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The Transition Times

HELPING NAVIGATE CHANGE **0** U

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Best of FAQs

You've got questions; we've got answers. It's a perfect combination! This issue of Transition Times compiles the answers to calls we receive most often into one handy "go to" resource. Topics are listed aphabetically.

Advertising

What are the rules regarding "advertising" pharmacists' credentials such as CDE, CRE?

Pharmacists may list their credentials, but may not call themselves a "specialist." Use of the terms "has an interest in", "has advanced education in", or "has experience in" are acceptable. (Section 15.6, Pharmacists *Profession Regulation*)

What information must be shown on a pharmacy website?

Section 23 of the Pharmacy and Drug Regulation outlines the information that a licensee must ensure is displayed on the pharmacy website.

If a licensed pharmacy uses a website to promote or offer pharmacy services to the public, the licensee must ensure that the website prominently displays

- (*a*) *a copy of the licence and information* required to be posted under section 22,
- (b) repealed AR 72/2009 s12,
- (c) the location, mailing address, e-mail address and telephone number of the licensed pharmacy,



- (d) the name, pharmacist practice permit number and business address of the licensee,
- (e) a statement that the licensee is required to provide, on the request of a patient, the name and practice permit number of any regulated member who provides a pharmacy service to the patient or who engages in the practice of pharmacy with respect to a patient,
- (f) the name and business address of the proprietor,
- (g) if the proprietor is a corporation, the name of the proprietor's representative, and
- (h) other information required to be displayed by the council.

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Advertising continued from page 1

If you use a website to promote or offer pharmacy services, you must ensure that all of the required information is prominently displayed. Any mention of a location and/or hours of operation is considered promotion.

A scanned copy of your pharmacy license will meet the requirements of Part (a). A scanned copy of the Patient Concerns poster as described above will meet the requirements of Part (h).

Are there restrictions on advertising incentives?

Advertising is addressed in the regulation to the *Pharmacy and Drug Act*. In part, Section 24 of this regulation states:

A licensee and a proprietor must ensure that advertising in relation to a licensed pharmacy

(a) is not false or misleading,

- (b) does not encourage the misuse or inappropriate use of drugs or otherwise have the potential to compromise patient safety, and
- (c) does not undermine the honour or integrity of the pharmacy profession.

The Code of Ethics addresses the issue of offering incentives. Principle I states pharmacists and pharmacy technicians must "hold the well-being of each patient to be my primary consideration." Point 13 under this principle states:

To uphold this principle, I do not provide rewards or incentives that have the potential to cause harm to a patient.

While the regulations and Code of Ethics do not prohibit incentives (or the advertising of incentives) outright, the college does not support these programs, particularly in instances where bonus coupons, one-day-only specials or rewards to transfer prescriptions are offered because these offers may compromise a patient's judgment and / or contribute to inappropriate drug use. Further, the college is of the opinion that if advertising or offering a reward program has the potential for causing harm to patients, these actions may form the basis of an unprofessional conduct or misconduct complaint and investigation.

Competence

Every pharmacist on the clinical register must earn at least 15 continuing education units (CEUs). These CEUs can either be accredited, non-accredited, or a combination of both. For more competence information, see the Continuing Competence section of ACP's website which offers links to the:

- Navigating Your Continuing Professional Development brochure,
- Competency Profile for Alberta Pharmacists,
- Competence Program Rules, and
- competence assessment information.

What can a pharmacist claim as accredited learning?

Alberta pharmacists may only claim as accredited learning those programs accredited by a recognized pharmacy accrediting body. Those are:

- the Canadian Council on Continuing Education in Pharmacy (CCCEP),
- the Alberta College of Pharmacists (ACP),
- the Accreditation Council on Pharmaceutical Education (ACPE), and
- other provincial pharmacy accrediting bodies such as the Ontario College of Pharmacists.

Continuing medical education programs may not be claimed as accredited learning unless they have been accredited by a **pharmacy** accrediting body, e.g., ACP, CCCEP, or ACPE.

