are authorized to engage in; and

2.3 Determining when you are NOT adapting a prescription.

## 2.1 Seven Fundamentals of Adapting a Prescription

PPP-58 outlines that you may dispense a drug contrary to the terms of an existing prescription (adapt a prescription) if the action is intended to optimize the therapeutic outcome of treatment with the prescription drug **and** you have addressed ***all*** of the following seven fundamental elements:

1. **Individual competence;**
2. **Appropriate information;**
3. **Prescription;**
4. **Appropriateness of adaptation;**
5. **Informed consent;**
6. **Documentation; and**
7. **Notification of other health professionals.**

Each of these elements provides structure to, and refines the process for, exercising professional judgment in your practice. When considering an adaptation you must consider the seven fundamentals in sequential order beginning with number 1 – Individual competence. If you are uncomfortable or unsure about any aspect along the way, **do not** adapt the prescription.

### 2.1.1 Individual Competence (Fundamental 1)

You must practice within your area of competency only. Do not adapt a prescription for any patient unless you have 'appropriate knowledge and understanding' of the condition being treated and the drug being prescribed.

It is not possible to establish parameters to define what is meant by 'appropriate knowledge and understanding', each situation like each patient, is unique. Therefore, in order for a pharmacist to determine if they feel that they have 'appropriate knowledge and information' they must rely on their own professional judgment.

In doing this, it is helpful to answer the following questions:

1. If someone asks why I made this decision, can I justify it?

2. Would this decision withstand a test of reasonableness (i.e., would another pharmacist make the same decision in this situation)?

## 2.1.2 Appropriate Information (Fundamental 2)

You must have 'sufficient information' about the patient's health status to be satisfied that adapting the prescription will maintain or enhance the effectiveness of the drug therapy, patient outcomes and will not put the patient at increased risk.

In doing this you must respect and consider all relevant information available to you. This would include, but is not limited to: a review of the patient's health record on local and PharmaNet data bases, the acknowledgement of any hand-written notations on the prescription by the prescriber, and any information obtained directly from the patient or their representative. You may also need to obtain additional information from an appropriate source such as relevant medical literature or other colleagues.

Again, it is not possible to establish parameters to define what is meant by 'sufficient information' as each situation, like each patient, is unique. Therefore, in order for a pharmacist to determine if they feel that they have 'sufficient information' they must rely on their own professional judgment.

In doing this, it is helpful to consider the following questions:

1. If someone asks why I made this decision, can I justify it?
2. Would this decision withstand a test of reasonableness (i.e., would another pharmacist make the same decision in this situation)?

## 2.1.3 Prescription (Fundamental 3)

You must have an **original prescription (an authorization from a practitioner to dispense a specified drug for use by a designated individual)** and it must be current, authentic, and otherwise appropriate for the patient. Pharmacists may not adapt a prescription if the original prescription has expired. All prescriptions have an expiry of one year from the date the **original prescription is written**. The exception is oral contraceptives, which have a two year expiry date.

***Reminder:***
*Irrespective of PPP-58, if, upon review of relevant information, your professional judgment is that a drug-related problem exists and the prescription should not be filled or the drug should not be sold, you must refuse to dispense or sell the drug.*

***Example(s) of Prescription Expiry:***
**If a prescription is written on January 1, it is valid until December 31 of that same year even though the prescriber may only authorize an initial quantity of 100 days (with no authorized refills).**

*continued on next page*

**If after the initial 100 days the pharmacist felt, based on following the Seven Fundamentals laid out in PPP-58 that it was appropriate for the patient, they could adapt (renew) the prescription for any portion of the days remaining – in this case to a maximum of 265 days. *(Note: while the decision to renew can be up to 265 days, it may also be significantly less and the duration is based on the professional judgement of the pharmacist)***

**It is never possible, however, for a pharmacist to adapt (renew) the prescription beyond its' validity date – in this case December 31. Therefore, if the patient requested that the pharmacist adapt (renew) the prescription on Dec 1, the pharmacist could only dispense a 30 day supply and must refer the patient back to their prescriber for a new prescription. *(Note: if the patient were to present to the pharmacist after the Dec 31 expiry date, the pharmacist could not adapt (renew) the prescription at all but could, for continuity of care purposes, provide an emergency supply under PPP-31)***

**It is also important to remember that the validity of a prescription is based on a period of time – in this example Jan 1 to Dec 31 – not on the overall quantity that could potentially be dispensed over that period of time.**

**To illustrate this point, let's assume that the patient has the initial 100 days dispensed on Jan 1 but then does nothing until Dec 1 of that same year. At that point he presents to the pharmacist requesting a renewal for another 100 days. Although there is enough undispensed quantity to accommodate this request the prescription is only valid for 30 more days so the pharmacist could only provide a renewal for up to 30 days and must refer the patient back to their prescriber for a new prescription.**

## 2.1.4 Appropriateness of Adaptation (Fundamental 4)

You must be sure that adapting the prescription is appropriate for the patient under the current circumstances, and will, in your professional judgment, optimize the therapeutic outcome of treatment.

You must maintain your professional independence at all times when making any adaptation and particularly when making therapeutic substitution decisions. You must critically evaluate evidence, clinical practice guidelines, information from pharmaceutical manufacturers, and approved indications. You may also be required to take into account formulary restrictions and other patient-related considerations. To be consistent with general practices and the College's Code of Ethics it is not appropriate to adapt a prescription for yourself or family members.

All decisions must be in the best interest of the patient and must focus on addressing the health needs of that patient. Any indication that a decision is based on benefit to the pharmacist or pharmacy rather than the patient will be considered professional misconduct.

# 2.1.5 Informed Consent (Fundamental 5)

## 2.1.5.1 General

In British Columbia, the obligation to obtain informed consent to healthcare from an adult patient, the criteria for consent and how to obtain consent, is defined in the *Health Care (Consent) and Care Facility (Admission) Act*.

The Act, states that every adult patient has the right to give, refuse or withdraw consent to treatment. Adaptation of a prescription in accordance with PPP-58 is a treatment that requires you to obtain consent from a particular patient.

The Act also sets out the criteria and process for obtaining valid consent. You must ensure that the consent has been **voluntarily** given to the proposed treatment by a capable adult patient.

You must also provide the patient with enough information to enable that patient to make an informed decision. Although this may sometimes be difficult to determine, you are required to decide:

*What the average prudent and reasonable person in the patient's particular position would agree to or not agree to, if all material and special risks of going ahead (with the treatment) or foregoing it were made known to him.*[1]

When advising a patient of risks, you must be familiar with the patient's circumstances, and take into account any special considerations that apply.

Informed consent is specific to the current treatment under consideration and not a blanket consent for any possible treatment. You **must** bring the following matter to the patient's attention:

- The specific condition for which the prescription adaptation is proposed;
- The nature of the proposed adaptation; and
- The risks and benefits of the adaptation that a reasonable patient would expect to be told about.

This list is not inclusive. Other matters may exist that need to be discussed with the patient, depending on the circumstances.

You must also provide an opportunity for the patient to ask questions and receive answers about the adaptation.

## 2.1.5.2 Substitute Consent - Adult Patients

Pharmacists frequently obtain consent from someone other than the patient being treated. This usually happens when an adult patient is no longer capable of providing an informed consent. In this situation, based upon the information that you have been provided, you must determine whether the patient has demonstrated that he or she is not able to give a valid consent.

[1] Reibl v Hughes, (1980) 14 C.C.L.T. 1 at paragraph 21

When this happens, the Act provides that you may obtain consent from a recognized representative from one of the following three categories:

- A committee appointed by the Supreme Court of British Columbia pursuant to the *Patients Property Act*;
- A representative named in a Representation Agreement validly made pursuant to the *Representation Agreement Act*; or
- A substitute decision maker pursuant to Section 16 of the *Health Care (Consent) and Care Facility (Admission) Act* where there is no committee or representative. The ranked list of acceptable substitute decision makers is:
  1. The patient's spouse;
  2. The patient's child;
  3. The patient's parents;
  4. The patient's brother or sister; or
  5. Any one else related by birth or adoption to the patient.

In order to give substitute consent, substitute decision makers must meet the following criteria. They must:

- Be at least 19 years old;
- Have had contact with the patient in the preceding twelve months;
- Have no dispute with the patient;
- Be capable themselves; and
- Be willing to comply with the duties in Section 19 of the *Health Care (Consent) and Care Facility (Admission) Act*.

If there is no one available to act as a substitute decision maker, you should contact the Health Care Decisions Consultant at the Public Guardian and Trustee for assistance. The Public Guardian and Trustee is authorized to provide consent in appropriate cases.

### 2.1.5.3 Consent of Minors

In British Columbia, the age of majority is 19 years. Normally a parent or guardian provides consent to healthcare on behalf of the minor. However, this is not always the case. The *Infants Act* provides that a minor may consent to treatment (adaptation of a prescription) if you have explained to and are satisfied that the minor understands the nature, consequences and can reasonably foresee risks and benefits of the treatment; and you have decided that in the circumstances the treatment is in the infant's best interest. A parent or guardian cannot overrule the decision made by the minor and is not entitled to disclosure of the information.

If a parent or a guardian is unavailable to provide consent and the infant is not mature enough to provide his or her own consent, it is customary for you to obtain the consent of grandparents, aunts, uncles, or other relatives as appropriate in the circumstances.

