

# Standards of practice for pharmacists and rural permit holders

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# Introduction

These standards are made under the authority of Section 2(2)(d), 3(1)(k) and 3(2)(c) of the Health Professions Act and section 6(1) of the Pharmacists Regulation. They are one component of the law that governs the practice of pharmacy in Yukon. These standards are part of and must be read in the overall legislative scheme that regulates the practice of pharmacists, and the practice of pharmacy of rural permit holder which includes:

- the Health Professions Act,
- the Pharmacists Regulation,
- the Code of Ethics for Pharmacists and Rural Permit Holders,
- the Pharmacy and Drug Act (once in force),
- the Pharmacy and Drug Regulation (once in force), and
- the Standards for the Operation of Licensed Pharmacies and Rural Dispensaries (in force).

Pharmacists and rural permit holders practicing in Yukon must know, understand and comply with this overall legislative scheme.

These standards are mandatory. They set out the minimum acceptable standard of practice for pharmacists and rural permit holders.

For each standard, there is a basic statement of principle followed by detailed rules set out in the Application of Standard. Both the basic statement of principle and the detailed rules are mandatory.



# Definitions

- 1. The following definitions apply throughout the standards for Designated Drugs, Listed Minor Ailments and Listed Preventable Diseases
  - a) Adapting a prescription means altering the dosage, route of administration, formulation or regimen for a drug, substituting another drug that is expected to have a similar therapeutic effect; or extending a prescription to ensure continuity of care, as set out in Section 3 of the Pharmacists Regulation.
  - b) **Collaborative relationship** means a relationship between two or more regulated health professionals that is developed to:
    - i. facilitate communication,
    - ii. determine mutual goals of therapy that are acceptable to the patient,
    - iii. share relevant health information, and
    - iv. establish the expectations of each regulated health professional when working with a mutual patient.
  - Drug means a drug as defined in the Pharmacy and Drug Act and Pharmacists Regulation.
  - d) Employee means an individual employed in a pharmacy or rural dispensary who is not a regulated member and includes a volunteer who works in a pharmacy or rural dispensary.
  - e) Health care products, aids or devices means a product, other than a drug, or an aid or a device that is used to promote health and treat diseases, dysfunctions and disorders, including;



- i. devices as defined in the Food and Drugs Act (Canada);
- ii. natural health products as defined in the Natural Health Products
   Regulations (Canada) SOR/2003-196; and
- iii. products, aids and devices that promote health and treat diseases, dysfunctions and disorders.
- f) Patient means a recipient of a service within the practice of pharmacy as defined in section 1 of the Pharmacists Regulation.
- g) **Patient's agent** means in respect of a patient, means a member of the patient's immediate family, an individual who has a close personal relationship with the patient or an individual who personally provides care to the patient as defined in section 1 of the Pharmacy and Drug Act.
- h) Pharmacist means a full registrant as defined in section 1 of the Pharmacists Regulation, unless the context requires otherwise.
- Practice of pharmacy means the scope of practice described in Section 2 and 3 of the Pharmacists Regulation.
- ) Prescriber means a prescriber as defined in section 1 of the Pharmacists Regulation.
- Professional service means any service that falls within the practice of pharmacy of pharmacist or practice of pharmacy of rural permit holder.
- **Professional relationship** means a relationship formed with a patient for the purpose of optimizing the patient's health or drug therapy.



- m) Regulated health professional means a registrant of a designated health profession under the Health Professions Act, a person who is entitled to practice medicine in Yukon under the Medical Professions Act, a registered nurse or a nurse practitioner under the Registered Nurses Profession Act, a practical nurse within the meaning of section 1 of the Licensed Practical Nurses Act, a chiropractor within the meaning of the Chiropractors Act, a dentist within the meaning of the Dental Professions Act, a denturist within the meaning of the Denturist Act, and an optometrist within the meaning of the Optometrists Act.
- n) Regulated member means an individual registered on a register referred to in 18(1) of the Pharmacists Regulation.
- Rural permit holder means a person who is registered as a rural permit registrant under the Pharmacists Regulation.
- p) Simple and uncomplicated compounding means to perform non-sterile compounding of two non-hazardous creams or ointments for topical use.
- Unless these standards provide a more specific definition, terms used in these standards have the same meaning as in the Health Professions Act, the Pharmacists Regulation, the Pharmacy and Drug Act, and its regulations.
- 3. Where a provisional pharmacist, or student pharmacist engages in the practice of pharmacy, that provisional pharmacist, or student pharmacist must comply with those standards applicable to the practice of a full registrant.



# Standard 1 Act professionally

Pharmacists and rural permit holders must act professionally

#### **APPLICATION OF STANDARD 1**

### Compliance with the law

- 1.1 Pharmacists and rural permit holders must practice in accordance with the law that governs each of their practices, including but not limited to:
  - a) the Health Professions Act, its regulations, these standards;
  - b) the Pharmacy and Drug Act, its regulations, and the Standards for the Operation of Licensed Pharmacies and Rural Dispensaries;
  - c) the Code of Ethics for Pharmacists and Rural Permit Holders;
  - d) the Food and Drugs Act and its regulations;
  - e) the Controlled Drugs and Substances Act, and its regulations, including the Narcotic Control Regulations; and
  - f) the Health Information Privacy and Management Act and its regulations.
- 1.2 Pharmacists and rural permit holders have a duty to be aware of changes in the law that governs their practices and adjust their practices to ensure compliance with the changes.



# Working collaboratively with colleagues

- 1.3 When required to serve the best interests of the patient, each pharmacist and rural permit holder must work collaboratively with colleagues, including other regulated health professionals, in the provision of permitted services. This obligation includes but is not limited to:
  - a) treating colleagues with respect;
  - b) acting as a positive role model;
  - c) fulfilling obligations to colleagues in a timely manner;
  - making appropriate and efficient use of the expertise and availability of colleagues; and
  - e) developing and maintaining collaborative relationships.
- 1.4 A pharmacist must not provide pharmacist services to a patient who cannot be appropriately treated within the practice of pharmacists.
- 1.5 A rural permit holder must not provide pharmacy services to a patient who cannot be appropriately treated within the practice of pharmacy of rural permit holders.
- 1.6 A pharmacist and rural permit holder must:
  - a) only practice within the practice of pharmacists and rural permit holder;
  - b) only engage in restricted activities that the pharmacist or rural permit holder is authorized and competent to perform and that are applicable to the pharmacist or rural permit holder's practice and the procedure being performed;



- c) be aware of the limits of the pharmacist or rural permit holder's personal
   competence and only provide pharmacy services within these limitations; and
- d) be aware of the circumstances in which the pharmacist or rural permit holder should refer the patient to another appropriately qualified regulated health professional, including when:
  - the pharmacist or rural permit holder does not have the training, experience or skills necessary to address the patient's needs;
  - ii. the condition of the patient cannot be effectively treated within the practice of pharmacy; or
  - iii. the patient's condition has not adequately or appropriately responded to drug therapy or other therapy within the practice of pharmacy.

#### Participation in quality assurance processes

- 1.7 Each pharmacist and rural permit holder must participate in the quality assurance processes required by the Standards for the Operation of Licensed Pharmacies and Rural Dispensaries (when available) or another workplace quality assurance program applicable to the pharmacists' or the rural permit holders' practice.
- 1.8 A pharmacist or rural permit holder who provides patient care in an environment where a quality assurance program does not exist or does not meet the minimum standards established under the Standards for the Operation of Licensed Pharmacies and Rural Dispensaries (when available) must implement a program that meets or exceeds the requirements outlined in the Standards for the Operation of Licensed Pharmacies and Rural Dispensaries (when available).



# Appearance, demeanour and identification as a regulated pharmacy professional

- 1.9 When engaged in their practices, each pharmacist and rural permit holder must:
  - a) maintain a professional appearance and demeanour; and
  - b) be readily identifiable to the public, other regulated health professionals and other workers in the health care system as a pharmacist or rural permit holder as the case may be.

### Preservation of professional independence

- 1.10 A pharmacist must not practice under conditions that compromise the pharmacist's professional independence, judgment or integrity.
- 1.11 A rural permit holder must not practice under conditions that compromise the rural permit holder's professional independence, judgment or integrity.
- 1.12 No pharmacist or rural permit holder may impose conditions on another pharmacist, rural permit holder or other regulated health professional that compromises the other professional's independence, judgment or integrity.
- 1.13 Neither a pharmacist nor a rural permit holder may:
  - a) accept gifts or other benefits from; or
  - b) enter into any association with, a patient, regulated health professional or any other person that could have the effect of compromising his or her professional independence, judgment or integrity.



- 1.14 A pharmacist must not prescribe a drug for:
  - a) the pharmacist themselves;
  - b) a family member of the pharmacist; or
  - anyone else with whom the pharmacist has a close personal relationship;
     except for minor conditions, in an emergency, or when another prescriber is not readily available to prescribe the drug.

### Requirement to be trained in CPR and first aid

1.15 A pharmacist must maintain current certificates in cardiopulmonary resuscitation (CPR) and first aid, at a level determined by the Registrar, if the pharmacist has been authorized to administer drugs by injection.