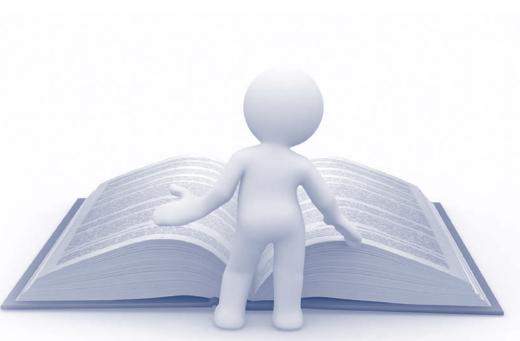
What can a pharmacist claim as non-accredited learning?

You may claim as non-accredited learning any learning that is relevant to your practice that has not been accredited by a pharmacy accrediting body. Examples are:

- research for a presentation;
- literature search to solve a patient or practice problem;
- discussion with colleagues or experts about a clinical problem; and
- computer course to enhance your practice, e.g., Excel to calculate drug dosages or creatinine clearance, Internet search skills.

Your non-accredited learning activity must:

- be relevant to your pharmacy practice,
- be documented on a non-accredited learning record, and
- be summarized on the continuing professional development log.



How many CEUs can a pharmacist claim for nonaccredited learning activities?

From the Competence Program Rules:

CEUs for non-accredited learning activities are assigned by the clinical pharmacist undertaking the activities as follows:

- (a) One hour of meaningful learning that is relevant to the pharmacist's pharmacy practice may be claimed for one CEU.
- (b) Meaningful learning is learning that is:
 - (i) new learning,
 - (*ii*) updated learning, or
 - (iii) reinforcing existing learning.
- (c) Meaningful learning is not replicating existing knowledge or social activities related to pharmacy events.

How do I claim non-accredited learning?

You may claim one CEU for each hour of meaningful learning in a non-accredited learning activity that is relevant to your pharmacy practice. In order to claim credit for a non-accredited learning activity you must complete a nonaccredited learning record. You may record up to eight CEUs per record. Non-accredited learning records are available to print or download from the Continuing Competence section of ACP's website.

I'm always in a rush to get my 15 CEUs before the renewal deadline. Can you give me any tips?

Getting the required number of CEUs each year shouldn't be hard if you remember to do a couple of simple things all year long.

- Start by making a CPD log file for yourself using a file folder, an envelope, or an electronic file folder on your computer.
- 2. Each time a patient, physician or other health care professional asks you a pharmacy question that requires you to research or read up on the topic, record the information and the source by taking a copy of the information (with permission), printing the website page, or bookmarking the info

and saving it in your *Favourites* folder. This learning collection will make up the bulk of your CPD log file.

3. When you attend a course, seminar, or other learning activity, be sure to pick up your attendance certificate providing the name of the course provider, the course title and number, and the amount of credits you received; keep the certificate in your CPD log file as well. When renewal season arrives, you'll be surprised at how many activities you've completed and how many CEUs you've accrued during the year. Many pharmacists forget or overlook the dayto-day learning they undertake during the course of their practice – don't sell yourself short!

Note: If you record your learning activities in the online log as you do

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How should a pharmacist prepare for an audit of their professional declarations?



- only claim learning that you are able to substantiate with certificates or non-accredited learning records;
- read the Guidelines for Audit of Professional Declarations carefully so you understand what you must submit to ACP;
- provide copies of course certificates for accredited programs;
- provide copies of non-accredited learning records for all nonaccredited learning activities claimed on your CPD log;
- provide a copy of your current professional liability insurance policy;
- fulfill all audit requirements within 30 days of notification; and
- make sure you're sending documents for the correct CE year.



- phone to ask if we received your fax. Each month two hundred pharmacists are selected for audit and we receive a flood of faxes. Check your fax machine for confirmation of number of pages sent. If there are any deficiencies or missing pages we will contact you.
- send copies of other supporting documentation such as exams, handouts, conference brochures;
- ask ACP to delete learning activities from your CPD log;
- alter course certificates in any way (e.g., strike out participant's name and write in another name);
- claim non-accredited "learning activities" that are not really learning activities, such as golf tournaments, presentations to lay people, and precepting students; and
- claim continuing medical education programs as accredited learning.

