Understanding Alberta’s Drug Schedules
Preface

In May 2002, the provincial drug schedules to the *Pharmaceutical Profession Act* were amended. In April 2007, the Alberta Regulation 66/2007 to the *Pharmacy and Drug Act*, the Scheduled Drugs Regulation, came into force. The changes mean that our schedules are now mostly aligned with the national drug scheduling model developed by the National Association of Pharmacy Regulatory Authorities (NAPRA). Future changes to the schedules will be made by reference to the national model, in accordance with the recommendations of the National Drug Scheduling Advisory Committee (NDSAC).

Drugs which are on the Prescription Drug List to the federal Food and Drug Regulations and in the schedules to the *Controlled Drugs and Substances Act* are included in Schedule 1 of the Scheduled Drugs Regulation.

This guide has been prepared to:

- provide pharmacists and pharmacy technicians with information on the drug schedule harmonization process in Canada,
- describe Alberta’s drug schedules,
- provide a reference to help pharmacists and pharmacy technicians understand the schedules, and
- describe the standards of practice that apply to Schedules 2 and 3.¹

¹ The standards of practice which apply to the non-prescription drug schedules are the *Health Professions Act* and the Standards of Practice for Pharmacists and Pharmacy Technicians, Standards 3, 4, 8, 9, and 18. These standards are included as Appendix A of this guide.
Alberta’s drug schedules – their origin and maintenance

Drug Schedule Harmonization Process
Alberta’s drug schedules are consistent with the national scheduling model described in the May 1995 report from the Canadian Drug Advisory Committee (CDAC), which was approved by the National Association of Pharmacy Regulatory Authorities (NAPRA) in the same year. Included in the CDAC’s report was a list of drugs recommended for each schedule. To ensure ongoing review and maintenance of the drugs listed in the model schedules, NAPRA established the National Drug Scheduling Advisory Committee (NDSAC) in August 1995. NDSAC includes drug experts from across Canada as well as a consumer and a physician. NDSAC's mandate is to advise the provincial pharmacy regulatory authorities on matters relating to the placement of drugs within the national scheduling model and to continually evaluate and maintain the drug scheduling factors within the model.

The CDAC model that NDSAC uses for making drug scheduling recommendations embodies a “cascading principle” in which a drug is first assessed using the factors for Schedule 1. Should sufficient factors pertain, the drug remains in that schedule. If not, the drug is assessed against the factors for Schedule 2, and if warranted it is subsequently assessed against the factors for Schedule 3. Should the drug not meet the factors of any schedule, it becomes unscheduled or non-restricted and available for sale from any retail outlet. This process promotes the listing of drugs in schedules corresponding to the conditions of sale, providing for proper drug use and patient safety.

As a result of applying the cascading principle, four categories of drugs resulted:
- **Schedule 1**: Drugs that require a prescription as a condition of sale.
- **Schedule 2**: Drugs that are available only from the pharmacist and without a prescription. There is no opportunity for patient self-selection.
- **Schedule 3**: Drugs that are available without a prescription from the self-selection area of a pharmacy.
- **Unscheduled**: Drugs not listed in Schedule 1, 2 or 3 that may be sold from any retail outlet.

The CDAC report states that the outcome of drug scheduling should serve the patient in the best and most sensible and reasonable manner possible in light of knowledge and practice. Scheduling factors were developed to reflect an assessment of drug use risk to the public and to establish the level of professional control required to provide safe and effective drug use for patients.

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However, patients have the ultimate responsibility for their health, and they should have access to self-selected drugs for self-medication or access to the selection of non-prescription drugs, with the assistance of a pharmacist. The safety and effectiveness of non-prescription drugs depends on their appropriate use to treat minor ailments. Consultation must be appropriate in level, scope and content to the needs of those seeking assistance.