### 2.1.5.4 Recording of Consent

*The Health Care (Consent) and Care Facility (Admission) Act* provides that consent may be expressed orally, in writing or may be inferred from the patient's conduct. Therefore, it is not strictly necessary for you to document that you have obtained consent. However, the recommended documentation/notification template form (Appendix D) includes an area to acknowledge, by a tick mark, that consent was obtained and if by a representative, their name.

Such documentation is a useful risk management tool. In fact, written evidence that informed consent has been obtained in a particular situation can have a significant influence on the outcome of a negligence case brought against a healthcare professional for failure to obtain informed consent.

## 2.1.6 Documentation (Fundamental 6)

You must document all adaptations of all prescriptions in a way that creates an accurate record of the circumstances and details of the adaptation. The documentation must always relate back to the original prescription and include (if applicable) reference to any and all previous adaptations. Attached to this Guide as Appendix D is a recommended documentation and notification template form (an electronic version of this form is available on the college website **www.bcpharmcists.org**). The intention of the form is that once complete it can easily be faxed to the prescriber for notification purposes and then attached to the adapted prescription and maintained in the pharmacy records.

Pharmacists can develop their own documentation process as long as they ensure that the method of record-keeping is consistent with College auditing policies and procedures. In other words, all original prescription hard copies must always be retained, including new prescription hard copies generated as part of the adaptation process. All of the required documentation information, listed below, must be captured and retained with the adapted prescription.

Documentation must include:

1. Patient (including PHN number) and Pharmacist (including signature and name of Pharmacy) information
2. Original prescription information (including prescribers name and contact information)
3. A description of the adaptation (including all relevant prescription details)
4. The rationale for the decision to adapt the prescription (including pertinent details of your assessment and patient history along with any instructions to the patient and relevant follow-up plan)
5. Acknowledgment of informed consent
6. The date and name of practitioner(s) notified

When adapting an existing prescription, during the prescription filling process on PharmaNet, you must input your pharmacist identification number in the prescriber field. This will confirm, within the system, that you have adapted the initial prescription and are now responsible for the adapted prescription.

Documentation establishes accountability and responsibility for your professional activities. It is a key component in demonstrating how you exercised your professional judgment and will be the primary tool used to communicate the rationale for your decision. It is also important to remember that every time you document you are creating a health care record. Following are some points to be considered:

- Complete your documentation as soon as possible (preferably immediately) after the activity;
- Use a standard format (preferably the template included with this Guide) for documenting that includes the information outlined above;
- Include all information deemed necessary to support the identification of drug-related problems, recommendations and decisions;
- Use clear, logical and precise language;
- Ensure all documentation is legible and non-erasable; and
- Do not delete, remove or rewrite from any part of the record. If you make an error, cross out the error with a single line and initial it.
- Remember that documentation must always relate back to the original prescription and include, if applicable, reference to any and all adaptations.

## 2.1.7 Notification of Other Health Professionals (Fundamental 7)

***Note:***
*The College of Pharmacists of BC developed this form with input from the College of Physicians and Surgeon of BC.*

At all times, when you adapt a prescription you must notify the **original prescriber**[2]. Notification must take place as soon as reasonably possible, preferably within 24 hours. **You must also notify the patient's most responsible clinician** if you are aware that the original prescriber is not your patient's usual practitioner. Although a requirement of PPP-58, one of the benefits of notification is that it provides enhanced opportunity for collaboration between you, the prescriber and the patient.

As introduced in Fundamental 6 and attached to this Guide as Appendix D is a recommended documentation and notification template form (an electronic version of this form is available on the college website **www.bcpharmcists.org**). The intention of the form is that once complete it can easily be faxed to the prescriber for notification purposes and then attached to the adapted prescription and maintained in the pharmacy records.

[2] For purposes of PPP-58, and included in the Glossary of Terms (Appendix B) the 'original prescriber' refers to the prescriber who authorized the first fill.

Pharmacists can develop their own notification process as long as all of the required notification information, listed below, is included.

Notification must include:

1. Patient (including PHN number) and Pharmacist (including signature and name of Pharmacy) information
2. Original prescription information (including prescribers name and contact information)
3. A description of the adaptation (including all relevant prescription details)
4. The rationale for the decision to adapt the prescription (including pertinent details of your assessment and patient history along with any instructions to the patient and relevant follow-up plan)
5. Acknowledgment of informed consent
6. The date and name of practitioner notified

Experience in other jurisdictions has shown that fax notification is a preferred method for notification of other health professionals. You will need to determine the most suitable notification method for your practice based on what works best for you and the practitioners you usually communicate with. Fax or written notification is the preferred method, however, in certain circumstances, verbal notification may be sufficient, but may lead to extra transcribing work at the receiver's end and introduces a margin of error if the information is transcribed incorrectly.

This Guide also includes, in Appendix E, a sample letter &/or fax directed to prescribers introducing them to PPP-58. You may choose to utilize this document as a means of preparing and informing your prescribers that you will be exercising your authority to adapt prescriptions, starting January 1, 2009, and introduce them to the type of documentation they can expect to see from you.

## 2.2 Activities considered Adapting a Prescription

Three professional activities are considered to be adapting a prescription within the current scope of pharmacy practice in BC:

***Remember:*** *Authorization does not mean obligation.*

1. **Change**: Changing the dose, formulation, or regimen of a prescription to enhance patient outcomes;
2. **Renew**: Renewing a prescription for continuity of care; and
3. **Substitution**: Making a therapeutic drug substitution within the same therapeutic class for a prescription to best suit the needs of the patient.

Exceptions:

- PPP-58 **does not** include adapting a prescription for narcotic, controlled drugs or targeted substances. If a change to a prescription for one of these categories of drugs is warranted, the pharmacist must contact the original prescriber to discuss modifying the original prescription.

- PPP-58 **does not** allow for the adaptation of a prescription if the original prescription has expired. All prescriptions have an expiry of one year from the date the original prescription is written. The exception is oral contraceptives, which have a two year expiry date.

You must use professional judgment to evaluate each situation and have addressed all of the seven fundamentals of adapting a prescription as described in Section 2.1 of this Guide.

## 2.2.1 Changing the Dose, Formulation, or Regimen of a New Prescription

Under PPP-58 you can change the dose, quantity, formulation, or regimen of a drug presented on a prescription without prior authorization from the prescriber if, in your professional judgment, the change will enhance the patient's outcome. This includes adding missing information.

**Changing the dose**

You can change the dose:

- If the strength of the drug prescribed is not commercially available;
- If the patient's age, weight or kidney or liver function requires you to change the dose; or
- If, in your professional judgment, you are satisfied the changed dose would otherwise benefit the patient.

**Changing the formulation or regimen**

You can change the formulation or the regimen of the medication to improve the ability of the patient to effectively take the medication.

**Miscellaneous**

You can also adapt a prescription dose, quantity, formulation or regimen if the information provided is incomplete but you determine what the intended treatment is through consultation with the patient and a review of your records (locally or on PharmaNet).

## 2.2.2 Renewing a Previously Filled Prescription for Continuity of Care

PPP-31 – Emergency Supply for Continuity of Care states pharmacists may exercise professional judgment in in the provision of emergency prescription supplies of a medication (see Appendix C). The intention of PPP-31 is to ensure continuity of care by allowing pharmacists to extend a prescription, for a short period of time, to enable the patient to get back to their prescriber for authorization.

Now under PPP-58 pharmacists, by adhering to *the Seven Fundamentals of Adapting a Prescription*, are able to adapt (renew) the prescription themselves on behalf of the patient without prior authorization from the prescriber for whatever period of time felt appropriate as long as it does not exceed the expiry of the prescription (refer to 2.1.3 of this Guide).

By doing this the pharmacist is utilizing their professional judgment and demonstrating that they have enough competence and information about the patient and their condition to determine that the prescription will maintain or enhance the patient's health outcome. PPP-58 provides pharmacists with the opportunity to practice to the full extent of their knowledge, skills and ability and demonstrate their value as medication experts.

Given the authority available to pharmacists under PPP-58, when faced with a situation requiring or requesting the renewal of a prescription for continuity of care, it is recommended that a pharmacist first consider the opportunity to fully adapt the prescription under PPP-58 before deferring to PPP-31.

It is important to remember that unlike PPP-31, where a pharmacist can provide an emergency supply without access to a prescription (evidence such as; an empty prescription vial, a label or a copy of a prescription receipt will suffice), PPP-58 requires that a pharmacist has the original prescription and that it is current, authentic and has not expired.

***Illustration:***
When a pharmacist is presented with a situation in which a patient has run out of a valid prescription (i.e.; it is current, authentic, appropriate and has not expired) and there are no authorized refills the pharmacist should:

- Step One: Consider adapting the prescription by referring to the first two of the seven fundamentals of PPP-58 and ask:
  a. Do I have 'appropriate knowledge and understanding' of the condition being treated and the drug being prescribed? If yes, then ask,
  b. Do I have 'sufficient information' about the patient's health status to be satisfied that adapting the prescription will maintain or enhance the effectiveness of the drug therapy, patient outcomes and will not put the patient at increased risk? If yes, then the pharmacist should consider adapting the prescription

- Step Two: If on the other hand the pharmacist answers no to either of the questions in step one they should not adapt the prescription but could either try to contact the prescriber to seek approval for a refill or defer to PPP-31 and provide an emergency supply

## 2.2.3 Making a Therapeutic Drug Substitution within the Same Therapeutic Class

You may adapt a prescription by making a therapeutic substitution. You are making a therapeutic substitution when you substitute the drug prescribed with a different drug that is expected to have a similar therapeutic effect, as long as that drug is from within the same therapeutic class. When making a therapeutic drug substitution, you must be satisfied that the dose and the dosing regimen of the new drug you select will have an equivalent therapeutic effect.