Competence continued from page 3

them, or regularly (weekly or monthly, for example) the renewal process will be even easier!

How does the college audit pharmacists' learning portfolios?

The Continuing Competence Committee has established the guidelines for audits. These guidelines will be provided to you if you are selected for Audit of Professional Declarations. Some of the audits will be random and some may be triggered by other factors, such as questionable entries on the continuing professional development log.

If you haven't been chosen for an audit, but would like a copy of the guidelines, please call the college office or email compentenceinfo@pharmacists.ab.ca. Learning portfolio reviews may be done in conjunction with another assessment, e.g., on-site assessment or field inspection.



How long must a pharmacist keep their learning portfolio documents?

At minimum, you must keep your CPD log and supporting documentation (e.g., certificates of course completion, non-accredited learning records) for the current year and the previous year. If you are selected for Audit of Professional Declarations, ACP will only ask for the previous year's records and will not go back further than that.

However, you may wish to keep some or all of previous years' records in your learning portfolio for your own purposes. You may feel that there is useful information from past courses in your learning portfolio. It's also rewarding to look back and see how far you've come over the past several years. Or you may want to show your learning portfolio to a current or potential employer to demonstrate how you have developed your knowledge in particular areas.

You may also find previous years' records of continuing professional development will help you complete an application for additional prescribing authorization. The application for additional prescribing authorization asks you to describe how, through formal and informal learning, you have acquired the knowledge, skills and abilities necessary for prescribing for initial access and/or to manage ongoing therapy.

Can pharmacists carry extra CEUs over to their next registration year?

No. CEUs must be claimed in the CE year in which the course was completed. The CE year runs from June 1 to the following May 31, to coincide with the deadline for registration renewal.



Complaints resolution

If a complaint is lodged against me, does it immediately go to hearing?

No. When ACP receives a complaint, it is forwarded to the Complaints Director to investigate and determine if unprofessional conduct has occurred. If a formal investigation is initiated, the pharmacist is normally provided with a copy of the complainant's statement. As part of the investigation into a formal complaint the pharmacist/respondent is required to submit a written response in regard to the concerns brought forward. After the investigation is completed the Complaints Director reviews the evidence gathered and decides how best to resolve the complaint. Actions the Complaints Director may take in resolving the complaint include dismissing the complaint or referring the matter for a hearing. ACP endeavors to resolve complaints in a way that protects the public and educates the pharmacist.

Confidentiality/ privacy of information



To whom can a pharmacist disclose health information without consent?

The *Health Information Act* (HIA) stipulates that a pharmacist may disclose individually identifying diagnostic, treatment and care information without consent:

- to another custodian for authorized purposes under Section 27;
- to a person responsible for providing continuing treatment and care;
- to a family member or another person with whom the individual is believed to have a close personal relationship, if the information is given in general terms and concerns the presence, location, condition, diagnosis, progress and prognosis of the individual on the day on which the information is disclosed and the disclosure is not contrary to the express request of the individual;
- to contact family members when the individual is injured, ill or deceased if the disclosure is not contrary to the express request of the individual;
- to an official of a penal or other custodial institution;
- to a person authorized to conduct an audit if the person agrees in

writing to destroy the information after the audit is concluded (at the earliest opportunity), and not to disclose the information to any other person, except as required to accomplish the audit or to report unlawful or improper conduct by the custodian or a health services provider;

- to a quality assurance committee (within the meaning of section 9 of the *Alberta Evidence Act*;
- for the purpose of a court or quasijudicial body proceeding;
- for the purpose of complying with a subpoena, warrant or order issued or made by a court, person or body having jurisdiction to compel the production of information or with a rule of court that relates to the production of information;
- to the police investigating a lifethreatening injury to the individual if the disclosure is not contrary to the express request of the individual;
- to another custodian to detect or prevent fraud or abuse of health services or prevent the commission of an offence;
- to an officer of the Legislature if the

information is necessary for the performance of the officer's duties;