Because drug scheduling using the cascading principle is based on factors of relative risk associated with taking medications with or without the advice of a health care professional, the standards of practice also reflect this concept. The standards of practice for Schedule 2 drugs include activities that must be undertaken by the pharmacist interacting with a patient desiring to self-medicate with one of these products. As patients may self-select Schedule 3 drugs, it is essential for pharmacists to be available for consultation. Patients should be encouraged to seek consultation on any concerns regarding the safety and/or effectiveness of either Schedule 2 or Schedule 3 drugs. Although the required activities may vary for Schedule 2 and 3 drugs, the consultation process on all non-prescription drugs is very similar.

The Alberta College of Pharmacists will follow NDSAC's recommendations to maintain its provincial drug schedules.

For more information about NDSAC recommendations, please refer to the NAPRA website at www.napra.ca.

Federal and Provincial Regulations
Drugs in Canada are both federally and provincially regulated.

Federal Regulations
Federally scheduled drugs include:
- Narcotics in the Schedule to the Narcotic Control Regulations;
- Controlled substances in Part I, II and III of the Schedule to Part G of the Food and Drug Regulations;
- Benzodiazepines and other targeted substances in the Schedule to the Benzodiazepines and Other Targeted Substances Regulations; and
- Drugs on the Prescription Drug List to the Food and Drug Regulations.

The Prescription Drug List of the Food and Drug Regulations is divided into two separate lists:
1. A list of medicinal ingredients that, when found in a drug, require a prescription for human use
2. A list of medicinal ingredients that, when found in a drug, require a prescription for veterinary use.

If a veterinary drug product is not on the “veterinary use” section of the List, it is considered a non-prescription drug for veterinary use.
**Provincial Regulations**
Since January 1, 1995, Alberta has had three provincial drug schedules.

**Schedule 1**
The drugs included in Schedule 1 require a prescription as a condition of sale, and in a pharmacy must be stored and sold only in the dispensary. Drugs in this schedule include all federally scheduled drugs and certain others, some of which are specific to Alberta. The latter may appear to be non-prescription drugs (as there will be no symbol directly on the drug product label). Pharmacists must be aware of these products to prevent possible sale without a prescription.

Drugs listed in Schedule 1 of the Scheduled Drugs Regulation are subject to all of the same considerations as drugs on the Prescription Drug List to the Food and Drug Regulations (Canada).

The standards of practice that apply to drugs in this schedule are the same standards that apply to all prescription medications.

**Schedule 2**
The drugs listed in Schedule 2 do not require a prescription as a condition of sale. These drugs may be sold only from a licensed pharmacy or an institution pharmacy by a pharmacist, or under the direct supervision of a pharmacist. Schedule 2 drugs must be stored and sold only in the dispensary. Standards of practice for assessment of therapy (Standard 3 and 4), patient counselling (Standard 8) and documentation (Standard 18) apply to Schedule 2 drugs.

**Schedule 3**
The drugs listed in Schedule 3 do not require a prescription as a condition of sale. These drugs may be sold only from a licensed pharmacy or an institution pharmacy. Schedule 3 drugs must be stored and sold only in the patient services area of the pharmacy. A pharmacist must take reasonable steps to offer assistance to a patient who wishes to purchase a Schedule 3 drug. (Standard 9)

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3 Standards of Practice for Pharmacists and Pharmacy Technicians, July 2011
4 Standards for the Operation of Licensed Pharmacies, Standard 4.6
Appendix A - Standards of Practice for Pharmacists and Pharmacy Technicians

STANDARD 3: Pharmacists must consider appropriate information for each patient.

APPLICATION OF STANDARD 3

Duty to consider appropriate information
3.1 A pharmacist must consider appropriate information to assess the patient and the patient’s health history and history of drug therapy each time:
   a) the pharmacist:
      i. prescribes a Schedule 1 drug or blood product;
      ii. conducts a review of a patient’s drug utilization; or
      iii. provides advice to a patient about a drug, a blood product or drug therapy.
   b) the pharmacist or a pharmacy technician practising with the pharmacist:
      i. dispenses a Schedule 1 drug or blood product under a new or a repeat prescription, or
      ii. dispenses or sells a Schedule 2 drug.