You must be satisfied that the following conditions are met when making a therapeutic substitution decision:

1. The decision is in the best interest of the patient by:
    a. Addressing the health needs of that patient,
    b. Maintaining or enhancing the safety or effectiveness of drug therapy,
    c. Not placing the patient at increased risk,
    d. Considering formulary or payer restrictions and other patient-related information, and
    e. Ensuring the drug is approved for the intended indication by Health Canada or strong evidence supports using the drug for the intended indication (e.g., clinical practice guidelines);
2. Your professional independence has been maintained and you avoid conflict of interest. If a decision is based on benefit to the pharmacist or pharmacy rather than the patient, this will be considered professional misconduct;
3. You have considered all relevant information about the patient, the condition and the drug, and you have effectively communicated this to the patient to ensure they agree with the decision; and
4. You take full responsibility for your decision.

# 2.3 Determining When You Are Not Adapting a Prescription

## 2.3.1 When You Call the Original Prescriber to Make a Change

When you identify a drug-related problem during the process of filling a prescription or discussing medication needs with a patient, you may choose to do what you have always done and contact the prescriber to discuss your concerns about the prescription. If, as a result of that conversation, the original prescriber directs you to make a change to the prescription, you may make the change and sign or initial it as you always have. In this case you are not adapting the prescription.

In fact, in any circumstance where you obtain prior authorization from the prescriber to make a change, provide a substitution or refill a prescription you are not adapting a prescription.

## 2.3.2 When You Dispense an Interchangeable Drug Product

Dispensing an interchangeable drug product, including generic substitution, is not adapting a prescription.

## 2.3.3 When an Approved Protocol Exists

If you practice in environments where a specific hospital board – or College Board – approved protocol exists and applies in that situation, you may be required to make changes to the prescription. In these circumstances, where you are simply applying the policy or treatment protocol (e.g. automatic substitution), and you are not using your professional judgment, you are not adapting a prescription.

## 2.3.4 When You Are Continuing Therapy by Advancing a Few Doses

As described in PPP-31 – Emergency Supply for Continuity of Care (see Appendix C), you are already authorized to assist patients in maintaining continuity of their drug therapy by advancing them a few doses or a few days supply if they run out of medication and an appointment with the prescribing physician is imminent. Advance supplies are not technically prescription renewals and do not fall under PPP-58, but you must evaluate the patient's need for the medication and be satisfied that providing any additional doses will not cause or worsen a drug-related problem for the patient.

# 3.0 Implementing PPP-58 in Your Practice

In addition to information posted on the College's website (www.bcpharmacists.org) and/or communicated in ongoing College publications such as ReadLinks, there are a number of resources available to support you in the effective implementation of PPP-58 in your practice.

## 3.1 Support is Available

### 3.1.1 Practical Resources

The following resources are provided in the appendix of this Guide:

- Appendix B – Glossary of Terms
- Appendix D – Documentation and Notification Template (an electronic version is also available on the College website - www.bcpharmacists.org)
- Appendix E – Sample letter/fax introducing PPP-58 to your prescribers
- Appendix F – Practical Examples

### 3.1.2 Need more support?

If you still have questions or concerns and want to implement the policy in your practice, please contact Practice Support through the College office at 604-733-2440 or by email at practicesupport@bcpharmacists.org.

# 4.0 Other Considerations

## 4.1 Liability and Insurance

Adapting a prescription is one activity within a pharmacist's current scope of practice that expands the potential for liability. Although a pharmacist is not obligated to adapt a prescription, should they choose to adapt a prescription, they are required to possess personal professional liability insurance – minimum $2 million.

## 4.2 Consequences for Failure to Follow PPP-58

Any pharmacist who adapts a prescription contrary to the requirements of PPP-58 will be forwarded to the Inquiry Committee process as per current College procedures.

All pharmacists are expected to abide by all aspects of professional practice as described in the College's Framework of Professional Practice, federal legislation (*the Food and Drug Act (FDA) and Regulations and the Controlled Drug and Substances Act*), provincial legislation (*the HPA, PODSA, and PSA along with related regulations and bylaws*), and the College's *Professional Practice Policies*.

## 4.3 Conflict of Interest

The implementation of PPP-58 may put pharmacists in a position of real or perceived conflict of interest with their patients. The adaptation of a prescription may lead to increased revenue thereby enhancing a pharmacist's financial interests.

Pharmacists must consider first and foremost the interest and well-being of their patients. Prescriptions must not be adapted unless it is in the best interest of a patient to do so.

Any indication that the decision was based on benefit to the pharmacist or pharmacy, rather than the patient, will be considered professional misconduct and reviewed through the Inquiry Committee process.

## 4.4 Conclusion

These are indeed exciting times for the profession of pharmacy in British Columbia as pharmacist's involvement in medication management activities continues to expand. PPP-58 creates the framework to guide pharmacists in the safe and effective adaptation of prescriptions allowing you to maximize your full educational and professional competencies to optimize therapeutic outcomes for your patients. In addition this policy provides a structure to the process of using professional judgment in practice and establishes a foundation for the further expansion of pharmacy practice in the future.
Take time to consider your competencies, your work environment, and your current and potential relationships with patients and other health professionals. And the next time you have the opportunity to adapt a prescription – use the seven fundamentals to help determine if it is the 'right' thing to do for your patient.

# 5.0 Declaration Form

## Medication Management
## (Adapting a Prescription)
## Professional Practice Policy #58 (PPP-58)

### Declaration of completion and understanding

I,_____ a registrant on the Register of Pharmacists of the College of Pharmacists of British Columbia, declare that I have thoroughly read and understood the PPP-58 Orientation Guide Medication Management (Adapting a Prescription).

I also declare and understand that although it is not mandatory that I adapt a prescription, should I choose to adapt a prescription in addition to having read and understood the Orientation Guide I must:

- Adhere to all of the seven fundamentals for adapting a prescription as outlined in PPP-58 and possess personal professional liability insurance (minimum $2 million).

Signature:_____ Date:_____

***Note:***
*You should retain this signed Declaration Form in your personal records.*

# Appendix A: Professional Practice Policy #58 Protocol for Medication Management (Adapting a Prescription)

**POLICY STATEMENT(S):**

A pharmacist may dispense a drug contrary to the terms of a prescription (adapt a prescription) if the action is intended to optimize the therapeutic outcome of treatment with the prescribed drug and meets **all** of the following elements of a protocol to adapt a prescription:

1. **Individual competence**
   a. Pharmacist has appropriate knowledge and understanding of the condition and the drug being dispensed in order to adapt the prescription.

2. **Appropriate information**
   a. Pharmacist has sufficient information about the specific client's health status to ensure that adapting the prescription will maintain or enhance the effectiveness of the drug therapy and will not put the client at increased risk.

3. **Prescription**
   a. Pharmacist has a prescription that is current, authentic, and appropriate.

4. **Appropriateness**
   a. Pharmacist determines whether adapting the prescription is appropriate in the circumstances.

5. **Informed consent**
   a. Pharmacist must obtain the informed consent of the client or client's representative before undertaking any adapting activity.

6. **Documentation**
   a. Pharmacist must document in the client's record any adaptation of the prescription, the rationale for the decision, and any appropriate follow-up plan.

7. **Notification of other health professionals**
   a. Pharmacist must notify the original prescriber (and the general practitioner if appropriate) as soon as reasonably possible (preferably within 24 hours of dispensing) and this must be recorded in the client's record or directly on the prescription hard copy.

**Note: PPP-58 is not a stand-alone document and must be read with the Orientation Manual and the Amendment to the Orientation Manual. For a pharmacist to use PPP-58 they will be required to sign the PPP-58 Declaration Form.**

BACKGROUND:

**Protocol for medication management (adapting a prescription)**

This professional practice policy enables pharmacists to maximize their full educational and professional competencies by providing authorization to adapt existing prescriptions. This policy is not mandatory and the decision whether to adapt a prescription is at the discretion of the individual pharmacist.

To guide decisions with respect to adapting a prescription, where a specific hospital board - or College of Pharmacists of BC - Board approved protocol does not exist, the pharmacist must refer to all applicable legislation and standards. This includes, but is not limited to, the *Health Professions Act, Pharmacy Operations and Drug Scheduling Act*, the Regulation and Bylaws of the College of Pharmacists of BC made pursuant to these Acts, the *Health Care (Consent) and Care Facility (Admission) Act*, the Framework of Professional Practice (FPP), the Code of Ethics and Professional Practice Policies. This specific policy (PPP-58) does not apply to controlled drug substances and cancer chemotherapy agents.