- to avert or minimize imminent danger to the health or safety of any person. "Imminent danger" must meet the criteria of clarity, danger and imminence;
- in the best interests of an incompetent individual who lacks the mental capacity to provide consent;
- to a descendant of a deceased individual, a substitute decision maker or a person providing health services to the descendant if necessary to provide health services to the descendant and the disclosure is restricted sufficiently to protect the privacy of the deceased individual;
- when authorized or required by an enactment of Alberta or Canada;
- to the successor of a custodian; or
- to a health professional body for an investigation, discipline proceeding, practice review or inspection (see the conditions for disclosure in this situation under Section 35(4)).

You should always document the disclosure of patient information.

Confidentiality/privacy of information *continued from page 5*

May pharmacists disclose information to the police if they suspect a forged prescription?

Section 37.1 of the HIA indicates that custodians may disclose individually identifying diagnostic, treatment and care information to the police without the individual's consent when the custodian reasonably believes that the information disclosed relates to the possible commission of an offence under a statute of Alberta or Canada and will detect, limit or prevent fraudulent use or abuse of the health system.

Pharmacists may disclose the following individually identifiable information:

- the individual's name, birth date, and personal health number;
- the nature of any injury or illness of the individual;
- the date on which a health service was sought or received;
- the locations where the health service was sought or received; and
- the name of any drug provided or prescribed to the individual, and the date the drug was provided or prescribed.



If there is no abuse or fraud to the health system, can I still release information to the police?

Yes, but the information you can release is different. Section 37.3 of the HIA deals with release of information when the custodian reasonably believes that the information disclosed relates to the possible commission of an offence under a statute of Alberta or Canada and the disclosure will protect the health and safety of Albertans. In this situation, the individually identifying information that can be released without consent includes:

- the individual's name and birth date,
- the nature of any injury or illness of the individual,
- the date on which a health service was sought or received, and
- the locations where the health service was sought or received.

Unlike Section 37.1, the personal health number and information regarding the drug provided or prescribed to the individual is not included in the information that can be released.

May a pharmacist release patient information to a home care nurse?

Pharmacists are allowed to disclose a patient's prescription information to a home care nurse. Section 35(1)(b) of the *Health Information Act* states:

A custodian may disclose individually identifying diagnostic, treatment and care information without the consent of the individual who is the subject of the information

(b) to a person who is responsible for providing continuing treatment and care to the individual

This then means that a pharmacist may disclose prescription information to a patient's home care nurse without requiring the patient's consent first.

Remember to document the disclosure on the patient's record. For tips on what else you should consider, view the Feb. 9, 2010 edition of The Link. You can find it, and all back issues, on the ACP website under *News & Events/ACP newsletters/The Link*.

If a patient is deceased, to whom can a pharmacist release their information?

A pharmacist may disclose individually identifying diagnostic, treatment and care information without consent to a descendant of a deceased individual, a substitute decision maker or a person providing health services to the descendant if necessary to provide health services to the descendant and the disclosure is restricted sufficiently to protect the privacy of the deceased individual (Section 35(1)(d.1), *Health Information Act*).

A pharmacist may disclose all of a deceased patient's health information to the patient's executor. (Section 104(1), *Health Information Act*).

How should pharmacists handle the disclosure of health information to family members, e.g., prescription receipts, releasing a prescription to a family member?

This answer comes directly from the Pharmacist's Guide to Applying the *Health Information Act* (https://pharmacists.ab.ca/document_li brary/Pharmacists_HIA_Guide.pdf)

SCENARIO

Mary Smith comes into your pharmacy to request a copy of prescription receipts for her entire family (husband John, daughter Susan (19 years old), daughter Cathy (16 years old), son Robert (7 years old) and her mother Rose (87 years old and living with the family).

How does HIA apply to this scenario?

Prescription receipts for income tax purposes contain individually identifying diagnostic, treatment and care information (DIN) and registration information. This information may be disclosed on the tax receipt if each family member has consented to the disclosure (Section 34) or the authorized representative of a family member has authorized Mary to act of their behalf to access the information (Sections 33 and 104).

