

Understanding the *Pharmacy and Drug Act* amendments and mail order pharmacy licensing

Background

As reported in the Spring 2009 issue of *acpnews*, ACP and Alberta Health and Wellness developed a new policy framework for the delivery of pharmacy services at a distance. The result was legislative amendments in December 2008 followed by amendments to the regulation.

Amendments to the *Pharmacy and Drug Act* and the Pharmacy and Drug Regulation came into effect on April 1, 2009. The amendments clarify that pharmacy services may be provided at a distance, subject to appropriate licensing. The amendments enhance accountability for all pharmacies. These measures are important to maintaining the integrity of the drug distribution system, and ensuring that pharmacy services are provided safely, effectively, and accountably. Changes addressed in the amendments include:

- when a mail order licence is required,
- licensing requirements,
- records that must be maintained,
- the ability of the college to place conditions on a licence throughout the year, and
- the ability for the college to share information found through investigation with regulatory bodies in other professions and jurisdictions.

We strongly encourage you to review carefully the amended legislation, which may be found on the ACP's website under *Practice Resources/Provincial legislation*. What follows is a brief introduction to the changes.

Amendment highlights

1. Clarification of general obligation to hold a licence

The *Pharmacy and Drug Act* now includes an updated set of definitions that govern when a licence must be obtained. Section 3 provides that except for limited exemptions:

no person shall provide a pharmacy service unless the service is provided
(a) from a licensed pharmacy with an appropriate category of license, and
(b) in accordance with the Act and any conditions imposed on the licence.

“Pharmacy service” is now defined in relation to the storage, compounding, dispensing and sale of drugs. In turn, there is a new definition of dispensing which includes any of the following activities required of pharmacists as part of the dispensing process:

- evaluating a prescription for a drug,
- assessing the patient and the patient's health history and medication record,
- packaging and labeling of a drug, or
- providing a drug to or for a person pursuant to a prescription.

The term “sale of a drug” continues to have the same broad meaning that it has always had which includes—in addition to the traditional concept of sale—giving away, keeping for sale and advertising or offering for sale. The definition of compounding remains unchanged.

2. Mail Order Pharmacy definitions and requirements

Mail order pharmacy and mail order pharmacy service are now defined in the *Pharmacy and Drug Act*:

1(1)(n.1) A “mail order pharmacy” means a community pharmacy with respect to which a mail order pharmacy license has been issued;

1(1)(n.2) A “mail order pharmacy service” means a pharmacy service provided to or for a patient for which neither the patient nor the patient’s agent attends at the community pharmacy to receive the service.

If a pharmacy is going to offer a mail order pharmacy service, it must hold both a community licence and a mail order licence (subject to limited exceptions.)

Exemptions from Mail Order Pharmacy licences

Based on the definitions, if you have patients to whom you provide services who do not come to your pharmacy or have a family member or care giver who comes to your pharmacy, you must have a mail order license. There are some exemptions from this requirement that are outlined in the amended regulation to the PDA (Section 6.1).

You do not require a mail order pharmacy licence if:

(a) the patient or patient’s agent regularly attends the community pharmacy to receive pharmacy services, but is unable to do so on a particular occasion because of a circumstance or condition affecting the patient like illness or travel or work away from the location of the community pharmacy;

(b) a clinical pharmacist or other pharmacist authorized under the Pharmacists Profession Regulation (AR 129/2006) regularly attends personally on the patient to assess the patient and monitor the patient’s response to drug therapy;

(c) there is

(i) a general health emergency or crisis, recognized by resolution of the council of the College,

(ii) a state of public emergency declared under the Public Health Act, or

(iii) a local state of public health emergency declared under the Public Health Act, that makes it unsafe or inadvisable for patients to attend the community pharmacy

Understanding Exemption (b)

If you provide pharmacy services to a nursing home, group home or other institution where the patients do not come to the pharmacy, you will require a mail order license unless there is a clinical pharmacist who visits the institution to monitor the patient’s response to drug therapy. The pharmacist(s) can be employed by your pharmacy, but they do not have to be. If the institution contracts a pharmacist to visit

the institution to provide clinical services, you likely will not require a mail order licence to dispense drugs to the institution.¹ If you provide pharmacy services to patients who cannot leave their homes and the patients do not have agents who visit the pharmacy, you will require a mail order licence unless you or another clinical pharmacist visits these patients to monitor their response to drug therapy.