3.2 Notwithstanding Standard 3.1(b), a pharmacist may delay the assessment of a patient if the pharmacist 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 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 or blood products being used;
   h) other health care products, aids and devices or other products being used that may affect the pharmacist’s decision;
   i) other health conditions that may affect the pharmacist’s decision; and
   j) any other information that a reasonable pharmacist would require to provide the pharmacist 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.

**Ordering laboratory tests and 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:
   a) order the appropriate laboratory test, or
   b) contact an appropriate regulated health professional and request that the laboratory test be ordered.

3.7 A pharmacist who orders a laboratory test must:
   a) only order laboratory tests that the pharmacist is personally competent to order and interpret;
   b) only order a laboratory test if indicated to assist with the management of drug therapy for a patient;
   c) review alternative sources of current laboratory data for the patient available to the pharmacist before ordering a test for the patient (e.g., electronic health record);
   d) have a system in place to ensure the appropriate follow-up of ordered laboratory testing, which must include arrangements to respond to and act upon any critical lab results that are reported 24 hours per day, 7 days per week;
   e) take appropriate action if the results of a laboratory test that the pharmacist orders are outside the normal or expected range; and
   f) record each laboratory test ordered by the pharmacist and the results of each test on the patient record.

3.8 A pharmacist 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 in Standard 18 and Appendix A,
   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 health care team.

3.9 A pharmacist who receives a request from a patient regarding a laboratory test that the pharmacist did not order must:
   a) only provide results of laboratory tests in accordance with the Information Exchange Protocol of 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.
STANDARD 4: Pharmacists must determine whether a patient has or is likely to have a drug therapy problem.

APPLICATION OF STANDARD 4
Pharmacists’ duty in relation to drug therapy problems

4.1 A pharmacist must consider whether a patient has a drug therapy problem or is likely to have a drug therapy problem, each time:
   a) the pharmacist:
      i. prescribes a Schedule 1 drug or blood product;
      ii. conducts a review of a patient’s drug utilization; or
      iii. provides advice to a patient about a drug, a blood product or drug therapy;
   b) the pharmacist or a pharmacy technician:
      i. dispenses a Schedule 1 drug or blood product pursuant to a new or a refill prescription, or
      ii. dispenses or sells a Schedule 2 drug.
STANDARD 8: Each time a pharmacist or a pharmacy technician dispenses a Schedule 1 drug or blood product pursuant to a prescription, or sells a Schedule 2 drug:
   a) the pharmacist or the pharmacy technician must confirm the patient’s identity, and
   b) a pharmacist 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 or blood product is dispensed or sold

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

Release of a drug by a pharmacy technician

8.2 In addition to the requirements outlined in Standard 8.1, a pharmacy technician who releases a drug or blood product provided under a prescription or sells a Schedule 2 drug must:
   a) ensure that a pharmacist has:
      i) assessed the patient, the patient’s health history and medication record and has determined that the drug therapy is appropriate for the patient;
      ii) evaluated the prescription when the drug is dispensed under a prescription; and
      iii) provided information as required in Standard 8.3;
   b) inform the patient that a pharmacist is available to speak with them if desired, and
   c) refer the patient to the pharmacist for a dialogue if:
      i) the patient requests a dialogue with the pharmacist;
      ii) the patient asks questions that require therapeutic knowledge, clinical analysis or assessment;
      iii) in the pharmacy technician’s professional opinion, a dialogue is required to:
         (1) provide the patient with sufficient information to enable the patient to receive the intended benefit of the drug therapy; or
         (2) avoid, resolve, or monitor a drug therapy problem.

Circumstances in which a dialogue is required

8.3 A pharmacist must enter into a dialogue with a patient:
   a) when a Schedule 1 drug or blood product is dispensed to the patient for the first time;
   b) when a Schedule 2 drug is sold to the patient for the first time;
   c) if the patient requests information; and
   d) if, in the pharmacist'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.