The pharmacist may disclose Robert's individually identifying health

information to Mary Smith because as the parent or guardian of Robert, she is his authorized representative (Section 104(1)(c)).

The pharmacist would have to obtain John's consent to disclose his tax receipts to Mary or John's written authorization for Mary to act on his behalf in accessing John's health information (Section 104(1)(i)).

In Cathy's case, the pharmacist would use his/her discretion before releasing this information to her mother (Section 104(1)(b)) since Cathy at age 16 probably understands the nature of consenting to the disclosure of her health information and the consequences of exercising that right or power. An example of such a situation would be if Cathy was taking oral contraceptives and her mother was not aware of this. Providing the information to Mary Smith would be a judgment call and the pharmacist should document his or her rationale for the decision made.

Mary states that she has a power of attorney for Rose (her mother). The pharmacist could disclose prescription receipts to Mary if she presented evidence of the power of attorney to the pharmacist.

If all of the disclosures are to the individual or their authorized representative (e.g., a parent on behalf of a child, a guardian or trustee on behalf of a mentally incompetent patient, or a personal representative on behalf of a deceased individual), a disclosure notation (Section 41) and notice to recipient (Section 42) is not required. If a disclosure is done with the individual's consent, a notice to recipient (Section 42) would be required.

Keep in mind that consent under HIA must always be written.

What if I have verbal consent from a patient to disclose health information?

Verbal consent is not recognized in the *Health Information Act*. Section 34(2) describes the requirements for consent and lists the information that must be included. This includes information about what information may be disclosed, to whom, for what purpose(s),



the date the consent becomes effective and when the consent expires. It also indicates that the consent or the revocation of consent must be signed by the person providing it. A sample consent form is included in the appendix to *Health Information Act Guidelines and Practices Manual* and is available on the ACP website

(www.health.alberta.ca/about/HIA_Gui delines-Practices-Manual.pdf).

How long do pharmacists have to keep the consent to disclose health information?

To be on the safe side, let's review the whole disclosure procedure.

- When you receive a request for disclosure of health information, check to see if the person is authorized to receive the information.
- Ensure the person is whom he/she says or, if acting as the individual's representative, ensure the representative is properly authorized to act on behalf of the individual (e.g. guardianship order, specific power of attorney, custody order, etc.).
- Determine if there is a valid need for individually identifying health information.

- Determine whether the individual has provided purpose-specific consent for the disclosure and if so, disclose the least amount at the highest level of anonymity.
- Ensure that the amount, detail and degree of anonymity are appropriate for the disclosure (may remove some identifying information and provide less information while still meeting the need).
- Ensure the information is accurate and complete and if so, disclose the information after confirming the identity of the recipient and notifying them that they must only use the information for the purpose specified in the request for disclosure (if the recipient is a non-custodian).
- If you disclose a record containing individually identifying diagnostic, treatment and care information without consent, make a notation of the purpose, date and recipient in the patient's record or in some other manner. Keep the disclosure notation for at least 10 years.

(Part 5, Division 1, Health Information Act)

Controlled substances

What are the rules for destruction of narcotic and controlled drugs?

For all controlled substances – with the exception of targeted substances – practitioners must apply for destruction through the Office of Controlled Substances in Ottawa.

The Compliance Unit requires the following by letter:

- date of the request;
- full name and address of the pharmacy;
- list of drugs by name including quantity, strength, lot# and expiry date;
- one list for products from the pharmacy inventory and a separate list for products returned to the pharmacy by patients; and
- the name and licence number of the pharmacist requesting permission to destroy the items.

There are dedicated phone and fax lines for inquiries:

Telephone: (613) 954-1541 Fax: (613) 957-0110

The office prefers a fax over a phone call if the fax lists the drugs to be destroyed. Such a fax enables them to give authorization for destruction more quickly.