The FPP is the standards of pharmacy practice in British Columbia. In adapting a prescription the pharmacist must follow the FPP Role 1 *Provide pharmaceutical care.* Role 1 elements include:

- Function A – Assess the client's health status and needs
- Function B – Develop a care plan with the client
- Function C – Support the client to implement the care plan
- Function D – Support and monitor the client's progress with the care plan
- Function E – Document findings, follow-ups recommendations, information provided and client's outcomes

**Benefits of professional practice policy**

The benefits to clients are to:

a) Optimize drug therapy leading to improved client health outcomes
   1) Better therapeutic responses.
   2) Reduced drug errors.
   3) Fewer adverse drug reactions/interactions.

b) Have an effective and efficient health care system
   1) Minimize delays in initiating and changing drug therapy.
   2) Make the best use of human resources in the health care system.

c) Expand the opportunities to identify people with significant risk factors.

d) Encourage collaboration among health care providers.

First approved: 21 Sep 2007 **PPP-58**
Revised:
Reaffirmed: 27 Mar 2009

# Appendix B: Glossary of Terms

For the purposes of Professional Practice Policy #58 *Protocol for Medication Management – Adapting a Prescription* – the terms below have the following meaning:

| | |
|---|---|
| **Adaptation** | • term used to describe the pharmacists' authority under PPP-58 to adapt an existing prescription when, in their professional judgment, the action is intended to optimize the therapeutic outcome of treatment |
| **Conflict of Interest** | • at all times pharmacists must maintain professional independence and adaptation decisions must first and foremost be made in the best interest of the patient with the intention of optimizing the therapeutic outcome of treatment<br>• any indication that a decision is based on benefit to the pharmacist or pharmacy, rather than the patient, will be considered professional misconduct |
| **Continuity of Care** (for medication management) | • the assurance of uninterrupted drug therapy for the best health outcome of the patient |
| **Liability** | • pharmacist assumes legal responsibility for the adapted prescription and as a mandatory condition of their authority to adapt possesses personal professional liability insurance (minimum coverage $2 million) |
| **Original Prescriber** | • refers to the prescriber who authorized the first fill |
| **Prescription Expiry** | • all prescriptions have an expiry of one year from the date the prescription is written (the exception is oral contraceptives, which is two years)<br>• a pharmacist may not adapt a prescription if the original prescription has expired<br>• a pharmacist may not adapt components of a prescription beyond its' expiry date (ie: quantity cannot exceed the time remaining) |

| | |
|---|---|
| **Refill** | • term used by the prescriber to indicate their authorization to provide a refill(s) to the original prescription |
| **Renew** | • term used to describe the extension of a prescription (not beyond its' expiry date) by a pharmacist; the act of renewing a prescription constitutes adaptation and thereby transfers liability to the adaptor |
| **Responsible Clinician** | • most responsible physician/provider who manages the patient's care on an ongoing basis (ie: family physician, nurse practitioner) |
| **Therapeutic Drug Substitution** | • substitution of the prescribed drug with a different drug, from the same therapeutic class, that is expected to have a similar therapeutic effect<br>• pharmacist must be satisfied that the dose and dosing regimen of the new drug will have an equivalent therapeutic effect |

# Appendix C: Other Relevant Professional Practice Policies

## CPBC Professional Practice Policy PPP-31 – Emergency Supply for Continuity of Care

See the most up-to-date Professional Practice Policy – 31 Emergency Supply for Continuity of Care on the CPBC website: http://library.bcpharmacists.org/6_Resources/6-2_PPP/5003-PGP-PPP31.pdf

# Appendix C: Prescription Adaptation Documentation and Notification Template

(an electronic version of this template is available on the College website www.bcpharmacists.org)

## Patient Information

Name: _____

PHN: _____

## Prescriber Information

Name: _____

Phone: _____

Fax: _____

## Pharmacist Information

Name: _____

Pharmacy: _____

_____

Phone: _____

Fax: _____

Signature: _____

## Original Prescription Information

Date of Prescription: _____

Prescription Details: _____

_____

## Adaptation Information

Date of Adaptation: _____

Adaptation Details: _____

_____

## Rationale for Adaptation (including instructions to patient and follow-up plan)

Rationale

_____

_____

_____

_____

_____

_____

_____

Instructions to Patient

_____

Follow-up Plan

_____

_____

## Informed Consent

The patient and/or their representative (name: _____) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent. ☐

## Notification Information

Date of Notification: _____ Name of Practitioner(s) Notified: _____

Method of Notification (fax preferred): _____

☐ Fax # _____ ☐ Phone # _____ ☐ Other _____

The information contained in this fax communication is confidential and is intended only for the use of the recipient named above If the reader of this fax memo is not the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this fax memo is strictly prohibited. If you have received this fax memo in error, please destroy the memo and notify the sender.

# Appendix E: Sample letter/fax introducing PPP-58

[drugstore letterhead]

Date

Doctor name
Address

Re: Introduction to Pharmacists enhanced scope of practice

Dear Dr. _____,

The purpose of this letter is to ensure that you are aware of some recent changes that have evolved the scope of practice for pharmacists in BC. Earlier this year the government introduced Bill 25 which, specific to the profession of pharmacy, formalized pharmacists' authority to 'renew' existing prescriptions.

In conjunction with this the College of Pharmacists of BC (CPBC) has introduced *Professional Practice Policy #58 (PPP-58) Medication Management – Adapting a Prescription* which provides the framework to guide pharmacists in the safe and effective adaptation, including renewal, of existing prescriptions.

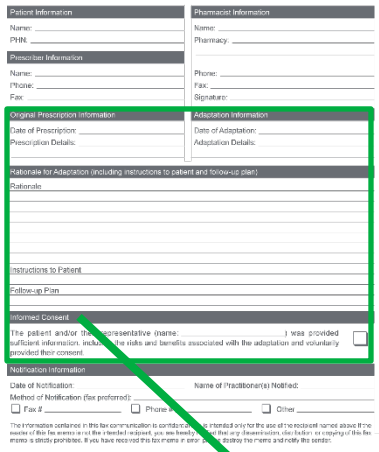
Although it is not mandatory that a pharmacist adapt a prescription, it is mandatory that should a pharmacist choose to adapt a prescription they adhere to the guidelines laid out in the PPP-58 Orientation Guide, which includes notification to the original prescriber (a copy of the PPP-58 Orientation Guide is available on the CPBC website www.bcpharmacists.org).

This means that from time to time you may receive a fax notification (sample attached) from a member of our pharmacy team to inform you of a prescription adaptation that has occurred. Pharmacists' authorization to implement this policy and thereby adapt prescriptions is effective January 1, 2009.

We value our professional relationship with you. Please feel free to contact (insert: pharmacy manager name) with any questions or comments you may have.

Sincerely,

# Appendix F: Practical Examples


Patient Information
Name:
PHN:
Pharmacist Information
Name:
Pharmacy:
Prescriber Information
Name:
Phone:
Fax:
Phone:
Fax:
Signature:
Original Prescription Information
Date of Prescription:
Prescription Details:
Adaptation Information
Date of Adaptation:
Adaptation Details:
Rationale for Adaptation (including instructions to patient and follow-up plan)
Rationale
Instructions to Patient
Follow-up Plan
Informed Consent
The patient and/or their representative (name: ) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent.
Notification Information
Date of Notification:
Name of Practitioner(s) Notified:
Method of Notification (fax preferred):
Fax #
Phone #
Other

***Example 1 – Changing the Dose:***

You receive a new prescription for alendronate 10mg once weekly for an elderly female patient. The PharmaNet record indicates the patient was previously taking alendronate 10mg once daily for the past year. You have a discussion with the patient and determine the following:

- The patient has been having difficulty with compliance of the once daily regimen.
- The physician discussed with her that she was changing the prescription to the once weekly formulation to make it easier for her to remember her dose.

**Original Prescription Information**

Date of Prescription: January 15, 2009

Prescription Details: Alendronate 10mg once weekly x 6 months

**Adaptation Information**

Date of Adaptation: January 16, 2009

Adaptation Details: changed Alendronate 10mg once weekly to 70mg once weekly x 3 months with 1 refill

**Rationale for Adaptation (including instructions to patient and follow-up plan)**

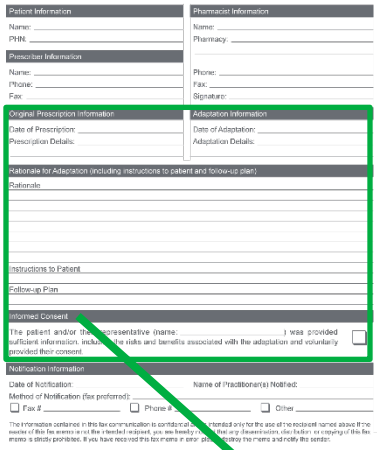
Rationale
- usual dose alendronate 10mg once daily or 70 mg once weekly
– product monograph indicates no dosage adjustment necessary for the elderly or for patients with mild to moderate renal insufficiency
– confirmed with patient that no impaired renal function
– patient confirmed doctor discussed change to weekly formulation for compliance reasons

Instructions to Patient: Instructed the patient to take 1 tablet once/week on the same day each week with plenty of water.

Follow-up Plan: contact her physician if any GI upset or unusual symptoms.

**Informed Consent**

The patient and/or their representative (name: _____) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent. ✓


Patient Information
Name:
PHN:
Prescriber Information
Name:
Phone:
Fax:
Pharmacist Information
Name:
Pharmacy:
Phone:
Fax:
Signature:
Original Prescription Information
Date of Prescription:
Prescription Details:
Adaptation Information
Date of Adaptation:
Adaptation Details:
Rationale for Adaptation (including instructions to patient and follow-up plan):
Rationale
Instructions to Patient
Follow-up Plan
Informed Consent
The patient and/or their representative (name: ) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent.
Notification Information
Date of Notification:
Name of Practitioner(s) Notified:
Method of Notification (fax preferred):
Fax #
Phone #
Other

***Example 2 – Incomplete Information:***

You receive a new prescription for an adult female patient for Betaderm 0.1% Cream; Apply TID. The patient indicated that her skin is really dry and scaly and that she would prefer a product with more of a moisturizing effect.