# Standard 2 Establish and maintain professional relationships with patients

Pharmacists and rural permit holders must establish and maintain professional relationships with their patients

#### **APPLICATION OF STANDARD 2**

- 2.1 A pharmacist and rural permit holder must:
  - a) establish a professional relationship with each patient to whom they provide services;
  - b) identify each patient's health needs and expectations;
  - c) collect the information required to provide pharmacy services to the patient,
  - d) take all information collected into consideration when providing the pharmacy services; and
  - e) make decisions in the best interest of the patient.
- 2.2 Each pharmacist and rural permit holder must deal directly with the patient unless:
  - a) it is in the best interest of the patient for the pharmacist or the rural permit holder to deal with the patient's agent; or



- b) the pharmacist or rural permit holder is satisfied that a regulated health professional acting within the scope of their profession is responsible for the administration of drugs to the patient.
- 2.3 The following factors may be taken into account in determining whether dealing with a patient's agent is in the best interests of the patient:
  - a) the express wishes of the patient;
  - b) the patient's health;
  - d) the patient's age;
  - d) the patient's mental state and capacity; and
  - e) the patient's absence from the area where the service is being provided.
- 2.4 All standards applicable to the relationship between the pharmacist or rural permit holder and the patient apply to the pharmacist or rural permit holder and the patient's agent with the necessary modifications to make them effective.
- 2.5 Nothing in this standard relieves a pharmacist or a rural permit holder from the duty to see a patient personally where specifically required elsewhere in these standards.

# Termination of patient relationship

Termination at the patient's request

2.6 A pharmacist and a rural permit holder must honour a patient's request to transfer care to another health professional.



- 2.7 As soon as reasonably possible after receipt of a request from a patient to transfer care to another pharmacist or another rural permit holder, the pharmacist or the rural permit holder must provide to the pharmacist or rural permit holder of the patient's choice:
  - a) transfer of active prescriptions with remaining refills that can be legally transferred; and
  - b) other information that, in the opinion of the transferring pharmacist or rural permit holder, may be required to ensure continuity of care, including but not limited to:
    - i. current prescriptions with no refills remaining,
    - ii. current prescriptions that cannot be legally transferred,
    - iii. inactive or discontinued prescriptions that may affect current care,
    - iv. drug therapy problems identified, and
    - v. monitoring and follow-up plans currently in place.

Termination by the pharmacist or rural permit holder

- 2.8 A pharmacist or rural permit holder who terminates a relationship with a patient must:
  - a) do so in accordance with the Code of Ethics for Pharmacists and Rural Permit Holders,
  - b) have reasonable grounds for ceasing to provide care to the patient and document those reasons on the patient record; and
  - give advance notice of the intention to terminate care and provide a timeline that is commensurate with the continuing care needs of the patient.



- 2.9 Notwithstanding Standard 2.8, a pharmacist or rural permit holder may terminate a relationship with a patient without providing advance notice if:
  - a) the patient poses a risk to the pharmacist, pharmacy staff, rural permit holder, rural dispensary staff or other patients;
  - b) the patient fails to respect professional boundaries;
  - c) the pharmacist or rural permit holder is leaving the practice location and another pharmacist or rural permit holder will assume the practice in the same location; or
  - d) the pharmacist or rural permit holder is leaving practice because of personal illness or other urgent circumstances; and
  - e) the pharmacist or rural permit holder provides for continuity of care by offering to provide information to another pharmacist or rural permit holder.



# STANDARD 3 Consider appropriate information

Pharmacists and rural permit holders must consider appropriate information for each patient

### **APPLICATION OF STANDARD 3**

# Duty to consider appropriate information

- 3.1 A pharmacist and a rural permit holder must consider appropriate information to assess the patient and the patient's health history and history of drug therapy each time:
  - i. the pharmacist prescribes a Schedule 1 drug;
  - ii. the pharmacist or rural permit holder conducts a review of a patient's drug utilization;
  - iii. the pharmacist or rural permit holder provides advice to a patient about a drug or drug therapy;
  - iv. the pharmacist or rural permit holder dispenses a Schedule 1 drug under a new or a repeat prescription; or
  - v. the pharmacist or rural permit holder dispenses or sells a Schedule 2 drug.



- 3.2 Notwithstanding Standard 3.1, a pharmacist or rural permit holder may delay the assessment of a patient if the pharmacist or rural permit holder is satisfied that:
  - a) drugs are dispensed in frequent, limited quantities only to assist patient to self-administer or to comply with distribution processes in institutions; or
  - b) drugs will only be administered by another regulated health professional; and
  - c) the delay will not negatively impact the patient.
- 3.3 A pharmacist or rural permit holder who delays an assessment under Standard 3.2 must ensure that appropriate information to assess the patient and the patient's health history and history of drug therapy is completed each time a new prescription or drug order is received, or every 90 days, whichever comes first.

### Meaning of appropriate information

- 3.4 Appropriate information means the following information in relation to a patient:
  - a) health condition to be treated and history of the condition;
  - b) symptoms or signs to be treated;
  - c) treatment history for the condition including drug therapy and outcomes;
  - d) age;
  - e) pregnancy or lactation status, if applicable;
  - f) allergies or intolerances to drugs, excipients or other products that may affect drug therapy;
  - g) other drugs being used;



- h) other health care products, aids and devices or other products being used that may affect the pharmacist's decision;
- ) other health conditions that may affect the pharmacist's or rural permit holder's decision; and
- ) any other information that a reasonable pharmacist or rural permit holder would require to provide the pharmacy service.

# Additional information that may be required

- 3.5 Information that may be required under Standard 3.4(j) includes:
  - a) patient demographic information;
  - b) patient's weight or other physical characteristics;
  - c) identity of other regulated health professionals or caregivers who are providing care to the patient;
  - d) diagnosis;
  - e) laboratory values;
  - f) relevant medical history; and
  - g) lifestyle information and social history, including tobacco, alcohol or recreational drug use.

### Use of laboratory data

3.6 When interaction with the patient or consideration of patient-specific information indicates that a pharmacist should review laboratory data and the data is not available, the pharmacist must contact an appropriate regulated health professional and request that the laboratory test be ordered.



- 3.7 A pharmacist or rural permit holder who makes a decision based on the interpretation of laboratory data must:
  - a) document the decision and the rationale for it in the patient record as required;
  - b) discuss the decision and the rationale for the decision with the patient if appropriate; and
  - c) include reference to the laboratory data in any communication about the decision with other members of the patient's healthcare team.
- 3.8 A pharmacist or rural permit holder who receives a request from a patient regarding a laboratory test must:
  - a) only provide results of laboratory tests in accordance with the Health Information and Privacy Management Act and its regulations, any protocols established for the electronic health record (EHR); and
  - b) not provide an interpretation of the results of laboratory tests unless it is pertinent to the pharmacist service being provided by the pharmacist or rural permit holder.



# STANDARD 4 Determine whether there is a drug therapy problem

Pharmacists and rural permit holders must determine whether a patient has or is likely to have a drug therapy problem

#### **APPLICATION OF STANDARD 4**

# Pharmacists' and rural permit holders' duty in relation to drug therapy problems

- 4.1 A pharmacist and a rural permit holder must consider whether a patient has a drug therapy problem or is likely to have a drug therapy problem, each time:
  - i. the pharmacist prescribes a Schedule 1 drug;
  - ii. the pharmacist or rural permit holder conducts a review of a patient's drug utilization;
  - iii. the pharmacist or rural permit holder provides advice to a patient about a drug or drug therapy;
  - iv. the pharmacist or rural permit holder dispenses a Schedule 1 drug pursuant to a new or a refill prescription; or
  - v. the pharmacist or rural permit holder dispenses or sells a Schedule 2 drug.



# Meaning of a drug therapy problem

4.2 A drug therapy problem includes the following circumstances in relation to a patient.

Nam	ne of problem	Description of problem
a)	Untreated condition	Requiring a drug but not receiving it
b)	Drug selection	Taking or receiving the wrong drug
c)	Sub-therapeutic	Taking or receiving too little of dosage of
		the right drug
d)	Over dosage	Taking or receiving too much of the right drug
e)	Non-adherence	Failure to take or receive a drug or taking or
		receiving a drug inappropriately
f)	Adverse reaction	Experiencing an adverse reaction to a drug
g)	Drug interaction	Experiencing a drug interaction including drug-drug,
_		drug- food, drug-laboratory test, drug-disease
h)	No indication	Taking or receiving a drug for no medically valid
		indication or substance abuse



# STANDARD 5 Take appropriate action if there is a drug therapy problem

If a pharmacist or rural permit holder determines that a patient has or is likely to have a drug therapy problem, the pharmacist or rural permit holder must take appropriate action.

### **APPLICATION OF STANDARD 5**

Pharmacist and rural permit holder to use professional judgment in relation to drug therapy problem

5.1 If a patient has or is likely to have a drug therapy problem, the pharmacist or rural permit holder must determine the appropriate response.

# Nature of the appropriate response to a drug therapy problem

- 5.2 The appropriate response to a drug therapy problem may include any one or more of the following:
  - a) gathering additional information from the patient, the patient's health record, the patient's agent or another regulated health professional;
  - b) implementing a plan to monitor the occurrence and impact of the drug therapy problem with mechanisms for intervention when required;



- c) for pharmacists, resolving or reducing the drug therapy problem to a clinically acceptable level by adapting a prescription under Section 3(1)(j) of the Pharmacists Regulation;
- advising the patient or the prescriber or both about the drug therapy problem and suggesting an alternative;
- e) entering into a collaborative relationship with another regulated health professional to manage the patient's drug therapy;
- f) refusing to dispense or sell the drug to the patient; or
- g) reporting an adverse reaction to a federal authority or program responsible for monitoring adverse drug reactions such as the Canadian Adverse Drug Reaction Monitoring Program.