You do not have to obtain permission to destroy targeted substances. However, you must:

- record, before the destruction, information related to the destruction, including the name, strength per unit and quantity of the targeted substance to be destroyed;
- ensure the method of destruction conforms with federal, provincial and municipal environmental legislation;
- record the date of the destruction;
- have the destruction witnessed by a pharmacist or a practitioner; and
- immediately after the destruction, you and the witness must sign and print your names on a joint statement, indicating you have witnessed the destruction, and the targeted substance destroyed has been altered or denatured to such an extent that its consumption has been rendered impossible or improbable.

These records must be kept for two years.

Can I transfer a prescription for a narcotic or controlled drug?

No.

Can I transfer a prescription for a targeted substance?

You can transfer a prescription for a targeted substance to another pharmacist, unless the prescription was previously transferred to you or your pharmacy. Targeted substances can only be **transferred once**.

What information do I need when I transfer a prescription for a targeted substance to another pharmacist?

You must record:

- the date of the transfer,
- the name of the pharmacist to whom the prescription is transferred,
- the name and address of the pharmacy where the prescription is being transferred, and
- if applicable, the number of refills being transferred.

Drug schedules

Use the following process to determine the schedule of a drug:

- Check on the ACP website under Pharmacist Resources/AB drug schedules to determine whether the drug is listed and whether the schedule is an "Alberta exception," meaning that the schedule is different in Alberta than it is in the National Drug Schedules. The Alberta Drug Schedules list both generic and common trade names. If the drug is not listed, proceed to Step 2
- 2. Check the National Drug Schedules on NAPRA's website at www.napra.org/pages/Schedules/Se arch.aspx.

NAPRA's schedules will list drugs that have been reviewed by NDSAC,

the National Drug Schedule Advisory Committee. This committee has not reviewed all drugs that are approved for use in Canada. If the drug is not listed on NAPRA's list, check Health Canada's Drug Product Database as per Step 3.

Note: when using NAPRA's list you must search by generic name only. Trade names are not cross-referenced.

- 3. Check Health Canada's Drug Product Database and consider using the following decision cascade.
 - Is it a narcotic or controlled substance? If yes, a prescription is required. If no...
 - Is it Schedule F? If yes, a prescription is required. If no...

■ Is it OTC?

You can find Health Canada's Drug Product Database at webprod.hcsc.gc.ca/dpd-bdpp/index-eng.jsp.

Chemicals and products not listed on the AB drug schedules documents are typically unscheduled, unless they are precursor chemicals. Pharmacists should be familiar with the 24 substances found in the schedule to the Precursor Control Regulations (found on the ACP website under *Pharmacist Resources/Federal Legislation*).

To see if a drug requires a TPP form, check the TPP medication list. The list is hosted on the College of Physicians & Surgeons of Alberta website and the link to it on the ACP website is under *Pharmacist Resources/TPP program*. HIT I HAVE AND A HAVE

Injection questions

What is the age limit restriction for pharmacists injecting?

Standard 17.4 of the Standards for Pharmacist Practice states, "A pharmacist must not administer an injection to a child younger than five years old."

Keep in mind that other age restrictions may be indicated in product monographs or set by Alberta Health and Wellness for provincially funded influenza programs.

What are the CPR requirements for injecting?

Pharmacists seeking authorization to administer drugs by injection must hold, at minimum, Level C CPR (e.g., St. John's Ambulance CPR-C training, Red Cross CPR Level C training). Pharmacists who currently hold the authorization to administer drugs by injection (and so currently have CPR and First Aid) will be "grandfathered" until their current CPR expires. When they re-certify their CPR, they must acquire at least Level C CPR. The following competencies must be covered at minimum.

- Adult/child/baby CPR one rescuer
- Adult/child/baby choking
- Barrier devices/pocket masks
- AED (where legislation permits)
- Adult/child CPR two rescuers

Pharmacists who are granted the authorization to administer injections must then maintain at least Level C CPR certification as long as they have this authorization.

Labelling requirements

What are the labelling requirements for blister packs and pouch packs?

Standard 6.8 of the Standards for Pharmacist Practice instructs:

When it is not practical to affix the prescription label to the drug package, the pharmacist 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.