Record keeping requirements for Mail Order Pharmacies

When patients do not attend a pharmacy in person, it is more difficult for pharmacists to assess patients and ensure appropriateness of drug therapy. For this reason, a specific reference to mail order pharmacies is included in Section 12.1(h) of the PDA Regulation with regard to records. This section specifies that, in addition to the records that must be kept in a community pharmacy, a mail order pharmacy is also required to keep the following records:

- (i) policies and procedures regarding how information is collected in order to assess individual patients and to obtain all the information necessary to allow the pharmacist to ensure the appropriateness of drug therapy for the patient, and*
- (ii) records that identify any arrangement or agreement under which patients are referred to the mail order pharmacy in order for the pharmacy to provide mail order pharmacy services to or for the patient.*

3. Licensing requirements for institution pharmacies amended

Section 4 of the PDA, which refers to institution pharmacies, has been amended. The Act now states that an institution pharmacy must be a licensed pharmacy if a pharmacy service is provided from the institution to persons who are not patients of the institution, or if persons are charged for a pharmacy service or drug provided from the institution pharmacy.

4. Record definition and requirements added for all pharmacies

A definition of a record has been added to the PDA. A “record” includes records of a pharmacy in all forms: written, photographic, magnetic, electronic and otherwise. The definition in Section 1(1)(z.1) of the Act and Section 12.1 of the Regulation outline in detail the requirements. The exact wording is included in the appendix. In general, you are required to keep records of your mandated activities. This includes:

- records required by federal or provincial legislation and the standards of practice;
- records of all prescriptions received by the pharmacy;
- records of the services provided by the pharmacy and the regulated members or others who are associated with the pharmacy, including records identifying all individuals involved in the processing of a prescription and dispensing a drug and their role; and
- records of all Schedule 1 and Schedule 2 drugs received by the pharmacy, dispensed from the pharmacy, or sold by the pharmacy other than pursuant to a prescription.

¹ Please note: This does not replace the responsibilities of the dispensing pharmacist as outlined in the Standards of Practice for Pharmacists and Pharmacy Technicians.

You are likely already creating most of these records; however, we recommend reviewing these sections of the Act and the Regulation to ensure that you are recording what is now required.

Section 12.1(d) of the Regulation does add one new requirement:

- If a drug is not picked up at the pharmacy by the patient or the patient's agent, you must record the method of delivery of the drug to the patient.

Records must be stored in the pharmacy unless . . .

Section 12(3) of the Regulation requires that the required records must be maintained at the pharmacy unless the licensee has applied to the registrar in writing to store them at a location other than the pharmacy.

When making a request to maintain records outside the pharmacy, you must include the following information:

- the exact physical location and address where the records will be located;
- the procedures and agreements regarding how you will maintain care and control of the records and meet the requirements of the *Standards for the Operation of Licensed Pharmacies*, including how the records will be secured and how access will be restricted and controlled; and
- the names and contact information of any persons who own or control the location where the records will be stored.

In addition, the registrar may require acknowledgements, agreements or undertakings to ensure the security and confidentiality of the records.

Appendix - Legislation references for records

Pharmacy and Drug Act, Section 1(1)(z.1)

“Record” means the records of a pharmacy, whether in written, photographic, magnetic, electronic or other form, and includes, without limitation,

