



College of Pharmacists
of British Columbia

Board Teleconference
October 7, 2016
8:00pm

MINUTES

Members Present:

Blake Reynolds, Chair & District 4 Board Member
Anar Dossa, Vice-Chair & District 6 Board Member
Tara Oxford, District 3 Board Member
Frank Lucarelli, District 5 Board Member
Arden Barry, District 7 Board Member
Sorell Wellon, District 8 Board Member
Kris Gustavson, Public Board Member
Jeremy Walden, Public Board Member

Regrets:

Norman Embree, Public Board Member
Mona Kwong, District 1 Board Member
Ming Chang, District 2 Board Member
George Walton, Public Board Member

Staff:

Bob Nakagawa, Registrar
Christine Paramonczyk, Director of Policy and Legislation
Lori Tanaka, Board & Legislation Coordinator

1. WELCOME & CALL TO ORDER

Chair Reynolds called the meeting to order at 8:00pm.

Registrar Nakagawa conducted a roll call to confirm quorum was present.



College of Pharmacists
of British Columbia

**Board Meeting Minutes
October 7, 2016**

2. CONFIRMATION OF AGENDA

It was moved and seconded that the Board:

Approve the October 7, 2016 Draft Board Teleconference Meeting Agenda as circulated.

CARRIED

3. LEGISLATION REVIEW COMMITTEE

PPP-58: Medication Management (Adapting a Prescription) – Orientation Guide Amendments

Board member and Chair of the Legislation Review Committee Jeremy Walden presented information as distributed in the briefing package (**Appendix 1**).

It was moved and seconded that the Board:

Approve:

Professional Practice Policy 58 – Amendment to Orientation Guide – Medication management (Adapting a Prescription) (December 2008 – revised February 2011/April 2016/October 2016), and

Professional Practice Policy 58 – Orientation Guide – Medication Management (Adapting a Prescription) (December 2008 – revised February 2011/April 2016/October 2016)

to allow adaptations on first and subsequent fills of an original prescription.

CARRIED

ADJOURNMENT

Chair Reynolds adjourned the meeting at 8:12pm.



College of Pharmacists
of British Columbia

BOARD MEETING

October 7, 2016

Professional Practice Policy-58: Medication Management (Adapting a Prescription) – Orientation Guide amendments

DECISION REQUIRED

Recommended Board Motions:

1. *Approve Professional Practice Policy 58 - Amendment to Orientation Guide – Medication Management (Adapting a Prescription) (December 2008 – revised February 2011/April 2016/October 2016) to allow adaptations on first and subsequent fills of an original prescription.*
2. *Approve Professional Practice Policy 58 - Orientation Guide – Medication Management (Adapting a Prescription) (December 2008 – revised February 2011/April 2016/October 2016) to allow adaptations on first and subsequent fills of an original prescription.*

Purpose

To seek Board approval to amend the College's adaptation guidelines to broaden the restrictions on adaptations to include refills of a prescription. This would also have the effect of better alignment with the Ministry of Health's PharmaCare program.

Background

Professional Practice Policy #58 (PPP-58) entitled "Protocol for Medication Management – Adapting a Prescription" approved by the College in September 2007, provides the framework to guide pharmacists in the safe and effective adaptation of existing prescriptions. It is applicable to pharmacists in all practice settings. The three primary activities considered under the notion of adapting a prescription include: change, renew, and substitution.

Currently, the PPP-58 Orientation Guide states adaptations can only be performed on a new or original prescription, which is explicitly defined as referring to the first fill of a prescription along with a clarifying notion that it does not need to be the beginning of a new therapy. Since a pharmacist is limited to performing an adaptation at the first fill of a new prescription, this means that they are not authorized to adapt a prescription during a refill.

The College previously approved changes to the PPP-58 Orientation Guide in April 2016 to align with PharmaCare's Reference Drug Program (RDP). This allowed for therapeutic substitution for all drugs that are now and subsequently will be included in the RDP.

Pharmacare's RDP

The RDP groups together drugs that treat the same illness or medical condition with equal effectiveness. The less costly drugs (called "reference" drugs) are eligible for full coverage, while the more costly drugs are eligible for partial coverage. Reference drugs are normally the drugs considered to be the standard first treatment of choice.