# Changes to prescriptions to be documented

5.3 If a pharmacist or rural permit holder changes a prescription as a result of an authorization received from the original prescriber, the pharmacist or rural permit holder must document and initial or sign the change on the original prescription or drug order.



# STANDARD 6 Determine the appropriateness of each prescription

Each time a pharmacist or a rural permit holder dispenses a Schedule I drug pursuant to a prescription, the pharmacist must determine that the prescription is appropriate and determine that the prescription is current, authentic, and complete.

### **APPLICATION OF STANDARD 6**

Factors to be considered in determining the appropriateness of a prescription

- 6.1 A pharmacist and rural permit holder must determine the appropriateness of a prescription by considering relevant factors that a reasonable pharmacist or rural permit holder would consider in the circumstances including, but not limited to, whether:
  - a) the prescription is accurate;
  - b) the prescription orders a drug for an indication that is:
    - i. approved by Health Canada,
    - ii. considered a best practice or accepted clinical practice in peer-reviewed literature, or



- iii. part of an approved research protocol;
- c) the dose, frequency and route of administration are appropriate;
- d) there is therapeutic duplication;
- e) there are actual or potential adverse reactions, allergies, or sensitivities;
- f) there are actual or potential drug interactions;
- g) the regimen for administration is practical, based on the patient's functional ability;
- h) the patient's organ function, such as renal and hepatic function, will tolerate the drug;
- ) the results of laboratory or other tests, if applicable, affect the appropriateness of the drug; and
- ) other patient-specific characteristics such as age, pregnancy or lactation status, cognitive, mental and physical challenges, lifestyle, cultural beliefs or living environment that may affect the appropriateness of the drug or blood product.
- 6.2 In addition to the information to be considered in Standard 6.1, when considering the appropriateness of a refill prescription, additional relevant factors that a reasonable pharmacist or rural permit holder would consider in the circumstances include, but are not limited to:
  - a) continued need for the drug;
  - b) the date of the last fill;
  - c) patient compliance with drug therapy; and
  - d) the patient's response to the drug therapy.



# Determining the currency of a prescription

- 6.3 Before dispensing a prescription, a pharmacist or a rural permit holder must review the prescription to determine when it was written.
- 6.4 Neither a pharmacist nor a rural permit holder may dispense a drug under a prescription that was issued more than one year before the date the drug is to be dispensed.
- 6.5 Neither a pharmacist nor a rural permit holder may refill a prescription for:
  - a) a benzodiazepine or other targeted substance, as defined in the regulations to the Controlled Drugs and Substances Act, for a period of greater than 12 months after the prescription was first written; or
  - b) a Schedule 1 drug for a period greater than 18 months after the prescription was first filled.

## Determining the authenticity of a prescription

- 6.6 Before dispensing a prescription, a pharmacist or a rural permit holder must determine the authenticity of the prescription by taking reasonable steps to:
  - a) identify the prescriber;
  - b) determine whether the prescriber is legally authorized to prescribe the drug for which the prescription has been given; and
  - c) assess whether the prescription has been altered, forged, or stolen.



# Determining the completeness of a prescription

- 6.7 Prior to dispensing a prescription, a pharmacist or a rural permit holder must determine the completeness of a prescription by ensuring that the prescription includes the;
  - a) name and address of the patient;
  - b) drug name;
  - c) drug strength, if applicable;
  - d) dosage, if applicable;
  - e) route of administration, if applicable;
  - f) quantity of drug to be dispensed;
  - g) directions for use;
  - h) number of refills authorized and interval between each refill, if applicable;
  - ) prescriber's name and phone number;
  - ) prescriber's signature, in the case of a written prescription; and
  - k) the date of the prescription.

### Verbal order to be reduced to writing

6.8 If a pharmacist or a rural permit holder receives a verbal order for a drug from a prescriber, the pharmacist or the rural permit holder must reduce the prescription to writing and sign or initial the prescription.



# STANDARD 7 Follow proper procedures when dispensing

Each time a pharmacist or a rural permit holder dispenses a Schedule I drug pursuant to a prescription, the pharmacist or the rural permit holder must ensure that the prescription is filled correctly, appropriate dispensing procedures are used, the drug is packaged properly, the container is labeled properly, and a final check is performed.

### **APPLICATION OF STANDARD 7**

# Filling the prescription correctly

- 7.1 A pharmacist or a rural permit holder who dispenses a drug must ensure that:
  - a) the drug is correct and in accordance with the prescription; and
  - b) the dosage form, strength, manufacturer and quantity dispensed are correct and in accordance with the prescription.



## Using appropriate dispensing procedures

- 7.2 A pharmacist or a rural permit holder who dispenses a drug must ensure that his or her dispensing procedure:
  - a) is hygienic;
  - b) maintains the stability of the drug;
  - c) uses the proper diluents and mixing procedures where applicable;
  - d) prevents cross contamination; and
  - e) complies with any requirements applicable to the specific drug.

### Proper packaging

- 7.3 A pharmacist or a rural permit holder who dispenses a drug must ensure that the drug is dispensed:
  - a) in an appropriate package, having regard for the nature of the drug, including sensitivity to light and temperature; and
  - b) in a child-resistant package unless:
    - i. the prescriber or patient directs otherwise,
    - ii. the pharmacist or the rural permit holder is satisfied that child-resistant packaging is not appropriate,



- iii. child-resistant packaging is not suitable because of the form of the drug;
   or
- iv. the pharmacist or the rural permit holder is unable to obtain a childresistant package for the drug because a supply of those packages is not reasonably available.

# Duty to warn when child-resistant packaging not used

- 7.4 If a drug is not dispensed in a child-resistant package, the pharmacist or the rural permit holder who dispenses the drug must be satisfied that:
  - a) the patient has been warned of the risks of not using a child-resistant package, or
  - b) the patient is aware of the associated risk.

# Proper labeling

- 7.5 A pharmacist or a rural permit holder who dispenses a drug must ensure that the container in which the drug is dispensed has a label that is clearly legible and includes the following:
  - a) the name of the patient for whom the drug is dispensed;
  - b) the name, address and telephone number of the pharmacy or rural dispensary;
  - c) the name of the prescriber of the drug;
  - d) a description of the drug in English by:
    - i. generic name, strength and the identity of the manufacturer for single entity drugs;



- ii. generic name, strength and the identity of the manufacturer for combination drugs, where possible, or the brand name and strength;
- iii. name of compounded drugs or ingredients and strength;
- e) instructions for the use of the drug;
- f) a unique prescription number;
- g) the date the drug was dispensed;
- h) the quantity of the drug dispensed; and
- ) the number of refills remaining if applicable.

#### Name of the pharmacy or rural dispensary to be used

7.6 The name of the pharmacy or rural dispensary under Standard 7.5(b) must be the name provided on the application for pharmacy or rural dispensary licence or another name approved by the registrar.

# Special circumstances when a DIN may be used

- 7.7 Despite Standard 7.5(d), a pharmacist or rural permit holder may use, only a Drug Identification Number (DIN) to identify the drug on the label in circumstances where:
  - a) it is in the best interests of the patient or required for the purpose of a medical or scientific investigation; and
  - b) the pharmacist or rural permit holder has consulted with the prescriber.



# Procedure if it is not practical to affix prescription label to drug package

- 7.8 When it is not practical to affix the prescription label to the drug package, a pharmacist or a rural permit holder who dispenses the prescription must ensure that:
  - a) the prescription label is affixed to the outer container; and
  - b) another label is attached to the drug package containing, at a minimum, the patient's name, the name of the drug and the drug strength.

# Procedure if it is not practical to affix prescription directions on the drug package

7.9 When it is not possible to place complete directions for use on the prescription label, the pharmacist or the rural permit holder who dispenses the prescription must ensure that complete written directions are provided on an instruction sheet accompanying the drug.

#### Labeling for a scientific or medical investigation

7.10 Despite Standard 7.5, if a drug is dispensed as a part of an official scientific or medical investigation, the drug container may be labeled in a manner appropriate to the investigation as long as the information on the label ensures that the contents can be readily identified in an emergency.



## Labeling to assist patients

7.11 Subject to meeting the requirements of Standard 7.5, a pharmacist or a rural permit holder may use a form of label that provides additional information or forms of information to facilitate understanding by patients with special needs, including visually impaired or non-English speaking patients.

# Labeling to ensure that humans do not use drugs, etc. intended for animals

7.12 In addition to compliance with labeling requirements for human products set out above, a pharmacist or a rural permit holder must ensure that all products, including drugs, compounded and sold for veterinary use are labeled "For Veterinary Use Only."

#### Exemption in institution pharmacy

7.13 Standards 7.5 to 7.11 inclusive do not apply if a drug is dispensed to a patient in a health care facility.

## Completing the final check

7.14 A pharmacist or a rural permit holder who dispenses a drug must perform a final check in order to be satisfied that each step in the dispensing process has been completed properly by verifying that:



- a) the drug dosage form, strength, manufacturer and quantity dispensed are correct according to the prescription;
- b) the prescription label is accurate according to the prescription and contains the information required under this standard and under federal and territorial legislation; and
- c) appropriate auxiliary instruction labels are affixed.
- 7.15 Whenever possible, a final check must be performed by a pharmacist or a rural permit holder who did not enter the prescription into the dispensing software system or select the drug from stock.