You have a discussion with the patient and determine the following:

- She had used Betaderm 0.1% Cream for one month and was getting results with the cream.
- You visually confirm that her skin is dry and scaly.

**Original Prescription Information**

Date of Prescription: January 15, 2009

Prescription Details: Betaderm 0.1% Cream; Apply TID

**Adaptation Information**

Date of Adaptation: January 15, 2009

Adaptation Details: changed Betaderm 0.1% Cream to etaderm 0.1% Ointment; Apply TID

**Rationale for Adaptation (including instructions to patient and follow-up plan)**

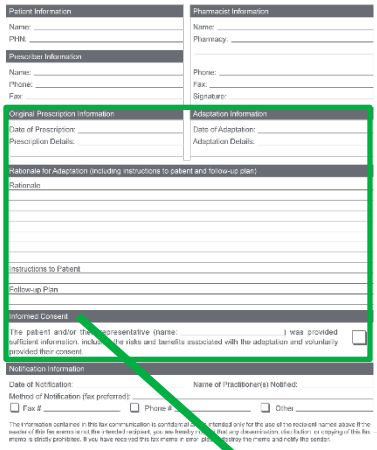
Rationale
- reviewed PharmaNet profile which indicates patient has been using Betaderm 0.1% Cream for one month
- patient indicated that the cream is helping her condition except that the affected area on her skin is dry and scaly
- change in formulation will still provide the same result with a more emollient effect

Instructions to Patient: Apply sparingly to affected area three times a day. If skin condition worsens, contact your doctor.

Follow-up Plan: See your doctor at your regular interval in one month.

**Informed Consent**

The patient and/or their representative (name: _____) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent. ☑




***Example 3 – Incomplete Information:***

You receive a new prescription for Ramipril – take one tablet daily. No strength is indicated on the prescription. The PharmaNet record indicates the patient has been getting the 10mg strength for the past 6 months.

You have a discussion with the patient and determine the following:

- The patient confirms that the prescription was intended for the same dose (10mg) as before and that the medication is being used for blood pressure control.

**Original Prescription Information**

Date of Prescription: January 4, 2009

Prescription Details: Ramipril
take 1 tablet daily, Mitte 90, no refills

**Adaptation Information**

Date of Adaptation: January 4, 2009

Adaptation Details: Ramipril 10mg
once daily Mitte 90, no refills.

**Rationale for Adaptation (including instructions to patient and follow-up plan)**

Rationale - PharmaNet record indicates patient has been on Ramipril 10mg once daily for 6 months
– Patient confirmed that his regular doctor is on holiday and the locum prescribed his regular medication (he was not expecting any changes)
– Patient confirms his blood pressure is on target (130/75)

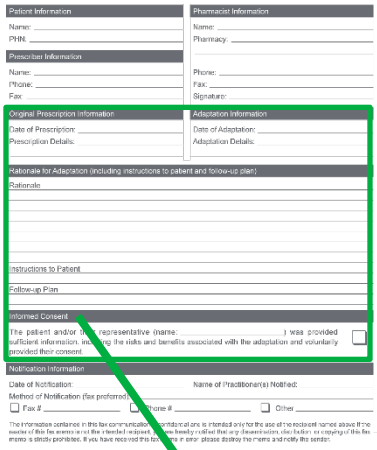
Instructions to Patient Take one Ramipril 10mg daily for blood pressure control.

Follow-up Plan Instructed to continue to check blood pressure regularly.

**Informed Consent**

The patient and/or their representative (name: _____) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent. ✓

**Notification Information**


Patient Information
Name:
PHN:
Prescriber Information
Name:
Phone:
Fax:
Pharmacist Information
Name:
Pharmacy:
Phone:
Fax:
Signature:
Original Prescription Information
Date of Prescription:
Prescription Details:
Adaptation Information
Date of Adaptation:
Adaptation Details:
Rationale for Adaptation (including instructions to patient and follow-up plan):
Rationale
Instructions to Patient
Follow-up Plan
Informed Consent
The patient and/or their representative (name: ) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent.
Notification Information
Date of Notification:
Name of Practitioner(s) Notified:
Method of Notification (fax preferred):
Fax #
Phone #
Other

***Example 4 – Renew a Prescription:***

A long standing patient of your pharmacy takes a thyroid supplement and diuretic every day. She comes to the pharmacy and requests a renewal of her prescriptions. You notice in your records that 3 months ago she received the same prescriptions but no refills were authorized. You review the PharmaNet record and determine she has been on the same dose of the same medications for 2 years.

You have a discussion with the patient and determine the following:

- She confirms that her TSH levels are being regularly monitored as well as her blood pressure.
- She confirms that she sees her physician every 6 months and that she is due for her follow-up in 3 months.

**Original Prescription Information**

Date of Prescription: October 4, 2008

Prescription Details: Hydrochlorthiazide 50mg OD
Synthroid 100mcg 1 OD, no refills

**Adaptation Information**

Date of Adaptation: January 16, 2009

Adaptation Details: Hydrochlorthiazide 50mg OD
Synthroid 100mcg 1 OD, renewed x 3mth supply

**Rationale for Adaptation (including instructions to patient and follow-up plan)**

Rationale
- PharmaNet record indicates patient has been on same dosage of both medications for 2 years
- Patient confirmed TSH and blood pressure are regularly monitored
- Patient confirmed she has follow-up with physician every 6 months and is seeing doctor in 3 months
- Most recent original prescription was 3 months ago (Oct. 4/08) therefore prescription is still a valid prescription

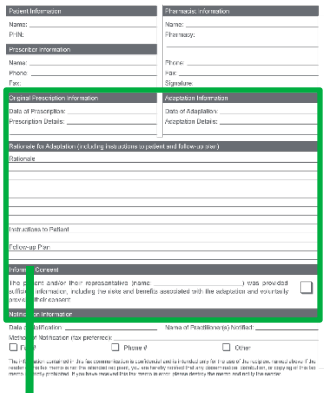
Instructions to Patient: Take 1 tablet of each medication daily, in the morning, on an empty stomach and continue monitoring your blood pressure regularly.

Follow-up Plan: Return for follow-up with your physician in 3 months as scheduled.

**Informed Consent**

The patient and/or their representative (name: _____) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent. ☑

Notification Information



***Note:***
*In the 'Notification' section of the form you would indicate that both physicians were notified of this adaptation.*

***Example 5 – Therapeutic Substitution:***

Patient arrives at your pharmacy with a prescription for Prevacid 30mg once daily x 3 months for GERD. You notice the prescription is from the local walk-in clinic physician. You check the PharmaNet profile and determine that the patient has previously been on Rabeprazole 20mg once daily x 6 months and has had Pharmacare coverage through special authorization for the Rabeprazole. You process the prescription for Prevacid 30mg once daily and notice that the patient does not have special authorization for the Prevacid.

You have a discussion with the patient and determine the following:

- The patient receives social assistance and cannot afford the prescription cost for the Prevacid.
- The patient had run out of the Rabeprazole prescription last week and couldn't get to her regular doctor, so went to the walk-in clinic.
- The patient wanted a renewal of the prescription she was previously on for her heartburn, but she couldn't remember the name of it when she went to the clinic and she didn't have her empty vial with her.
- Her previous prescription had been controlling her symptoms very well and she had not had any side effects.
- Patient is anxious to get her Rabeprazole medication as her symptoms have increased over the past week since she has been out of her medication.

**Original Prescription Information**

Date of Prescription: January 15, 2009
Prescription Details: Prevacid 30mg OD x 3 months

**Adaptation Information**

Date of Adaptation: January 16, 2009
Adaptation Details: changed to Rabeprazole 20mg OD x 3 months

**Rationale for Adaptation (including instructions to patient and follow-up plan)**

Rationale
- Patient previously on Rabeprazole 20mg OD over last 6 months
– Patient has Pharmacare special authority coverage for Rabeprazole
- Patient cannot afford cost of Prevacid (no SA for Prevacid)
– Product monograph for GERD Rabeprazole 20mg OD
– Patient confirms she has had good control of symptoms and no side effects on Rabeprazole 20mg
- Patient confirmed she had run out of medication 1 week ago and needed refill ASAP but couldn't remember the name of her Rx when she saw the walk-in clinic physician

Instructions to Patient: Take one tablet daily ½ hour before food. Try non-drug measures to help control symptoms. Elevate the head of the bed, eat smaller more frequent meals. Avoid spicy food and alcohol.

Follow-up Plan: Do a diary of food intake to see what foods make you feel worse or better. Review in 1 month.

**Informed Consent**

The patient and/or their representative (name: _____) was provided sufficient information, including the risks and benefits associated with the adaptation and voluntarily provided their consent. ☑

# Patient Inquiries About Renewals

*Over the coming months the public will become more aware of the expanded scope pharmacists have been given which will likely lead to a little confusion and a lot of questions.*

*The scenario below is an example of a potential conversation between a patient and pharmacist and is intended to help guide you in answering some of the questions which will likely arise.*

**Patient asks...**
"I heard somewhere that you can now renew my prescription – is that true?"

**Pharmacist responds…**
"Maybe. It is true that pharmacists now have the authority to renew prescriptions however each situation has to be considered independently. What it really depends on is how well I know your condition and your drug therapy. Let's take a look..."