Beginning December 1, 2016, the RDP will include three more categories of drugs and reference drugs in three existing categories will be updated. If a patient's drug coverage is affected by the changes, they may decide to switch medications to retain full coverage or keep taking their current drug and pay the difference in cost. Affected patients will have until December 1, 2016, to make a decision about switching drugs.

Discussion

The Ministry of Health (the Ministry) and the BC Pharmacy Association (BCPhA) have raised that the College's adaptation guideline's "first fill" requirement is a significant barrier to the modernized RDP. Affected patients seeking to switch medications after the first fill may be delayed as pharmacists are not able to provide therapeutic substitutions after the first fill.

To ensure patients have timely access to PharmaCare full benefit drugs in the various RDP categories and they do not have to pay out of pocket, pharmacists require the authority to complete adaptations, including therapeutic substitutions, on all fills of a prescription and not only the first fill. Allowing adaptations on refills would also address lost opportunities for therapeutic substitutions for patients who seek out refills at their community pharmacies.

The urgency of the proposed amendment is linked to a Ministry communiqué in which approximately 110,000 patients will be receiving personal letters outlining options for therapeutic substitutions. College staff understand that the information in each letter will outline details related to Pharmacare benefits with the overall intent to encourage patients to request appropriate therapeutic substitutions. The letters are expected to be sent out throughout mid-to-late October 2016, which is just prior to the December 2016 RDP deadline.

It is important to note that the decision to adapt a prescription or not is at the discretion of the individual pharmacist. Further, pharmacists are expected to use their professional judgement to determine any therapeutic risks and ensure suitability for any adaptations.

The College has proposed amendments to the guidelines in which pharmacists may adapt an original prescription, including the first and subsequent refills of that prescription, in

accordance with PPP-58. For clarity, there are still many limits and conditions on adaptations. For instance, original prescriptions do not include transferred prescriptions, previously adapted prescriptions or emergency refills, and the original prescription must not be expired.

Recommendation

The College recommends that the Board:

1. *Approve Professional Practice Policy 58 - Amendment to Orientation Guide – Medication Management (Adapting a Prescription) (December 2008 – revised February 2011/June 2016/October 2016)* to allow adaptations on first and subsequent fills on an original prescription.
 2. *Approve Professional Practice Policy 58 - Orientation Guide – Medication Management (Adapting a Prescription) (December 2008 – revised February 2011/April 2016/October 2016)* to allow adaptations on first and subsequent fills of an original prescription.
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Appendix	
1	For decision: Professional Practice Policy 58 - Amendment to Orientation Guide – Medication Management (Adapting a Prescription) (December 2008 – revised February 2011/June 2016/October 2016) to allow adaptations on first and subsequent fills of an original prescription.
2	For decision: Professional Practice Policy 58 - Orientation Guide – Medication Management (Adapting a Prescription) (December 2008 – revised February 2011/April 2016/October 2016) to allow adaptations on first and subsequent fills of an original prescription.



College of Pharmacists
of British Columbia

IMPORTANT INFORMATION

Amendment to

Orientation Guide – Medication Management (Adapting a Prescription) (December 2008 – revised February 2011/April 2016/October 2016)

This update makes minor changes to the December 2008 amendment to PPP 58. This second update (2016) makes minor changes to the original document that was developed in 2008. The first update occurred in 2011 and at that time, considered feedback from pharmacists (one year post implementation) and from other stakeholders, namely the College of Physicians and Surgeons (CPSBC) and the BC Medical Association (BCMA)[‡].

There have not been any changes to the seven fundamentals to Adapting a Prescription as outlined in Professional Practice Policy #58 (PPP 58) and pharmacists are required to follow the fundamentals when choosing to renew or adapt any prescription.

Commented [RS1]: Deleted information is now outdated and no longer fully relevant to the updates in the table.

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.	<p>October 2016:</p> <ul style="list-style-type: none">Pharmacists may adapt an original prescription, including the first and subsequent refills of that prescription, in accordance with PPP-58.The adaptation does not need to be the beginning of a new drug therapy.Original prescriptions do not include transferred prescriptions, previously adapted prescriptions, or emergency refills. <p>Commented [RS2]: New update.</p>

[‡]Currently known as Doctors of BC.