### Requirement for an audit trail of the dispensing process

- 7.16 A pharmacist or a rural permit holder who engages in dispensing must ensure that their dispensing activities are recorded in a clear audit trail that identifies:
  - all individuals who were involved in the processing of a prescription and dispensing of the drug; and
  - b) the role of each individual.
- 7.17 If more than one regulated member is involved in dispensing a drug, they must work together to ensure that:
  - a) the role and responsibility of each regulated member is clear;
  - b) each step required to be performed is properly performed; and
  - c) the audit trail clearly identifies the regulated member that fulfilled each role and responsibility.



# STANDARD 8 Release of drugs and providing patients with sufficient information

Each time a pharmacist or a rural permit holder dispenses a Schedule 1 drug pursuant to a prescription, or sells a Schedule 2 drug, the pharmacist or the rural permit holder must confirm the patient's identity, and a pharmacist or a rural permit holder must provide the patient with sufficient information to enable the patient to receive the intended benefit of the drug therapy.

#### **APPLICATION OF STANDARD 8**

# Confirmation of patient's identity when a drug is dispensed or sold

- 8.1 Before the release of a drug provided under a prescription or the sale of a
   Schedule 2 drug, the pharmacist or the rural permit holder who releases the drug
   must ensure communication occurs with the patient to confirm:
  - a) the identity of the patient;
  - b) the identity of the drug being dispensed or sold; and
  - c) refill information, if applicable.



## Circumstances in which a dialogue is required

- 8.2 A pharmacist or a rural permit holder must enter into a dialogue with a patient:
  - a) when a Schedule 1 drug is dispensed to the patient for the first time;
  - b) when a Schedule 2 drug is sold to the patient for the first time;
  - d) if the patient requests information; and
  - d) if, in the pharmacist's or the rural permit holder's professional opinion, a dialogue is required to:
    - i. provide the patient with sufficient information to enable the patient to receive the intended benefit of the drug therapy; or
    - ii. avoid, resolve, or monitor a drug therapy problem.
- 8.3 Despite Standards 8.1 to 8.2, a communication or dialogue with a patient may not be required if the drug being dispensed or sold will only be administered by or under the supervision of a regulated health professional acting within the scope of their profession.

### Dialogue to be specific to the patient

- 8.4 The pharmacist or a rural permit holder must:
  - a) focus the dialogue on the particular patient's condition and needs;
  - b) assess the patient's level of understanding; and
  - c) endeavour to respond to the patient at the appropriate level.



# Required elements of the dialogue when a drug is dispensed or sold to a patient for the first time

- 8.5 The dialogue under Standard 8.2(a) or (b) must include:
  - a) procedures to be followed for the proper administration or use of the drug;
  - b) instructions for proper drug storage, handling and disposal;
  - common or important adverse effects that may apply to the patient and recommendations to minimize the risk associated with them;
  - d) signs and symptoms that indicate a therapeutic response, a therapeutic failure or an adverse reaction;
  - e) cautions regarding activities, food or other drugs that:
    - i. may affect the therapeutic effect of the drug, or
    - ii. pose a risk to the patient in conjunction with the drug; and
  - f) when it is necessary to seek additional care or advice.

### Professional judgment to guide pharmacist or rural permit holder in other circumstances when a dialogue is required

8.6 In the case of a dialogue under Standards 8.2(c) or (d), the dialogue must include those components of Standard 8.5 that, in the professional opinion of the pharmacist or rural permit holder, are applicable to the patient.

#### Use of written materials

8.7 A pharmacist or rural permit holder may provide written information to a patient to enhance understanding about the patient's drug therapy, but the written



materials cannot be used to replace the dialogue required under Standards 8.1 and 8.2.

#### Written materials must be specific to the patient

- 8.8 Subject to Standard 8.7, written materials provided to a patient must specifically address the patient and the patient's needs.
- 8.9 A pharmacist or a rural permit holder may provide written materials that are general in nature if the pharmacist or rural permit holder identifies those portions of the information that are relevant to the patient.
- 8.10 If a patient has special needs, including a hearing impairment or inability to speak English, the pharmacist or rural permit holder may use appropriate written materials to assist in counseling the patient.



# STANDARD 9 Offer assistance with Schedule 3 products

A pharmacist or a rural permit holder must take reasonable steps to offer assistance to a patient who wishes to purchase a Schedule 3 drug or a health care product, aid, or device.

#### **APPLICATION OF STANDARD 9**

- 9.1 A pharmacist or a rural permit holder must be available and accessible to a person who wishes to purchase a Schedule 3 drug or a health care product, aid or device.
- 9.2 A pharmacist or a rural permit holder must take reasonable steps to enter into a dialogue with or provide information to a person who:
  - a) requests a Schedule 3 drug or a health care product, aid or device;
  - b) requests assistance in making a choice about a Schedule 3 drug or a health care product, aid or device;
  - appears to be having difficulty in making a choice about a Schedule 3 drug or a healthcare product, aid or device;
  - d) is observed to be making purchases of a Schedule 3 drug or a healthcare product, aid or device in a quantity or at a frequency that is therapeutically inappropriate; or



- e) the pharmacist or a rural permit holder recognizes as someone who may face a risk from the selection or use of a Schedule 3 drug or a health care product, aid or device.
- 9.3 A pharmacy or rural dispensary employee must refer to the pharmacist or rural permit holder:
  - a) anyone the employee recognizes as someone who requires assistance with or may face a risk from the selection or use of a Schedule 3 drug; and
  - b) any questions that require therapeutic knowledge, clinical analysis or assessment.



# STANDARD 10 Compound according to written formula and process

Each time a pharmacist or a rural permit holder compounds a drug, the pharmacist or the rural permit holder must ensure that the compounded drug is prepared according to a written compounding formula, and a written preparation process.

#### **APPLICATION OF STANDARD 10**

# Rural permit holder restrictions in relation to compounding

10.1 A rural permit holder may only compound a drug if the compounding is simple and uncomplicated. For greater clarity this means to perform non-sterile compounding of two non-hazardous creams or ointments for topical use.

# Requirements in relation to the compounding formula and preparation process

10.2 The formula must include a calculation of the amount of each ingredient and a description of the process of compounding that is specific enough to allow the process to be replicated in formulation and production.



## Reputable source required for the formula

10.3 Whenever possible, a pharmacist or a rural permit holder who compounds a drug must do so according to a compounding formula from a reputable source such as a pharmacy text or peer-reviewed published journal.

### Requirements if no formula is available

- 10.4 If no formula is available, a pharmacist must use the pharmacist's pharmaceutical knowledge, including but not limited to knowledge in pharmaceutics, pharmacology, medicinal chemistry and therapeutics to create a formula and reduce it to writing.
- 10.5 If no formula is available, a rural permit holder must refer the patient to a pharmacist

#### Written preparation process to be followed

- 10.6 Whenever possible, a pharmacist or a rural permit holder who compounds a drug must ensure that deviations from the written preparation process are avoided.
- 10.7 If a deviation from the process is necessary, a pharmacist must use the pharmacist's pharmaceutical knowledge, including but not limited to knowledge in pharmaceutics, pharmacology, medicinal chemistry and therapeutics to ensure the deviation is appropriate and will not negatively impact the stability or therapeutic effectiveness of the preparation.



10.8 If a deviation from the process is necessary, a rural permit holder must refer the patient to a pharmacist

#### Documenting deviations from the written preparation process

10.9 A pharmacist who deviates from the written process while preparing a compound must ensure that the deviation and the rationale for it are documented.

#### Approved ingredients to be used in compounding

- 10.10 A pharmacist or a rural permit holder who compounds a drug must ensure that all ingredients used in compounding have an approved designation of standard of quality such as:
  - a) British Pharmacopeia (BP);
  - b) United States Pharmacopeia (USP); or
  - c) National Formulary (NF)

unless such a designation does not exist for the ingredient.

#### Beyond-use date to be assigned to a compounded drug

- 10.11 A pharmacist or a rural permit holder who compounds a drug must ensure that a beyond-use date based upon a reputable source of information such as a pharmacy text or a peer-reviewed published journal is assigned to each compounded drug.
- 10.12 If no reputable source of information for a beyond-use is available, a pharmacist must use the pharmacist's pharmaceutical knowledge, including but not limited



to knowledge in pharmaceutics, pharmacology, medicinal chemistry and therapeutics to determine an appropriate beyond-use date.

10.13 If no reputable source of information for a beyond-use is available, a rural permit holder must obtain an appropriate beyond-use date from a pharmacist.

#### Additional documentation requirements for compounded drugs

- 10.14 In addition to the documentation requirements for dispensing a drug in Standards 16.1 and 16.2, a pharmacist or a rural permit holder who compounds a drug must ensure that a record is created that includes the:
  - a) name, lot number, expiry date and quantity of each ingredient used to prepare the compounded drug;
  - b) formula used to prepare the compounded drug;
  - c) beyond-use date assigned to the compounded drug; and
  - d) a clear audit trail that identifies all individuals who were involved in the preparation and verification of the compounded drug, and the role of each individual.

#### Requirements in relation to sterile products

10.15 A pharmacist who engages in sterile compounding of drugs or mixing other products for parenteral or ophthalmic use, must do so in an environment and according to procedures that meet the requirements of a reputable source such as the Canadian Society of Hospital Pharmacists (CSHP), American Society of Health System Pharmacists, or the United States Pharmacopeia (USP).