8.4 Despite Standards 8.1 to 8.3, 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

8.5 The pharmacist must:
a) focus the dialogue on the particular patient’s condition and needs,
b) assess the patient’s level of understanding, and
c) endeavor to respond to the patient at the appropriate level.

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

8.6 The dialogue under Standard 8.3(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;
   c) 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 blood product, or
      ii. pose a risk to the patient in conjunction with the drug or blood product; and
   f) when it is necessary to seek additional care or advice.

**Professional judgment to guide pharmacist in other circumstances when a dialogue is required**

8.7 In the case of a dialogue under Standards 8.3(c) or (d), the dialogue must include those components of Standard 8.6 that, in the professional opinion of the pharmacist, are applicable to the patient.

**Use of written materials**

8.8 A pharmacist 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 8.3.

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

8.9 Subject to Standard 8.8, written materials provided to a patient must specifically address the patient and the patient’s needs.

8.10 A pharmacist may provide written materials that are general in nature if the pharmacist identifies those portions of the information that are relevant to the patient.

8.11 If a patient has special needs, including a hearing impairment or inability to speak English, the pharmacist may use appropriate written materials to assist in counseling the patient.
STANDARD 9: A pharmacist or a pharmacy technician 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 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 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;
   c) appears to be having difficulty in making a choice about a Schedule 3 drug or a health care product, aid or device;
   d) is observed to be making purchases of a Schedule 3 drug or a health care product, aid or device in a quantity or at a frequency that is therapeutically inappropriate;
   e) the pharmacist 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; or
   f) is identified by a pharmacy technician as someone who requires assistance or may face a risk from the selection or use of a Schedule 3 drug or health care product, aid or device.

9.3 A pharmacy technician must refer to the pharmacist:
   a) anyone the pharmacy technician 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.

9.4 A pharmacy technician may enter into a dialogue with or provide information to a person who:
   a) requests a health care product, aid or device;
   b) requests assistance in making a choice about a health care product, aid or device;
   c) appears to be having difficulty in making a choice about a health care product, aid or device; or
   d) the pharmacy technician recognizes as someone who may face a risk from the selection or use of a health care product, aid or device.
STANDARD 18:
A pharmacist must create and maintain patient records for pharmacist services provided by that pharmacist.

A pharmacy technician must create and maintain patient records for pharmacy technician services provided by that technician.

APPLICATION OF STANDARD 18

Transaction record

18.1 Each time a pharmacist or a pharmacy technician dispenses a Schedule 1 drug or blood product, the pharmacist or the pharmacy technician 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

18.2 A pharmacist or a pharmacy technician who:
   a) dispenses a Schedule 1 drug or blood product;
   b) sells a Schedule 2 drug; and
   a pharmacist who:
   a) prescribes a Schedule 1 drug or blood product;
   b) administers a drug or blood product; 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

18.3 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, blood products, or vaccines administered;
      iv. other information related to patient care practice.

18.4 In addition to the requirements set out in this standard, a patient record must meet the requirements of Appendix A.

Amending a patient record
18.5 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
   c) the date of the alteration.

**Patient record to be current**

18.6 A pharmacist or a pharmacy technician must keep the patient record accurate and current with regard to the pharmacist’s or the pharmacy technician’s activities.

**Form of patient record**

18.7 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.

18.8 A pharmacist or a pharmacy technician who provides professional services in an institution pharmacy, as defined in the *Pharmacy and Drug Act*, or in an environment with other regulated health professionals who have a shared medical or patient record may:
   a) document the pharmacist’s or pharmacy technician’s activities in the institution’s medical record or the shared medical or patient record for the patient; and
   b) 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 pharmacy technician is satisfied that the information required in Standards 18.1, 18.3, and 18.4 is available to the pharmacist or the pharmacy technician.

18.9 A pharmacist or a pharmacy technician 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.

18.10 A pharmacist who provides professional services outside of a pharmacy, an institution pharmacy 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;
   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.
      i. 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.