Liability Insurance	<p>Minimum requirements for liability insurance:</p> <ul style="list-style-type: none"> • Personal professional liability insurance (minimum \$2 million) 	<p>Section 4.1; Page 19</p>	December 2008: Minimum requirements for liability insurance are: <ul style="list-style-type: none"> • The policy provides a minimum of \$2 million coverage, and • The policy provides occurrence-based coverage or claims-made coverage with an extended reporting period of at least three years, and • If not issued in the pharmacist's name, the group policy covers the pharmacist as an individual.
			February 2011: No change
			April 2016: No change
			October 2016: No change
Topic	Current wording in Orientation Guide	Reference in Orientation Guide	Clarification / Update
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: <ul style="list-style-type: none"> • Pharmacists will honour handwritten (not pre-stamped) "Do Not Renew / Adapt" notification on prescriptions • If a prescriber electronically produces their prescriptions they must sign or initial beside the notation February 2011: No change April 2016: No change October 2016: No change
Renewals – specific	No limits and/or conditions stated	n/a	December 2008: <ul style="list-style-type: none"> • Renewals apply to stable, chronic conditions (same medication, with no



conditions &/or drugs			<p>change, for a minimum of six months)</p> <ul style="list-style-type: none"> For psychiatric medications renewals are reserved for pharmacists working in multidisciplinary teams
			<p>February 2011:</p> <ul style="list-style-type: none"> Renewals apply to stable, chronic conditions (same medication, with no change) <i>Note: 'no change' is defined as usually a minimum of six months</i> For psychiatric medications renewals are reserved for pharmacists working in multidisciplinary teams
			<p>April 2016: No change</p>
			<p>October 2016: No change</p>
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	<p>December 2008:</p> <ul style="list-style-type: none"> Maximum renewal up to 6 months from the date of the original prescription <p>February 2011:</p> <ul style="list-style-type: none"> For whatever period of time felt appropriate as long as it does not exceed the expiry of the prescription <p><i>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</i></p>
			<p>April 2016: No change</p>
			<p>October 2016: No change</p>



Topic	Current wording in Orientation Guide	Reference in Orientation Guide	Clarification / Update
Change: dose or regimen	No limits and/or conditions stated	Section 2.2.1; Page 14	<p>December 2008: Unless in practice settings such as hospital, long-term care facilities or multi-disciplinary environments where collaborative relationships or appropriate protocols are established, pharmacists:</p> <ul style="list-style-type: none"> • Will not change the dose or regimen of prescriptions for: cancer, cardio-vascular disease, asthma, seizures or psychiatric conditions • Pharmacists can complete missing information on a prescriptions if there is historical evidence to support it <p>February 2011: No change</p> <p>April 2016: No change</p> <p>October 2016: No change</p>
Therapeutic Substitution	No limits and/or conditions stated	Section 2.2.3; Page 16	<p>December 2008: Unless in practice settings such as hospital, long-term care facilities or multi-disciplinary environments where collaborative relationships or appropriate protocols are established, pharmacists:</p> <ul style="list-style-type: none"> • Will limit therapeutic substitution to: Histamine 2 receptor blockers (H2 blockers), Non-steroidal anti-inflammatory drugs (NSAIDs), Nitrates, Angiotension converting enzyme inhibitors (ACE inhibitors), Dihydropyridine calcium channel blockers (dihydropyridine CCBs) and Proton pump inhibitors (PPIs) <p>February 2011: No change</p> <p>October 2016: No change</p>
			<p>April 2016: Unless in practice settings such as hospital, long-term care facilities or multi-disciplinary environments where collaborative relationships or appropriate protocols are established, pharmacists:</p>



		<ul style="list-style-type: none">• 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 <p><u>October 2016:</u> <u>No change</u></p>
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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:

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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:

- Understand the elements of *Medication Management (Adapting a Prescription)*;
- Understand the professional requirements and expectations when you undertake *Medication Management (Adapting a Prescription)*;
- Understand the specific consent, documentation and notification requirements of implementing this policy in your practice;
- Implement specifically defined Medication Management activities; and
- 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 new or the original prescription (an authorization from a practitioner to dispense a specified drug for use by a designated individual)^a

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.