### Duty regarding final check

- 10.16 A pharmacist or a rural permit holder must perform a final check of all compounded drugs to be satisfied that each step in the compounding process has been completed accurately by verifying that:
  - a) the drug, strength, manufacturer and quantity compounded are correct;
  - b) the compound was correctly prepared according to the written formula and process;
  - c) calculations and measures were completed accurately;
  - d) the label includes the information required in these standards; and
  - e) the package and packaging material are appropriate to protect the compounded product from light and moisture as necessary and to minimize the potential for interaction between a drug or health care product and the container.
- 10.17 Whenever possible, a final check of a compounded product must be performed by a pharmacist or a rural permit holder who did not prepare the label, complete calculations, select the ingredients from stock or prepare the compound.



# STANDARD 11 Comply with regulatory framework if prescribing (excluding initial prescribing)

A pharmacist who prescribes a drug must understand the regulatory framework in relation to pharmacist prescribing and must comply with it.

#### **APPLICATION OF STANDARD 11**

- 11.1 A pharmacist must understand the restrictions and requirements applicable to prescribing by pharmacists set out in these standards and Section 3 of the Pharmacists Regulation including adapting a prescription (s3(1)j), 3(4),(5),(6) and 3(7)(b)
- 11.2 A pharmacist who chooses to engage in prescribing must prescribe in accordance with these standards.

## Adapting a prescription

- 11.3 In accordance with Standard 12, a pharmacist may prescribe a drug by adapting a prescription from another prescriber by:
  - a) altering the dosage, route of administration, formulation or regimen;
  - b) substituting another drug that is expected to have a similar therapeutic effect; or
  - c) extending or renewing a prescription to ensure continuity of care.



## Prescribing only for approved uses of drugs

- 11.4 A pharmacist must not prescribe a drug unless the intended use:
  - a) is an indication approved by Health Canada;
  - b) is considered a best practice or accepted clinical practice in peer-reviewed clinical literature; or
  - c) is part of an approved research protocol.

## Fundamentals of prescribing

- 11.5 A pharmacist must only engage in prescribing a drug where the pharmacist:
  - a) has or develops a professional relationship with the patient;
  - b) has adequate knowledge and understanding of the condition being treated and the drug being prescribed;
  - c) has adequate information about the patient's health status and the disease or condition being treated;
  - d) takes reasonable steps to be satisfied that the patient has enough information to participate in the decision-making process and obtains the patient's informed consent to prescribe;
  - e) is satisfied that the patient is not inappropriately seeking drug therapy from the pharmacist in circumstances where that therapy has been refused by another prescriber; and
  - f) takes responsibility for the prescribing decision.



# Duty to inform other health professionals

- 11.6 A pharmacist who prescribes a drug must communicate as soon as reasonably possible to any regulated health professionals whose care of the patient may be affected by their prescribing decision:
  - a) that they have prescribed for the patient;
  - b) the type and amount of the drug prescribed;
  - c) the rationale for prescribing the drug;
  - d) the date the drug was prescribed; and
  - e) instructions given to the patient, if applicable.

#### Obligation to document prescribing process and decisions

- 11.7 A pharmacist who prescribes a drug must reduce the prescription to writing in a clear, concise and easy-to-read format that includes all information required in a complete prescription as outlined in Standard 6.7.
- 11.8 A pharmacist who prescribes a drug must document in the patient's record:
  - a) the prescribing decision, the rationale for it and the information required in Standard 11.6;
  - b) a follow-up plan; and
  - c) a record of the notification of any other health professional.



# STANDARD 12 Follow proper procedures when adapting a prescription

Pharmacists who adapt an existing prescription under Sections 3(1) of the *Pharmacists Regulation* must have the original prescription, determine whether adapting the prescription is appropriate in the circumstances, document the adaptation, and inform the original prescriber.

#### **APPLICATION OF STANDARD 12**

- 12.1 A pharmacist who does not have an original prescription, but is 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 an immediate need for drug therapy; and
  - c) it is not reasonably possible:
    - i. for the patient to attend the pharmacy that dispensed the original prescription to obtain a refill or
    - ii. to have the prescription transferred from the pharmacy that dispensed the original prescription

may renew a prescription to ensure continuity of care.



- 12.2 A pharmacist who renews a prescription under Standard 12.1 must:
  - a) see the patient personally before renewing the prescription; and
  - b) only prescribe the minimum amount of the drug necessary to give the patient sufficient time to attend the pharmacy that dispensed the original prescription or see the prescriber of the original prescription.
- 12.3 In addition to the notification and documentation required in Standard 11.7, a pharmacist who renews a prescription under Standard 12.1 must:
  - a) notify a pharmacist at the pharmacy that dispensed the original prescription;
     and
  - b) document that notification.
- 12.4 A pharmacist who receives the notification required in Standard 12.3(a) must document the information on the patient's record.

# Duty to determine whether it is appropriate to adapt a prescription

- 12.5 In determining whether it is appropriate to adapt a prescription, a pharmacist must:
  - a) obtain the patient's informed consent for the adaptation;
  - b) have sufficient knowledge about the patient's health status and the disease or condition being treated to make the decision to adapt the prescription;
  - consider the currency and appropriateness of the prescription being adapted;
  - d) consider appropriate information as described in Standard 3;
  - e) be satisfied that the adaptation will maintain or enhance the effectiveness of the therapy;



- f) be satisfied that the adaptation cannot reasonably be expected to cause a drug therapy problem;
- g) be satisfied that the adaptation will not place the patient at increased risk;
- h) be satisfied that the intended use of any drug prescribed in the process of the adaptation is for an approved use as described in Standard 11.4; and
- comply with any directions of Pharmacy Advisory Committee in relation to the adaptation of prescriptions.
- 12.6 A pharmacist may adapt a prescribed scheduled drug, by means of:
  - a) substituting the generic equivalent of the prescribed drug;
  - b) substituting another drug for a prescribed drug, if the substituted drug is expected to deliver a therapeutic effect that is similar to the therapeutic effect of the prescribed drug;
  - c) substituting another dosage form for a prescribed dosage form, if the substituted dosage form is expected to deliver a therapeutic effect that is similar to the therapeutic effect of the prescribed dosage form

# Restrictions on altering dosage, route of administration, formulation or regimen

- 12. 7 As outlined in the Pharmacists Regulation, a pharmacist may alter a dosage, route of administration, formulation or regimen for a prescribed drug, if:
  - a) the strength or formulation of the prescribed drug is not commercially available to the pharmacists or is temporarily unavailable from the supplier at the time of the alteration; or



- b) the alteration will improve the patient's ability to effectively ingest, apply, inhale, insert, instill or inject the drug or to adhere to or tolerate the drug therapy; or
- c) the information provided on the prescription is incomplete and the pharmacist determines the alteration is supported after reviewing historical evidence or consulting the patient and reviewing patient records; or
- d) the alteration will reduce the cost to the patient without reducing the effectiveness of the drug therapy.

#### Restrictions on extending a prescription

- 12. 8 As outlined in the Pharmacists Regulation, a pharmacist can extend the existing prescription beyond the refills authorized by the prescriber who issued the prescription if;
  - a) the prescription has not previously been extended more than once. (For clarity, no more than two extensions);
  - b) it is not reasonably possible for the patient to see the prescriber to renew the prescription or obtain a new prescription before the existing prescription expires;
  - c) the patient has immediate need to continue the drug therapy;
  - d) the amount of the drug prescribed does not exceed the greater of:
    - a. the lessor of the amount identified in the original prescription and the amount required for 30 days of treatment based on the dosage prescribed in the original prescription\*, and

\* Pharmacists must follow restrictions for Opioid Agonist Treatment as developed by the Health and Social Services program areas.



b. the amount contained in the minimum package size that is commercially available to the pharmacist.

#### Duty to document the adaptation

- 12.9 In addition to the requirements for documentation outlined in Standards 11.7 to11.9, a pharmacist who adapts a prescription must:
  - a) provide a clear reference on the new prescription to the original prescription; and
  - b) retain both the new prescription and the original prescription where applicable.

# Circumstances that do not require notification to the original prescriber

- 12.10 Despite Standard 11.7, notification of the original prescriber and other health professionals is not required:
  - a) for the substitution of a generic drug for a prescribed drug, unless the prescriber has directed that there be no substitutions on the original prescription; or
  - b) for the substitution of one dosage form for another dosage form, unless the dosage form change requires a change in regimen or dose.



# STANDARD 13 Separate prescribing and dispensing

A physician who prescribes a drug must not dispense the drug himself or herself, unless there is no other rural permit holder available to dispense the drug

#### **APPLICATION OF STANDARD 13**

## Same rural permit holder should not prescribe and dispense

- 13.1 A rural permit holder who dispenses a drug that the rural permit holder himself or herself as a physician has prescribed must:
  - a) have advised the patient that the patient may choose to have the prescription dispensed by a pharmacist at a pharmacy;
  - b) take reasonable steps to be satisfied the patient has enough information to participate in the decision-making process;
  - c) post this information in the rural dispensary in a location and clearly visible to the patient;
  - d) obtain the patient's informed consent to dispense the drug; and
  - e) document compliance with each step of the dispensing process required under Standard 7.



# STANDARD 14 Ensure proper procedures and environment when administering a drug or vaccine

A pharmacist who administers a drug or vaccine must: have policies and procedures for handling emergencies, and ensure that the environment in which the drug or vaccine is to be administered is appropriate.

#### **APPLICATION OF STANDARD 14**

Policies and procedures to be developed and updated

14.1 A pharmacist who administers a drug or vaccine must have in place and be prepared to implement current policies and procedures for handling emergencies.