**Patient asks...**
"How can I trust that you know what you are doing?"

**Pharmacist responds...**
"Pharmacists really are medication experts and we have more training in drug therapy than almost any other health care provider. But more importantly, I won't renew a prescription unless I'm confident that it will optimize your treatment and you are comfortable with the decision. Once I renew the prescription, I take responsibility for it, so you can be sure that I will be confident in my decision."

**Patient asks…**
"What about my doctor? Is he going to be upset by this? Does this mean I never have to go back to see him?"

**Pharmacist responds...**
"My renewal of your prescription in no way replaces the role your physician plays. First of all, as part of the process of renewing your prescription I will be notifying your doctor of what we have done and why. In the unlikely event that your doctor has any concerns about this they will contact one of us. Secondly, I cannot renew your prescription beyond the life of the prescription, which is one year, so at some point I will be referring you back to your doctor."

College of Pharmacists of British Columbia

# 6. Amendments to Professional Practice Policy-58 Medication Management (Adapting a Prescription)

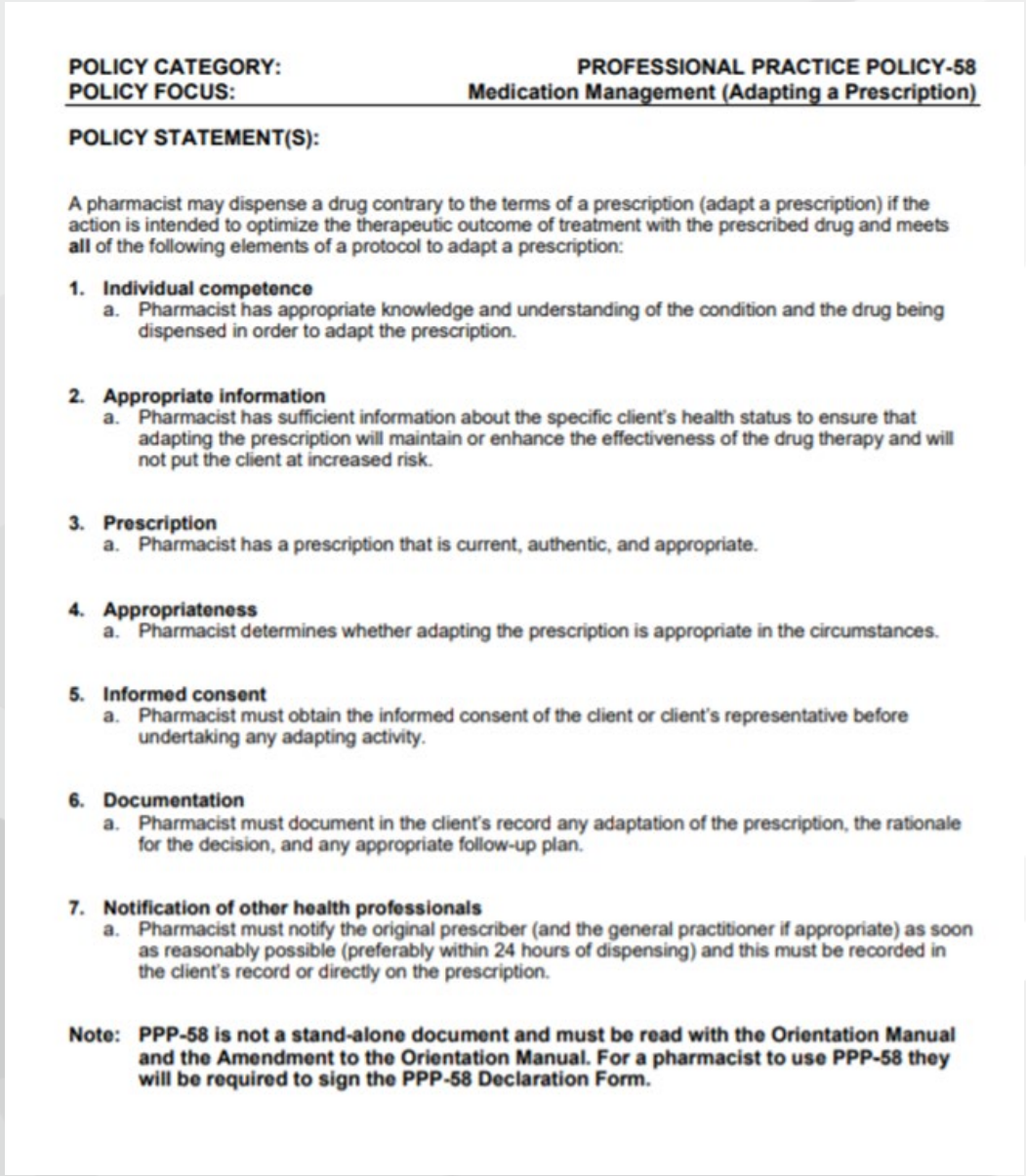
**Anu Sharma**

Acting Director of Policy and Legislation

College of Pharmacists of British Columbia

# Background

- Developed in 2008, *Professional Practice Policy 58* (PPP-58) *Medication Management (Adapting a Prescription)* currently permits pharmacists to **dispense a drug contrary to the terms of a prescription** if the action is intended to optimize the therapeutic outcome of treatment with the prescribed drug and meets all elements of the protocol to adapt a prescription.



**POLICY CATEGORY:** **PROFESSIONAL PRACTICE POLICY-58**
**POLICY FOCUS:** **Medication Management (Adapting a Prescription)**

**POLICY STATEMENT(S):**

A pharmacist may dispense a drug contrary to the terms of a prescription (adapt a prescription) if the action is intended to optimize the therapeutic outcome of treatment with the prescribed drug and meets **all** of the following elements of a protocol to adapt a prescription:

1. **Individual competence**
   a. Pharmacist has appropriate knowledge and understanding of the condition and the drug being dispensed in order to adapt the prescription.

2. **Appropriate information**
   a. Pharmacist has sufficient information about the specific client's health status to ensure that adapting the prescription will maintain or enhance the effectiveness of the drug therapy and will not put the client at increased risk.

3. **Prescription**
   a. Pharmacist has a prescription that is current, authentic, and appropriate.

4. **Appropriateness**
   a. Pharmacist determines whether adapting the prescription is appropriate in the circumstances.

5. **Informed consent**
   a. Pharmacist must obtain the informed consent of the client or client's representative before undertaking any adapting activity.

6. **Documentation**
   a. Pharmacist must document in the client's record any adaptation of the prescription, the rationale for the decision, and any appropriate follow-up plan.

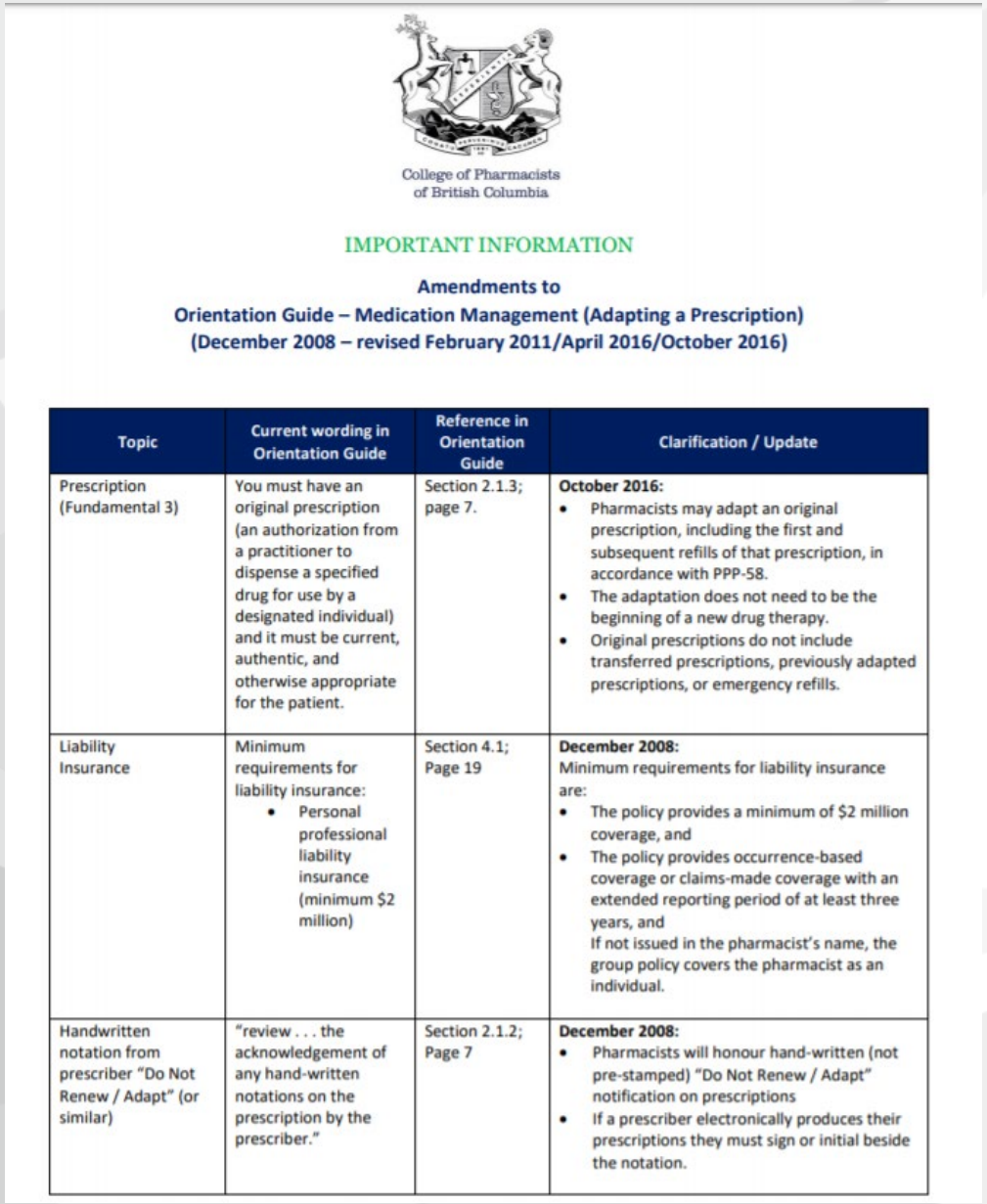
7. **Notification of other health professionals**
   a. Pharmacist must notify the original prescriber (and the general practitioner if appropriate) as soon as reasonably possible (preferably within 24 hours of dispensing) and this must be recorded in the client's record or directly on the prescription.