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.

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).

^aFor purposes of PPP-58, and included in the Glossary of Terms (appendix B), a ‘new’ or ‘original’ prescription is defined as the first fill of a prescription and does not need to be the beginning of a new therapy.

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.²

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.

² 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.bcparmacists.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**³. 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.bcparmacists.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.

³ 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 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
- 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)

New and/or Original Prescription

~~refers to the first fill of a prescription and does not need to be the beginning of a new drug therapy~~

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)
- a pharmacist may not adapt a prescription if the original prescription has expired
- 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
 - 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: _____	Pharmacist Information Name: _____ Pharmacy: _____ Phone: _____ Fax: _____ Signature: _____
Prescriber Information Name: _____ Phone: _____ Fax: _____	Adaptation Information Date of Prescription: _____ Prescription Details: _____ Date of Adaptation: _____ Adaptation Details: _____
Rationale for Adaptation (including instructions to patient and follow-up plan) <u>Rationale</u> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	
Instructions to Patient <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	
Follow-up Plan <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	
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. <input type="checkbox"/>	
Notification Information Date of Notification: _____ Name of Practitioner(s) Notified: _____ Method of Notification (fax preferred): _____ <input type="checkbox"/> Fax # _____ <input type="checkbox"/> Phone # _____ <input type="checkbox"/> 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

Patient Information	Pharmacist Information
Name: _____ PIN: _____	Name: _____ Pharmacy: _____
Prescriber Information	
Name: _____ Phone: _____ Fax: _____	Phone: _____ Fax: _____ Signature: _____
Original Prescription Information	Adaptation Information
Date of Prescription: _____ Prescription Details: _____	Date of Adaptation: _____ Adaptation Details: _____
Rationale for Adaptation (including instructions to patient and follow-up plan)	
Instructions to Patient _____	
Follow-up Plan _____	
Informed Consent	
<p>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.</p> <input type="checkbox"/>	
Notification Information	
<p>Date of Notification: _____ Name of Practitioner(s) Notified: _____</p> <p>Method of Notification (if performed): _____</p> <p><input type="checkbox"/> Fax # <input type="checkbox"/> Phone <input type="checkbox"/> Other</p> <p>The information contained in this prescription is confidential and is intended only for the use of the recipient named above. If the name of the prescriber or of the intended recipient is not clearly legible, or if any changes are made, do not use this prescription. If you have received this form in error, return it to the sender or destroy the form and notify the sender.</p>	

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: <u>January 15, 2009</u>	
Prescription Details: <u>Alendronate 10mg</u>	
<u>once weekly x 6 months</u>	
Rationale for Adaptation (including instructions to patient and follow-up plan)	
<p>Rationale</p> <ul style="list-style-type: none"> - 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 	
<p>Instructions to Patient <u>Instructed the patient to take 1 tablet once/week on the same day each week with plenty of water.</u></p> <p>Follow-up Plan <u>contact her physician if any GI upset or unusual symptoms.</u></p>	
Informed Consent	
<p>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.</p> 	

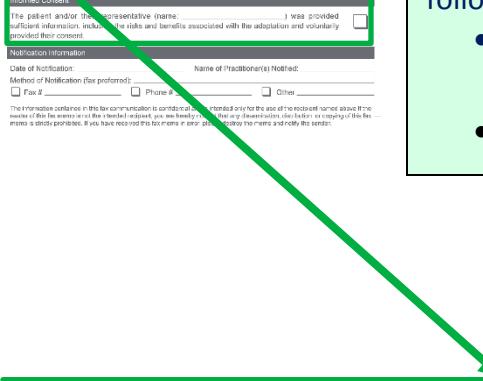
Patient Information	Pharmacist Information		
Name: _____	Name: _____		
PHN: _____	Pharmacy: _____		
Prescription Information			
Name: _____	Name: _____		
Phone: _____	Phone: _____		
Fax: _____	Fax: _____		
Original Prescription Information			
Date of Prescription:	Date of Adaptation:		
Prescription Details:	Adaptation Details:		
Rationale for Adaptation (including instructions to patient and follow-up plan)			
Comments:			
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 (Pharmacist(s)) Notified:		
Method of Notification (check preferred):			
<input type="checkbox"/> Fax	<input type="checkbox"/> Phone	<input type="checkbox"/> Email	<input type="checkbox"/> Other
<small>The information contained in this communication is confidential and intended only for the use of the recipient. Please advise if the message has been received in error. If you have received this message in error, please destroy the message and notify the sender.</small>			