# Obligation to review policies and procedures

14.2 A pharmacist who administers a drug or vaccine must, at a minimum, review the policies and procedures required under Standard 14.1 annually.



# Environment within which drugs or vaccines will be administered

14.3 A pharmacist who administers a drug or vaccine must ensure that the environment within which the drug or vaccine will be administered is clean, safe, appropriately private and comfortable for the patient.



# STANDARD 15 Ensure patient safety when administering a drug or vaccine

A pharmacist who administers a drug, or vaccine must have proper regard for the interests of the patient and take all steps necessary to ensure that the drug or vaccine is administered safely.

#### **APPLICATION OF STANDARD 15**

#### Steps required for the safe administration of a drug or vaccine

- 15.1 A pharmacist who administers a drug or vaccine to a patient must:
  - a) obtain informed consent from the patient;
  - b) be satisfied that there has been compliance with Standard 6 in relation to the appropriateness of the drug or vaccine that will be administered; and
  - c) take appropriate steps to ensure the patient is given the right drug or vaccine,for the right reason, in the right dose, at the right time, using the right route.



- 15.2 In addition to the requirements in Standard 15.1, a pharmacist who is authorized to administer drugs by injection who administers an injection to a patient must:
  - a) ensure that:
    - i. there is ready access to drugs and health care products, aids and devices used to treat adverse reactions to injectable drugs and vaccines; and
    - ii. the pharmacist is trained to administer the drugs and use the health care products, aids and devices used to treat reactions to injectable drugs and vaccines, and to manage reactions to injectable drugs and vaccines;
  - b) be satisfied that the drug or vaccine to be administered:
    - i. has been prepared for administration using aseptic technique,
    - ii. is stable, and
    - iii. has been stored and labeled appropriately prior to and following reconstitution or mixing,
  - c) observe routine precautions for infection control; and
  - d) use aseptic technique.

#### Routine precautions for infection control defined

- 15.3 For the purpose of Standard 15(2)(c), routine precautions for infection control include precautions to help prevent the spread of infection, including but not limited to:
  - a) handling all body fluids and tissues as if they were infectious, regardless of the patient's diagnosis;



- b) washing hands before and after caring for the patient, and after removing gloves; and
- c) wearing gloves when required to prevent contact with body fluids, excretions or contaminated surfaces or objects.

#### Steps required after administration

- 15.4 Following the administration of a drug or vaccine, a pharmacist must:
  - a) ensure the patient is appropriately monitored;
  - b) respond appropriately to complications of therapy if they arise;
  - c) ensure devices, equipment and any remaining drug or vaccine is disposed of safely and appropriately;
  - d) document the administration in the patient record as required in Standard 16 and Appendix A; and
  - e) provide relevant information to other regulated health professionals and provincial health agencies as appropriate.

### No injection for a child younger than five years

15.5 A pharmacist authorized to administer drugs by injection must not administer an injection to a child younger than five years old.



# STANDARD 16 Create and maintain patient records

A pharmacist and a rural permit holder must create and maintain patient records for pharmacy services provided by that pharmacist or rural permit holder.

#### **APPLICATION OF STANDARD 16**

#### Transaction record

- 16.1 Each time a pharmacist or a rural permit holder dispenses a Schedule 1 drug, the pharmacist or the rural permit holder must ensure that a written transaction record is created that includes:
  - a) the name of the patient for whom the drug was dispensed;
  - b) the name of the prescriber of the drug;
  - c) the date the drug was dispensed;
  - d) the name, strength, and dosage form of the drug dispensed;
  - e) the DIN of the drug dispensed;
  - f) the quantity of drug dispensed;
  - g) route of administration and directions for use; and
  - h) a unique prescription and transaction number.



## Duty to enter information in a patient's record

- 16.2 A pharmacist or a rural permit holder who:
  - a) dispenses a Schedule 1 drug;
  - b) sells a Schedule 2 drug; and

a pharmacist who:

- a) prescribes a Schedule 1 drug;
- b) administers a drug; or
- c) establishes a follow-up plan or other patient care plan

must ensure that an appropriate entry is made in the patient's record.

#### Requirements of a patient record

- 16.3 A patient record must include:
  - a) patient demographics;
  - b) a profile of drugs provided; and
  - c) a record of care provided including but not limited to:
    - i. drug therapy problems identified and/or interventions, monitoring plans or actions related to drug therapy problems,
    - ii. prescriptions written,
    - iii. drugs or vaccines administered,
    - iv. other information related to patient care practice.
- 16.4 In addition to the requirements set out in this standard, a patient record must meet the requirements of Appendix A.



## Amending a patient record

- 16.5 When a record of patient care is amended after the fact to correct an error the following must be identifiable:
  - a) the original entry;
  - b) the identity of the pharmacist or the pharmacy technician who made the alteration; and
  - d) the date of the alteration.

#### Maintaining patient records

- 16.6 A pharmacist or a rural permit holder must keep the patient record accurate and current with regard to the pharmacist's or the rural permit holder's activities.
- 16.7 A pharmacist or a rural permit holder must keep the patient record for at least 10 years from the date of last entry or, in the case of minors, 10 years from the date the patient would have reached the age of majority (19 years in the Yukon).
- 16.8 A pharmacist may keep physical or electronic patient records as appropriate according to the pharmacist's professional judgment. In either case, the pharmacist must ensure safeguards are in place to protect the confidentiality and security of patient records.



## Form of patient record

- 16.9 The patient record must be kept:
  - a) in a clear, concise and easy-to-read format; and
  - b) in a manner that facilitates sharing, ease of use and retrieval of patient information by authorized individuals.
- 16.10 A pharmacist or a rural permit holder who provides professional services in an institution or in an environment with other regulated health professionals who have a shared medical or patient record may:
  - a) document the pharmacist's or rural permit holder's activities in the institution's medical record or the shared medical or patient record for the patient; and rely upon documentation within the drug distribution system and the institution's medical record or the shared medical or patient record if the pharmacist or rural permit holder is satisfied that the information required in Standards 16.1, 16.3, and 16.4 is available to the pharmacist or the pharmacy technician.
- 16.11 A pharmacist or a rural permit holder who provides professional services in an environment with other regulated health professionals who share a medical or patient record must:
  - a) determine ownership of the patient record; and
  - b) collaborate with other regulated health professionals to ensure the creation and maintenance of patient records meet the requirements outlined in these standards.



- 16.12 A pharmacist or a rural permit holder who provides professional services outside of a pharmacy, rural dispensary, an institution or an environment with other regulated health professionals who share a medical or patient record must:
  - a) create and maintain a patient record that meets the requirements for format and content outlined in these standards and all other applicable legislation;
  - b) ensure the records are created, stored and maintained in a manner that meets or exceeds the requirements outlined for record keeping in the Standards for the Operation of Licensed Pharmacies and Rural Dispensaries;
  - c) retain the record for a period of not less than 10 years after the last pharmacy service or two years past the age of majority of the patient, whichever is greater; and
  - d) create a plan for transfer of the records when they cease the practice.
  - e) The plan must include provision of notice to the college of the location of the patient records and how they may be accessed when the transfer occurs.

#### Transfer of prescriptions

- 16.13 Only a pharmacist or rural permit holder may transfer a prescription for a prescription drug to another pharmacist as per the Food and Drug Act and Regulations and the Controlled Drugs and Substances Act and Regulations. This task must not be delegated.
- 16.14 Upon request, a pharmacist or rural permit holder must transfer to a pharmacy licensed in Canada a prescription for a drug, subject to 16.13(a).



- 16.15 When transferring a prescription, the pharmacist or rural permit holder must:
  - a) confirm that the prescription may be legally transferred:
    - Prescriptions for targeted substances under the Controlled Drugs and Substances Act can only be transferred if they have not previously been transferred (Benzodiazepines and Other Targeted Substances Regulations, s. 54);
  - b) provide to the receiving pharmacist:
    - i. a copy of the prescription as written by the prescriber or as reduced to writing in the case of verbal prescriptions,
    - ii. the number of authorized refills remaining,
    - iii. the date of the last refill, the name and address of the pharmacist or rural permit holder that is transferring the prescription, and
    - iv. any other information that the transferring pharmacist or rural permit holder deemed necessary; and
  - c) render the prescription inactive to ensure that no further sales are made under the prescription and the prescription is not transferred to another pharmacist; and
  - d) document that the prescription has been transferred in the patient record including:
    - i. the name and location of the pharmacist or rural permit holder to whom the prescription was transferred, and
    - ii. the name of the pharmacist or rural permit holder transferring the prescription.



# STANDARD 17 Do not accept drugs or health products for reuse

Neither a pharmacist nor a rural permit holder may accept the return of a drug or a health care product, aid, or device for reuse.

#### **APPLICATION OF STANDARD 17**

- 17.1 After a drug, health care product, aid or device has been dispensed or sold, neither a pharmacist nor a rural permit holder may:
  - a) accept that drug or health care product for reuse, or
  - b) reuse that drug or health care product.
- 17.2 Despite Standard 17.1, a pharmacist or a rural permit holder may repackage a drug, health care product, aid or device for reuse if:
  - a) the drug, health care product, aid or device will be reused only for the patient for whom it was originally dispensed; or
  - b) the drug or health care product, aid or device is in a tamper-resistant package and was provided to a health care facility and maintained under the control of a regulated health professional at all times while in that facility; and



- c) the pharmacist or rural permit holder is confident that the drug or healthcare product:
  - i. has not been tampered with, and
  - ii. has been stored in a manner that would not adversely affect its stability.
- 17.3 Standard 17.1 does not apply to a drug that was dispensed for a patient by an institution pharmacy, as defined in the Pharmacy and Drug Act, if the pharmacist is satisfied that the drug distribution system is adequate to ensure the integrity of the drug and the safety of any patient who may receive the drug.