**Note: PPP-58 is not a stand-alone document and must be read with the Orientation Manual and the Amendment to the Orientation Manual. For a pharmacist to use PPP-58 they will be required to sign the PPP-58 Declaration Form.**

College of Pharmacists of British Columbia

# Background, continued

- PPP-58 must be read with the Orientation Manual, and the Amendment to the Orientation Manual.



College of Pharmacists of British Columbia

IMPORTANT INFORMATION

**Amendments to**
**Orientation Guide – Medication Management (Adapting a Prescription)**
**(December 2008 – revised February 2011/April 2016/October 2016)**

| Topic | Current wording in Orientation Guide | Reference in Orientation Guide | Clarification / Update |
|---|---|---|---|
| Prescription (Fundamental 3) | You must have an original prescription (an authorization from a practitioner to dispense a specified drug for use by a designated individual) and it must be current, authentic, and otherwise appropriate for the patient. | Section 2.1.3; page 7. | **October 2016:**<br>• Pharmacists may adapt an original prescription, including the first and subsequent refills of that prescription, in accordance with PPP-58.<br>• The adaptation does not need to be the beginning of a new drug therapy.<br>• Original prescriptions do not include transferred prescriptions, previously adapted prescriptions, or emergency refills. |
| Liability Insurance | Minimum requirements for liability insurance:<br>• Personal professional liability insurance (minimum $2 million) | Section 4.1; Page 19 | **December 2008:**<br>Minimum requirements for liability insurance are:<br>• The policy provides a minimum of $2 million coverage, and<br>• The policy provides occurrence-based coverage or claims-made coverage with an extended reporting period of at least three years, and<br>If not issued in the pharmacist's name, the group policy covers the pharmacist as an individual. |
| Handwritten notation from prescriber "Do Not Renew / Adapt" (or similar) | "review . . . the acknowledgement of any hand-written notations on the prescription by the prescriber." | Section 2.1.2; Page 7 | **December 2008:**<br>• Pharmacists will honour hand-written (not pre-stamped) "Do Not Renew / Adapt" notification on prescriptions<br>• If a prescriber electronically produces their prescriptions they must sign or initial beside the notation. |

College of Pharmacists of British Columbia

# Background – Scope of PPP-58

Three professional activities are considered to be adapting a prescription within the current scope of pharmacy practice in British Columbia:

1. Change: changing the dose, formulation, or regiment of a prescription to enhance patient outcomes;
2. Renew: renewing a prescription for continuity of care; and
3. Substitution: making a therapeutic drug substitution within the same therapeutic class for a prescription to best suit the needs of the patient.

College of Pharmacists of British Columbia

# PPP-58 in the Context of COVID-19

- A fulsome review of PPP-58 is planned as part of the Policy and Legislation Department's five year operational plan for policy and legislative changes.
- However, in light of the COVID-19 public health emergency, the Board had expressed interest in reviewing the following aspects of PPP-58 to support patient care during the pandemic:
  - prescriber notification requirements of renewals;
  - adaptation of transferred prescriptions; and
  - the limitation on drug categories for therapeutic substitution.

College of Pharmacists of British Columbia

# Policy Development Steps Followed to Determine Recommended Changes to PPP-58

- In reviewing the specific aspects of PPP-58 as requested by the Board, staff conducted a jurisdictional scan of similar requirements in the policies of other Pharmacy Regulatory Authorities (PRAs) and particular attention was paid to any amendments made due to COVID-19.
- Feedback was requested from internal and external stakeholders where possible, though a fulsome consultation was not possible due to the expedited timeline.
- Based on the jurisdiction scan and feedback received, staff developed options for the Board's consideration, including pros and cons for each option.
- Staff also proposed recommended options for the Board's consideration.

College of Pharmacists of British Columbia

# Prescriber Notification Requirements

College of Pharmacists of British Columbia

# Prescriber Notification Requirements

In accordance with PPP-58, a pharmacist must notify the original prescriber (and the general practitioner, if appropriate) as soon as reasonably possible when adapting a prescription. Notification must include:

1. Patient (including PHN number) and Pharmacist (including signature and name of Pharmacy) information
2. Original prescription information (including prescribers name and contact information)
3. A description of the adaptation (including all relevant prescription details)
4. The rationale for the decision to adapt the prescription (including pertinent details of your assessment and patient history along with any instructions to the patient and relevant follow-up plan)
5. Acknowledgment of informed consent
6. The date and name of practitioner notified

College of Pharmacists of British Columbia

# COVID-19 Context

- At the outset of the COVID-19 pandemic, a joint statement was issued by the Minister of Health and BC's provincial health officer advising pharmacies to provide patients with a prescription refill or an emergency supply of their medications, if needed.
  - This recommendation was expected to result in an increase in the use of PPP-58 to provide medication renewals, and an increase in renewal notifications being sent to prescribers by pharmacists.
- In the recent weeks, BC has experienced a reduction in the number of confirmed new cases of COVID-19.
- There has also been a steady decline in cases currently in hospital and Intensive Care units since mid-April.

College of Pharmacists of British Columbia

# Jurisdictional Scan

| Policy Component | BC | AB | SK | MB | ON | NB | NS | PEI | N&L | YK |
|---|---|---|---|---|---|---|---|---|---|---|
| **Prescriber Notification** | | | | | | | | | | |
| The pharmacist must notify the original prescriber when **renewing a prescription.** | ✓ | ✓[i] * | ✓ * | ✓ | ✓ | ✓[ii] | ✓ * | ✓ | ✓ | ✓* |

**Note:** An asterisk (*) indicates the removal of this requirement during the coronavirus pandemic.

---

[i] A pharmacist who renews a prescription must also notify a pharmacist at the original dispensing pharmacy and document that notification.

[li] A pharmacist who adapts an existing prescription must inform the original prescriber (where such exists) when the change to the prescription the pharmacist is adapting is clinically significant.

College of Pharmacists of British Columbia

# Jurisdiction Scan Summary

- The majority of PRAs require the pharmacist to notify the original prescriber when renewing a prescription.
- In light of COVID-19, four jurisdictions removed the requirement for the pharmacist to notify the original prescriber when renewing a prescription.
  - All of these changes were made in early April.

College of Pharmacists of British Columbia

# Consultation/Feedback

- Discussion occurred with the College of Physicians and Surgeons of BC and the Doctors of BC to determine potential impacts that may result from the removal of the prescriber notification requirement during the COVID-19 pandemic.
  - Generally, physicians benefit from the current notification requirements and any perceived administrative burden of receiving a notification is largely outweighed by the benefits of staying informed.
  - Notification for prescription renewal supports continuity of care.
  - Many physicians have seen a drop in the number of patient visits due to physical distancing measures.

College of Pharmacists of British Columbia

# Options for the Board's Consideration

- Option 1: Maintain the Notification Requirement for Renewals.

- Option 2: Remove the Notification Requirement for Renewals for the duration of the COVID-19 Public Health Emergency in BC.

College of Pharmacists of British Columbia

# Staff Recommendation

- Staff recommend that the Board proceed with Option 1, which is to maintain the current notification requirement within PPP-58.
  - ✓ Maintains an informed circle of care and provides enhanced opportunity for collaboration amongst health professionals.
  - ✓ Aligns with feedback received from the College of Physicians and Surgeons of BC and the Doctors of BC.
  - ✓ Aligns with notification requirements of PPP-31.
  - ✓ Although public health orders and physical distancing measures remain in place, BC has experienced a reduction in the number of confirmed cases of COVID-19 in the province and it is understood from discussion with prescribers that the notification is manageable and appreciated.

College of Pharmacists of British Columbia

# Adaptation of Transferred Prescriptions

College of Pharmacists of British Columbia

# Original Prescription Requirements

- In accordance with PPP-58, in order to adapt a prescription a pharmacist must have a prescription that is current, authentic, and appropriate.
  - A pharmacist must have the original prescription (an authorization from a practitioner to dispense a specified drug for use by a designated individual).
  - A pharmacist may not adapt if the original prescription has expired.
  - Original prescriptions do not include transferred prescriptions, previously adapted prescriptions, or emergency refills.