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	Adaptation Information
Date of Prescription: <u>January 15, 2009</u>	Date of Adaptation: <u>January 15, 2009</u>
Prescription Details: <u>Betaderm 0.1% Cream;</u>	Adaptation Details: <u>changed Betaderm 0.1% Cream to</u>
<u>Apply TID</u>	<u>Betaderm 0.1% Ointment; Apply TID</u>
Rationale for Adaptation (including instructions to patient and follow-up plan)	
<p>Rationale</p> <ul style="list-style-type: none"> - 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 <u>Apply sparingly to affected area three times a day. If skin condition worsens, contact your doctor.</u>	
Follow-up Plan <u>See your doctor at your regular interval in one month.</u>	
Informed Consent	
<p>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.</p>	

Patient Information	Pharmacist Information	
Name: _____	Name: _____	
PHN: _____	Pharmacy: _____	
Prescription Information		
Name: _____	Name: _____	
Phone: _____	Phone: _____	
Fax: _____	Fax: _____	
Original Prescription Information		
Date of Prescription:	Date of Adaptation:	
Prescription Details:	Adaptation Details:	
Rationale for Adaptation (including instructions to patient and follow-up plan)		
Patient note:		
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. <input type="checkbox"/>		
Notification Information		
Date of Notification:	Name of (Pharmacist(s)) Notified:	
Method of Notification (check preferred):		
<input type="checkbox"/> Fax	<input type="checkbox"/> Phone	<input type="checkbox"/> Other
<small>The information contained in this communication is confidential and intended only for the use of the recipient. Please advise if the message has been intercepted or forwarded in error, or if you have received this message in error, and do not copy or release this message to anyone else.</small>		

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	Pharmacist Information
Name: _____	Name: _____
PHN: _____	Pharmacy: _____
Prescription Information	
Name: _____	Name: _____
Phone: _____	Phone: _____
Fax: _____	Fax: _____
Original Prescription Information	
Date of Prescription:	Date of Adaptation:
Prescription Details:	Adaptation Details:
Rationale for Adaptation (including instructions to patient and follow-up plan)	
Patient note:	
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. <input type="checkbox"/>	
Notification Information	
Date of Notification:	Name of Practitioner(s) Notified:
Method of Notification (check preferred):	
<input type="checkbox"/> Fax	<input type="checkbox"/> Phone
<input type="checkbox"/> Email	<input type="checkbox"/> Other
<small>The information contained in this communication is confidential and is intended only for the use of the recipient. Please advise if the message has been received in error or is being forwarded to another individual. If you are not the intended recipient, please destroy the message and contact the sender.</small>	

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	Adaptation Information
Date of Prescription: October 4, 2008	Date of Adaptation: January 16, 2009
Prescription Details: Hydrochlorthiazide 50mg OD Synthroid 100mcg 1 OD, no refills	Adaptation Details: Hydrochlorthiazide 50mg OD Synthroid 100mcg 1 OD, renewed x 3mth supply
Rationale for Adaptation (including instructions to patient and follow-up plan)	
<p>Rationale</p> <ul style="list-style-type: none"> - 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. <input checked="" type="checkbox"/>	
Notification Information	

Patient Information	Pharmacy Information
Name: _____ Title: _____ Address: _____ Phone: _____ Fax: _____	Name: _____ Phone: _____ Signature: _____
Original Prescription Information	Acceptable Information
Date of Prescription: _____ Prescription Details: _____	Date of Adaptation: _____ Acceptable Details: _____
Rationale for Adaptation (including instructions to patient and follow-up plan)	
Instructions to Patient Follow-up Plan	
Name: _____ I am and/or their representative (name): _____ I was given cost 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.”