# STANDARD 18 Provide direction and supervise others responsibly

A pharmacist or rural permit holder who provides direction to an employee must do so in accordance with these standards. A pharmacist or rural permit holder who supervises others in the practice of pharmacy must do so in accordance with Section 43 of the *Pharmacists Regulation*, ensure that the person being supervised acts within the limits established by the *Pharmacists Regulation*, and remain responsible for the delivery of all components of any restricted activity that require the professional skills and training of the pharmacist or rural permit holder.

### **APPLICATION OF STANDARD 18**

### **Providing direction**

- 18.1 A pharmacist or rural permit holder who provides direction to an employee must:
  - a) be engaged in the practice of pharmacy in the same pharmacy as the employee to whom the pharmacist or rural permit holder is providing direction, unless otherwise authorized by the registrar in writing;



- b) be authorized to perform the restricted activities that the employee will provide under the pharmacist or rural permit holder's direction;
- ensure there is a system in place in the pharmacy or rural dispensary to ensure compliance with these standards and the Standards for the Operation of Licensed Pharmacies and Rural Dispensaries including but not limited to:
  - i. ensuring that a pharmacist or rural permit holder or is available to:
    - a. evaluate each prescription;
    - assess each patient, the patient's health history, and medication record and determine that the drug therapy provided is appropriate for the patient;
    - c. counsel the patient and monitor the patient's drug therapy; and
    - d. consult with, provide guidance or provide assistance to the employee if required.

### Supervising pharmacy students and provisional pharmacists

- 18.2 A pharmacist who supervises a pharmacy student or a provisional pharmacist must ensure:
  - a) the pharmacist is registered on the student register or the provisional register; and
  - b) the duties being supervised and the method of supervision are in accordance with the pharmacy student's university training guidelines and directives, or in the case of a provisional pharmacist, a provincial regulator's approved internship program.



18.3 A rural permit holder may not supervise or accept the placement of any pharmacy students, provisional pharmacist or other persons in or recently graduated from a professional training or other program, for training in the practice of pharmacy or the provision of rural permit holder services.

### Supervising employees

- 18.4 A pharmacist or rural permit holder who supervises an employee must ensure that if the employee engages in compounding a drug, providing a drug for sale, or selling a drug under the pharmacist or rural permit holder's supervision the employee does not engage in any component of the activity which requires the training and skills of a pharmacist or rural permit holder.
- 18.5 An employee engaged in selling a drug or providing a drug for sale must do so under the direct supervision of a pharmacist or rural permit holder and must not engage in any component of those restricted activities other than assisting the pharmacist or rural permit holder by:
  - a) placing a drug into stock;
  - b) entering information into the information management system about the sale of a drug;
  - c) gathering information for submission of an account to an insurance carrier;
  - d) selecting a drug from stock;
  - e) counting and packaging a drug;
  - f) entering information about the sale into the patient record; or
  - g) finalizing the commercial aspects of the sale.



- 18.6 An employee engaged in compounding a drug must do so under the direct supervision of a pharmacist or rural permit holder and must not engage in any component of those restricted activities other than by assisting the pharmacist or rural permit holder by:
  - a) selecting a drug from stock;
  - b) measuring the quantities of the drugs to be compounded;
  - d) physically mixing the drugs; or
  - d) entering information into the information management system about the act of compounding.



# STANDARD 19

# Protect patient safety when repackaging

A pharmacist or a rural permit holder who repackages drugs must take appropriate steps to protect patient safety.

### **APPLICATION OF STANDARD 19**

### Duty regarding audit trail

- 19.1 A pharmacist or a rural permit holder who repackages a drug must ensure that in respect of that drug there is sufficient documentation to provide a clear audit trail of the repackaging process.
- 19.2 The documentation required under Standard 19.1 must identify:
  - a) drug information from the original container including:
    - i. DIN, NPN or HN,
    - ii. lot number,
    - iii. expiry date; and
  - b) all individuals involved in the repackaging and verification process and the role of each individual.



### Duty regarding labeling

- 19.3 A pharmacist or a rural permit holder who dispenses or sells a repackaged drug must ensure that each repackaged drug has a label affixed to the package that meets the requirements of a prescription label required under Standard 7 or that explicitly identifies the following:
  - a) a description of the drug, in English, by:
    - i. generic name, strength and the identity of the manufacturer for a single-entity drug, or
    - ii. generic name, strength and the identity of the manufacturer for a combination drug, where possible, or the brand name and strength;
  - b) the size of the package or quantity;
  - c) a lot number that links to the audit trail described in Standard 19.1; and
  - d) an expiry date for the drug.

### Duty regarding directions

19.4 A pharmacist or a rural permit holder who engages in repackaging drugs for sale to patients must ensure that the label includes a direction statement which has on it the words:

"Take or use [insert the manufacturer's suggested doses or use] or as directed by the prescriber."



### Duty regarding final check

- 19.5 A pharmacist or a rural permit holder must perform a final check of all repackaged drugs or health care products to be satisfied that each step in the repackaging process has been completed accurately by verifying that:
  - a) the drug or health care product, dosage form, strength, manufacturer and quantity packaged is correct;
  - b) the information on the label is accurate according to the original container, including the drug, dosage form, strength and manufacturer;
  - c) the label includes the information required in these standards; and
  - d) the package and packaging material are appropriate to protect the drug or health care product from light and moisture as necessary and to minimize the potential for interaction between a drug or health care product and the container.
- 19.6 Whenever possible, a final check of repackaged products must be performed by a pharmacist or rural permit holder who did not create the label or select the drug from stock.

### Special labeling requirements for individually packaged drugs

- 19.7 A pharmacist or a rural permit holder must ensure that, when dispensed to a patient, individually packaged medications which include a drug (such as a lollipop) are:
  - a) individually labeled with the name of the drug or compound, lot number and expiry date; and
  - b) put in a larger container that bears a prescription label.



# STANDARD 20

## Initial prescribing

Pharmacist prescribing provides key benefits to the healthcare system by decreasing pressures on emergency rooms and doctors' offices. It enables pharmacists to apply their expertise in drug therapy management to care for their patients by prescribing at initial access for:

- Listed Minor Ailments as per schedule A of the Regulation to Amend the Pharmacists Regulation, O.I.C 2022/113 of the Health Professions Act.
- Listed Preventable Diseases as per schedule B of the Regulation to Amend the Pharmacists Regulation, O.I.C 2022/113 of the Health Professions Act.
- Listed Designated Drugs as per schedule C of the Regulation to Amend the Pharmacists Regulation, O.I.C 2022/113 of the Health Professions Act.

Pharmacists must use their professional judgment to determine whether it is appropriate and in the best interests of the patient to prescribe at initial access in accordance with this standard.

### 20 Prescribing at initial access

### Authorized Drugs

- 20.1 A pharmacist only prescribes a drug for an indication approved for the product by Health Canada, or for an off-label indication, in accordance with Standards 1 – 19 of this document, if the pharmacist is satisfied that the indication is:
  - a. generally accepted practice referenced in peer-review clinical literature; or
  - b. consistent with a research protocol in which the patient is enrolled.

### Competencies, Knowledge and Professional Ethics

20.2 When a pharmacist prescribes:

They are responsible for their prescribing decisions and any related actions, omissions and impacts. This includes all decisions they make, including not to prescribe.

When deciding to prescribe a drug, the pharmacist:

- 20.2.1 is satisfied that they have the requisite competency to prescribe in that given circumstance, including taking reasonable steps to assess their competence against current best practices; and
- 20.2.2 recommends that the patient include another healthcare provider in the care of the condition, when appropriate.



20.3 A pharmacist does not prescribe for themselves under any circumstance.

- 20.4 A pharmacist does not prescribe for an immediate family member, except in extraordinary circumstances when no other prescriber is readily available and drug treatment is required to avoid serious deterioration to the patients' health. If prescribing in this situation, the pharmacist documents the exceptional circumstances, including their relationship to the patient.
- 20.5 When the same pharmacist both prescribes and dispenses a drug, the pharmacist provides information to the patient(s) about the benefits of involving another pharmacist in the process to mitigate the risks of confirmation bias. Patients should be offered the option of having the prescription dispensed by a different pharmacist. If the patient chooses to fill the prescription at another pharmacy, the pharmacist supports the patient's decision.
- 20.6 A pharmacist must have the appropriate endorsements on their license before prescribing at initial access. Pharmacists must apply to add initial prescribing as an endorsement to their Yukon license.
  - 20.6.1 Pharmacists applying for an endorsement to prescribe vaccination for the preventable diseases listed in Schedule B must submit:

Proof of completion of an approved travel vaccine course. The courses listed below have been approved by the Registrar of Pharmacists. Pharmacists who wish to complete a course that is not listed below must obtain pre-approval from the Registrar.