College of Pharmacists of British Columbia

# COVID-19 Context

- Although adapting a transferred prescription is currently not permitted under PPP-58 requirements, during the COVID-19 public health emergency it may be beneficial for a pharmacist to adapt transferred prescriptions due to physical distancing measures and travel restrictions in place.

College of Pharmacists of British Columbia

# Jurisdictional Scan

| Policy Component | BC | AB | SK | MB | ON | NB | NS | PEI | N&L | YK |
|---|---|---|---|---|---|---|---|---|---|---|
| **Original Prescription** | | | | | | | | | | |
| The pharmacist must have the original prescription when adapting[i] a prescription. | ✓ | ✓[ii] | ✓[iii] | ✓ | ✗ * | ✗ | ✗ | ✗[iv] * | ✗ | ✓[v] |

**Note:** An asterisk (*) indicates the removal of this requirement during the coronavirus pandemic.

[i] Each PRA defines adaptation slightly differently

[ii] A pharmacist who does not have an original prescription may **renew** a prescription to ensure continuity of care IF they are satisfied that:

a) the patient has presented evidence of current ongoing therapy based on a prescription (such as an empty prescription vial),
b) there is immediate need for drug therapy, and
c) it is not reasonably possible for the patient to attend the original dispensing pharmacy or to have the prescription transferred from the original dispensing pharmacy.

[iii] When **renewing** a prescription previously initiated by a practitioner, a pharmacist may do so without the original prescription if the pharmacist confirms in the Pharmaceutical Information Program (PIP) that the medication is safe (i.e. the condition is chronic and stabilized) to renew. If the patient is from out of province and the pharmacist is unable to check the PIP, then they must take reasonable steps (e.g. contact originating pharmacy) to obtain medication history.

[iv] An original prescription is not required for adaptation or therapeutic substitution. There was previously a requirement to have the original prescription in order to prescribe for continuity of care (similar to renewal), but this requirement was removed.

[v] A pharmacist who does not have an original prescription may **renew** a prescription to ensure continuity of care IF they are satisfied that:

a) the patient has presented evidence of current ongoing therapy based on a prescription (such as an empty prescription vial),
b) there is immediate need for drug therapy, and
c) it is not reasonably possible for the patient to attend the original dispensing pharmacy or to have the prescription transferred from the original dispensing pharmacy.

College of Pharmacists of British Columbia

# Jurisdictional Scan Summary

- Included: Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, PEI, Newfoundland & Labrador, Yukon.
- Four of nine PRAs require a pharmacist to have the original prescription when adapting a prescription.
- Five of nine PRAs do not require an original prescription when adapting a prescription.
  - In these provinces, pharmacists are permitted to adapt a prescription that has been transferred.
- In light of COVID-19, two jurisdictions (Ontario and PEI) have amended original prescription requirements.

College of Pharmacists of British Columbia

# Options for the Board's Consideration

- Option 1: Permit Transferred Prescriptions to be Adapted for the Duration of the COVID-19 Public Health Emergency in BC

- Option 2: Maintain the Original Prescription Requirement for Adaptations

College of Pharmacists of British Columbia

# Staff Recommendation

- Staff recommend that the Board proceed with Option 1, which is to permit transferred prescriptions to be adapted during the COVID-19 public health emergency.
  - ✓ Transferred prescriptions may be more common during the COVID-19 public health emergency, and permitting the pharmacist to adapt a transferred prescription may increase patient health outcomes.
  - ✓ It allows a pharmacist to use their professional judgement to determine whether to adapt a transferred prescription.
  - ✓ It would alleviate the potential of a delay in patient therapy as the pharmacist would not need to contact the prescriber.

College of Pharmacists of British Columbia

# Therapeutic Substitution

College of Pharmacists of British Columbia

# Therapeutic Substitution

- Therapeutic substitution is the substitution of a prescribed drug with a different drug, from the same therapeutic class, that is expected to have a similar therapeutic effect.
- The pharmacist must be satisfied that the dose and dosing regimen of the new drug will have an equivalent therapeutic effect.
- Currently limited to those drug categories in the Ministry of Health's Reference Drug Program (RDP), unless in practice settings such as hospital, long-term care facilities or multi-disciplinary environments where collaborative relationships or appropriate protocols are established.

College of Pharmacists of British Columbia

# Drug Shortages & COVID-19 Context

- While drug shortages have been increasing in recent years, additional drug shortages are occurring, or are expected to occur, as a result of the COVID-19 pandemic.
- Drug shortages occur for many reasons:
  - Shortage of active ingredients
  - Supply chain disruptions
  - Increased demand (unanticipated)
- Drug shortages drugs within RDP classes have occurred recently, including ARBs and H2RAs, but drug shortages do extend beyond the categories of the RDP.
- The ability of the pharmacist to provide a therapeutic substitution with another drug in the same class can mitigate some of the impacts of these drug shortages.

College of Pharmacists of British Columbia

# Jurisdictional Scan

| | BC | AB | NB | NS | PEI | N&L | YK |
|---|---|---|---|---|---|---|---|
| Substitution of drug prescribed with a different drug that is expected to have a similar therapeutic effect, as long as that drug is from the same therapeutic class | ✓ | ✓ | ✓[i] | ✓ | ✓[i] | ✓[i] | ✓[ii] |
| No limits on therapeutic classes that can be substituted (excluding drugs listed in the Controlled Drugs and Substances Act and Regulations) | ✗[iii] | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Therapeutic substitution is considered a type of prescribing | ✗ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Orientation or training requirement | ✓ | ✗ | ✗ | ✗ | ✗ | ✓ | ✗ |

[i] Therapeutic substitution is not limited to within therapeutic class
[ii] Definition is unclear, seeking additional information from PRA
[iii] Limited to practice settings such as hospital, long-term care facilities or multi-disciplinary environments where collaborative relationships or appropriate protocols are established; or, where these don't exist, limited to categories under MoH Reference Drug Program (angiotensin converting enzyme inhibitors, angiotensin receptor blockers, dihydropyridine calcium channel blockers, histamine2 receptor blockers, nitrates, non-steroidal anti-inflammatory drugs, proton pump inhibitors, statins)

College of Pharmacists of British Columbia

# Jurisdictional Scan Summary

- All included jurisdictions, except for BC, consider therapeutic substitution to be a type of prescribing.
- Only BC has restriction on therapeutic classes that can be substituted.
- 3/7 jurisdictions require substitution to be within the same therapeutic class.
    - The remaining 4/7 do not as long as the substituted drug is expected to have a therapeutically equivalent effect.

College of Pharmacists of British Columbia

# Consultation/Feedback

- The Ministry of Health pays clinical service fees to pharmacies for adaptations that are consistent with the definition of adaptation in PPP-58.
- College staff discussed the proposed amendments to the therapeutic substitution component of PPP-58 with staff from the Pharmaceutical Services Division and the Professional Regulation Branch the Ministry of Health.
- Staff from the Pharmaceutical Services Division have indicated that changes to PPP-58 to allow for shortage-based therapeutic substitutions during the COVID-19 public health emergency would be supported by the Ministry of Health.

College of Pharmacists of British Columbia

# Options for the Board's Consideration

- Option 1: Remove the limitation on drug categories for therapeutic substitution for the duration of the COVID-19 public health emergency in British Columbia, where there is an actual drug shortage for a prescribed drug, and no interchangeable drug is available.

- Option 2: Maintain existing limitation on therapeutic substitution to only those categories under the Ministry of Health RDP.

College of Pharmacists of British Columbia

# Staff Recommendation

- It is recommended that the Board proceed with Option 1, which is to remove the limitation on drug categories for therapeutic substitution for the duration of the COVID-19 public health emergency in British Columbia, where there is an actual drug shortage for a prescribed drug, and no interchangeable drug is available.
  - ✓ Global events in the midst of the COVID-19 pandemic may further impact drug shortages in British Columbia.
  - ✓ Allowing pharmacists to substitute where drug shortages exist will support continuity of care for patients and minimize delays in initiating or changing drug therapy.
  - ✓ The potential unanticipated consequences due to lack of a fulsome consultation may be lessened by only allowing therapeutic substitution outside of the RDP where there is an actual drug shortage, and only during the COVID-19 public health emergency in British Columbia.

College of Pharmacists of British Columbia

# Minor Updates to PPP-58

College of Pharmacists of British Columbia

# Additional Minor Updates to PPP-58

- Minor updates to the Orientation Guide are recommended to align with the recent changes to *Professional Practice Policy 31 – Emergency Supply for Continuity of Care*, as approved by the Board in November 2019.

College of Pharmacists of British Columbia

# 6. Amendments to Professional Practice Policy-58 Medication Management (Adapting a Prescription)

**MOTION 1:**

Approve amendments to *Professional Practice Policy 58 - Amendment to Orientation Guide – Medication Management (Adapting a Prescription)* in light of COVID-19, to be effective immediately.

College of Pharmacists of British Columbia

# 6. Amendments to Professional Practice Policy-58 Medication Management (Adapting a Prescription)

**MOTION 2:**

Approve amendments to *Professional Practice Policy 58 - Orientation Guide – Medication Management (Adapting a Prescription)* in light of COVID-19, to be effective immediately.