- (i) the records of the proprietor of the pharmacy, the licensee, the regulated members engaged by the proprietor or any other person associated with the pharmacy,
- (ii) any record required to be kept under this Act, the *Health Professions Act*, the *Controlled Drugs and Substances Act* (Canada) or the *Food and Drugs Act* (Canada) or the regulations or standards under those Acts,
- (iii) a record of all prescriptions the pharmacy receives, including an identification of the prescriptions that the pharmacy transfers to another pharmacy or pharmacist,
- (iv) a record of all drugs dispensed from or through the pharmacy, including the prescription, the name of the drug, the amount dispensed, the name and contact information of the patient and the name and contact information of the prescribing practitioner,
- (v) a record of the pharmacy services provided, including the name of the person or persons who dispensed a drug,
- (vi) a record of the names and contact information of the patients to whom pharmacy services are provided,
- (vii) a record of the counselling services provided to a patient,
- (viii) any other record created or received by a proprietor, licensee, regulated member engaged by the proprietor or other person associated with the pharmacy and the provision of pharmacy services;

Pharmacy and Drug Regulation, Section 12.1

The following types of records constitute records for the purposes of Section 1(1)(z.1) of the Act:

- (a) any record required to be kept under
 - (i) the Act, its regulations, and the standards for operating licensed pharmacies established under section 29.1 of the Act,
 - (ii) the *Health Professions Act*, its regulations, and the standards for pharmacist practice established under section 133 of the *Health Professions Act*,
 - (iii) the *Food and Drug Act* (Canada) and its regulations,
 - (iv) the *Controlled Drugs and Substances Act* (Canada), its regulations and the *Narcotic Control Regulations*,
 - (v) the *Health Information Act* and its regulations, or
 - (vi) the *Personal Information Protection Act* and its regulations;
- (b) records of all Schedule 1 and Schedule 2 drugs received by the pharmacy, which must include
 - (i) any information relating to the drugs required by any of the legislation and standards referred to in clause (a),
 - (ii) the name and contact information of the suppliers who sell or provide drugs to the pharmacy,
 - (iii) the name and quantity of each drug received by the pharmacy, and

- (iv) the date on which each drug was received;
- (c) records of all prescriptions received by a pharmacy, which must include
 - (i) any information relating to prescriptions required by any of the legislation and standards referred to in clause (a), and
 - (ii) details of any arrangement between the pharmacy and another person pursuant to which patients or prescriptions are referred or transferred to or from the pharmacy on a regular basis;
- (d) records of all Schedule 1 and Schedule 2 drugs dispensed from or through the pharmacy, which must include
 - (i) all information regarding the processing of a prescription and the dispensing of a drug required by any of the legislation and standards referred to in clause, and
 - (ii) where the drug was not picked up at the pharmacy by the patient or the patient's agent, the method of delivery of the drug to the patient and the method of dealing with environmental concerns where appropriate;
- (e) records of the pharmacy services provided by the pharmacy and any regulated members or other persons associated with the pharmacy, including
 - (i) all information regarding the provision of pharmacy services required by any of the legislation and standards referred to in clause (a), and
 - (ii) records identifying all individuals who were involved in the processing of a prescription and the dispensing of the drug and the role of each individual in the process;
- (f) records of patients, including all information regarding patient records required by any of the legislation and standards referred to in clause (a);
- (g) records of any Schedule 1 or Schedule 2 drugs released or sold to any person by the pharmacy other than pursuant to a prescription dispensed to or on behalf of a patient, including
 - (i) the name and contact information of the person receiving the drugs from the pharmacy,
 - (ii) the name and quantity of the drugs released or sold and the date on which the drugs were released or sold, and
 - (iii) the location to which the drugs were sent by the pharmacy;
- (h) in respect of a mail order pharmacy, the following additional records:
 - (i) policies and procedures regarding how information is collected in order to assess individual patients and to obtain all the information necessary to allow the pharmacist to ensure the appropriateness of drug therapy for the patient, and
 - (ii) records that identify any arrangement or agreement under which patients are referred to the mail order pharmacy in order for the pharmacy to provide mail order pharmacy services to or for the patient;
 - (i) any record created or received by a
 - (i) proprietor or a person associated with a proprietor,
 - (ii) licensee,
 - (iii) regulated member engaged by the proprietor, or
 - (iv) other person associated with the pharmacy that relates to acquisition of drugs by the pharmacy or the provision of pharmacy services by the pharmacy.