- a. Health Learning: The Basics of Travel Medicine for Pharmacists and Advanced Travel Health Services;
- or
- b. British Columbia Pharmacy Association: Travel Medicine Program
- 20.6.1.1 A pharmacist providing vaccination must document all immunizations in accordance with the reporting requirements under the Yukon Immunization Program.
- 20.6.2 Pharmacists applying for endorsements under Schedules A and C are not required to submit proof of additional training. It is the pharmacist's responsibility to practice within their scope of professional competence and the requirements under the Health Professions Act, Pharmacists Regulation, Standards of Practice for Pharmacists, and Code of Ethics for Pharmacists.
- 20.6.3 Pharmacists applying to administer drugs by intramuscular or subcutaneous injection pursuant to Standard 1.15 must submit:
  - a. Current certificates in First Aid and Cardiopulmonary resuscitation (CPR); and
  - b. Proof of completion of an approved immunization and injection program.



### Patient involvement

- 20.7 When prescribing, the pharmacist obtains informed and voluntary consent from the patient for prescribing services and decisions.
- 20.8 The pharmacist completes a patient assessment to support their prescribing decisions. The assessment considers, as appropriate and applicable for the prescribing activity, the patient's:
  - a. demographic information;
  - b. physical characteristics, conditions and measurements (i.e. height and weight);
  - c. presenting aliment/condition/disease or drug related problem, including its symptoms, signs, history and any treatment;
  - d. date, extent and results of last assessment of condition;
  - e. laboratory or other diagnostic test results;
  - f. objective and subjective findings;
  - g. diagnosis;
  - h. medical history;
  - i. family medical history;
  - j. current medical conditions, medications, non-medical therapies, healthcare products / devices, and treatments;
  - allergies and intolerances to drugs, excipients, or other substances relevant to drug therapy;



- I. pregnancy and lactation status;
- m. risk factors;
- n. other healthcare providers and individuals involved in providing treatment / care;
- o. personal circumstances, practical needs, values, and preferences; and
- p. other information relevant to the assessment.

As part of the patient assessment, the pharmacist may, with appropriate patient consent, obtain pertinent information from family, friends, caregivers or other healthcare providers.

- 20.9 The pharmacist assesses the patient in-person when prescribing under this Standard, except in extraordinary circumstances when in-person assessment is not reasonably practical. If a pharmacist assesses a patient by any means other than in-person, the pharmacist must document the reason(s) for not conducting the assessment in-person.
- 20.10 The pharmacist bases the prescribing decision and drug selection on patient need, clinical suitability and cost effectiveness in line with the Schedules to the Regulation.
- 20.11 When assessing the patient in order to make decisions about prescribing, the pharmacist conducts in-person discussions about personal health information in a secure, private and professional environment.



## Documentation

- 20.12 The pharmacist documents the prescribing information in a timely manner. Prescribing activities will be documented and maintained as part of the pharmacy's patient record.
  - 20.12.1 The method by which documentation is completed (i.e. electronic or paper based) is left to the professional judgement of the prescribing pharmacist but must be complete enough so that others accessing the patient record will have a clear understanding of the prescribing activities and rationale.
- 20.13 Documentation of general patient information and prescription details may include, as appropriate, the following:

#### General patient information

- a. Name
- b. Contact information
- c. Date of birth
- d. Yukon Health Care Identification Number or other provincial or territorial health card number
- e. Sex / gender
- f. Weight and height
- g. Any known contradictions or allergies / intolerances to drugs, excipients, or other substances related to drug therapy
- h. Medical conditions
- i. Pregnancy and lactation status



j. Other relevant information

#### **Prescription Details**

- a. Date of prescribing decision
- b. Present health ailment/condition/disease or drug related problem including symptoms, signs, history and any treatment
- c. Patient assessment details / findings relevant to the prescribing decision (see 20.7)
- d. Description of prescribing decision, its rationale, and any supporting information / documents
- e. Instructions to the patient
- f. Follow up plan details to allow other healthcare providers or caregivers to monitor patient's progress
- g. Name of prescribing pharmacist
- h. Date and method of notifying other healthcare providers
- i. Patient informed and voluntary consent
- j. Details of subsequent monitoring and follow up
- 20.14 Documentation of prescription orders must include the following:

#### **Prescription Order**

- a. Patient name and address
- b. Patient date of birth or Yukon Health Care Identification Number



- c. Date of prescription
- d. Drug name, strength and dosage form
- e. Quantity
- f. Directions for use and route of administration
- g. Number or refills and intervals between each
- h. Name of prescribing pharmacist
- i. License number of prescribing pharmacist
- j. Contact information for prescribing pharmacist
- k. Signature of prescribing pharmacist

### Follow-up and monitoring

- 20.15 The pharmacist uses professional judgment to establish and document a follow-up plan appropriate to the patient's needs and the prescribing activity in the patient record.
- 20.16 The pharmacist ensures the follow up plan provides enough detail to allow others accessing the patient record to have a clear understanding of the prescribing activities and related follow up.
- 20.17 The pharmacist ensures any patient monitoring required by the follow up plan is completed and the results are documented as appropriate. The pharmacist may arrange for another pharmacist, primary care provider, or specialist to complete the follow-up and monitoring as needed.



## Communicate to the Patient's Circle of Care

- 20.18 The pharmacist communicates the prescribing information to the patient's primary care provider or specialist and must include, at a minimum:
  - a. A clear indication of whether action needs to be taken by the primary care provider or specialists (i.e. response required or for your records)
  - b. Date
  - c. Patient information including name, date of birth and Health care card number
  - d. Relevant patient assessment details
  - e. Prescriptions details
  - f. Pharmacist information, including name, Yukon license number and contact information
  - g. Pharmacy information, including name and contact information.
- 20.19 If the patient does not have a primary care provider or specialist, the pharmacist:
  - a. Provides the prescribing information to the patients; and
  - b. Informs the patient that they will subsequently forward the prescribing information to a primary care provider or specialist, upon the patient's request and direction.



# Appendix A

## Patient record requirements

Element of	Required information	Form of
record		the record
Patient	Patient demographics	Electronic
demographics	a) The patient's name, address and telephone	
	number, ifavailable	
	b) The patient's date of birth	
	c) The patient's personal health number (PHN)	
	d) The patient's sex/gender	
	e) Any known drug allergies, drug sensitivities and	
	other contraindications and precautions	
	f) Disease states and chronic conditions	
	g) Weight and height, if applicable	
	h) Pregnancy and lactation status, if applicable	



Drug profile	Schedule 1 drugs dispensed	Electronic
	a) The name of the patient for whom the drug was	
	dispensed or sold	
	b) The name of the prescriber of the drug	
	c) The date the drug was dispensed or sold	
	d) The name, strength, and dosage form of the	
	drug dispensed or sold	
	e) The DIN of the drug dispensed or sold	
	f) The quantity of drug dispensed or sold	
	g) Route of administration and directions for use	
	h) Unique prescription and transaction numbers	
	i) The number of refills and interval between each	
	refill, if applicable	
Drug profile	Schedule 2 drugs sold	Electronic
	a) The name of the patient for whom the drug was	
	dispensed or sold	
	b) The date the drug was sold	
	c) The name, strength, and dosage form of the	
	drug sold	
	d) The DIN of the drug sold	
	e) The quantity of the drug sold	
	f) A unique prescription or transaction number	
	/ 1 1 1	



Record of	Drug therapy problem identified and/or	Electronic		
care	interventions, monitoring plans or actions related to drug therapy problems	or written		
				a) Drug therapy problem identified including whether it
	is actual or potential			
	b) A summary of information provided to the patient			
	c) A summary of any consultations with other health professionals, if applicable			
	d) A summary of any recommendations made, if			
	applicable			
	e) A follow-up plan that is sufficiently detailed to			
	<ul> <li>monitor the patient's progress and ensure continuity of care by other regulated health professionals or caregivers, if applicable</li> <li>f) Any additional information that is necessary for colleagues to provide care</li> <li>g) The date of the action</li> <li>h) Identification of the pharmacist who made the intervention or provided the care</li> </ul>			
		Record of		Other information
		care	a) Information about prescriptions that were	or written
			invalidated or not filled	
b) A summary of any consultations with other				
regulated health professionals about the patient				
c) Identification of the pharmacist or the pharmacy				
technician who made the entry onto the record of				
care				



Record of	Prescription adapted by a pharmacist	Electronic
care	a) That the prescription has been adapted	or written
	b) The nature of the adaptation	
	c) The rationale for the adaptation	
	d) The date of the adaptation	
	e) Identification of the pharmacist who adapted the	
	prescription	
	f) The date and method of notification of the original	
	prescriber as required under Standard 12.9	
Record of care	Drug prescribed under Section 3(1)(j) of the	Electronic
	Pharmacists Regulation	or written
	a) The circumstances under which the drug was	
	prescribed	
	b) The rationale forprescribing	
	c) A summary of their assessment of the patient	
	d) The completeprescription information as	
	described in Standard 6	
	e) A follow-up plan that is sufficiently detailed to	
	monitor the patient's progress and ensure the	
	continuity of care by other regulated health	
	professionals or caregivers, if applicable	
	f) Any additional information that is necessary for	
	colleagues to provide continuity of care	
	g) The date of the prescription	
	h) Identification of the pharmacist who prescribed	
	i) The date and method of notification of other	
	regulated health professionals	



Record of care	Drug or vaccine administered	Electronic
	a) Drug, dose and route of injection	or written
	b) Site of injection, if applicable	
	c) Patient response	
	d) Patient counseling provided	
	e) Adverse reactions, if any, and management	
	f) Plans for follow up	
	g) Date of administration	
	h) Identification of the pharmacist who	
	administered the drug or vaccine	