What are the requirements for labelling methadone?

Methadone stock solutions prepared in advance of dispensing to patients must have the following.

- The aqueous stock solution must be prominently labeled and stored in a container that is distinct and not easily confused with other stock solution containers (such as water bottles).
- 2. The label on the stock solution must list the strength of the methadone solution, date of preparation, the individual(s) involved in the preparation and the beyond use date.
- 3. A written record must be maintained in the pharmacy as to the preparation of the methadone stock solutions. This information should include the initials of the individuals involved in preparation, the lot number and expiry date of the methadone powder, and beyond use date.
- 4. The stock solution container must have an appropriate warning label indicating the medication may cause harm or toxicity if consumed by other than for whom it was prescribed.

Labelling requirements

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- 5. When you dispense "carry" doses, in addition to including the information on the label as prescribed in the standards, ensure the label includes administration instructions that clearly outline whether the medication is diluted at the time of dispensing as well as the total amount to be consumed in one daily dose (in milligrams). The suggested additional wording is: "Drug is diluted. Consume full bottle. Total daily dose is X mg."
- Additionally, the following label or similar cautionary warning must be affixed to the final product.
 "Methadone may cause serious harm to someone other than the intended patient. Not to be used by anyone other than the patient for whom it was intended."

Pharmacists providing methadone prescriptions are encouraged to review Methadone Treatment in Alberta: Guidelines for Dispensing Pharmacists, available under Pharmacist Resources/ACP practice guidelines on the ACP website.

Mailing prescriptions outside Canada

How do I send prescriptions to my Alberta patients who are temporarily in the US?

Medications arriving in the US from Canada are subject to the laws of the USA. Under the US federal *Food, Drug and Cosmetic Act,* the Food and Drug Administration (FDA) "may refuse admission to any drug that 'appears' to be unapproved, placing the burden on the importer [the patient] to prove that the drug sought to be imported is in fact approved by the FDA."

"Unapproved new drugs are any drugs, including foreign-made versions of US approved drugs, which have not been manufactured in accordance with and pursuant to an FDA approval."

Officially, all seizure is at the discretion of the American government. Therefore, we recommend that pharmacies sending prescription medications to their Alberta patients who are temporarily in the US do the following:



- ensure all prescriptions are properly packaged and labelled;
- include a letter from the pharmacist, on pharmacy letterhead, confirming that the medications were dispensed as a result of legal prescriptions;
- include the physician's name and address; the pharmacist's name, address and phone number; recipient's name, address and phone number in the US; with instructions to call the pharmacy if there are any questions;
- send the package via insured mail or courier; and,
- limit the quantities dispensed to the amount needed for the personal stay in the US.

Please note that following these recommendations still does not guarantee that the package will be delivered to the intended recipient.

(Quotations are taken from Information on Importation of Drugs, Division of Import Operations and Policy, FDA; retrieved from www.fda.gov/ora/import/pipinfo.htm.)

Can pharmacists mail controlled substances to patients residing outside of Canada?

No. According to the Controlled Drugs and Substances Act, Section 6(1):

Except as authorized under the regulations, no person shall import into Canada or export from Canada a substance included in Schedule I, II, III, IV, V or VI.

This notice applies to all **controlled substances**, including narcotics, controlled drugs, and targeted substances. Mailing non-controlled prescription medications to your vacationing patients is still permitted.

Pharmacy resources

What references do I have to have in my pharmacy?

Pharmacies are required to have one current edition from each category listed in the Recommended Reference Sources list, found on the ACP website under *Registration & Licensure*/ *Pharmacies*.

Electronic comprehensive pharmacy information system databases may be used and must be current. (Standards for Operating Licensed Pharmacies – Standards 38 to 42.)

What information must be posted within a pharmacy?

Pharmacy and Drug Regulation, Section 22A states a pharmacy must display, in a conspicuous public part of the pharmacy:

- its licence,
- the poster explaining how a complaint about the operation of the pharmacy or the practice of pharmacy by a regulated member may be given to the college, and
- the Code of Ethics poster.

The Code of Ethics and complaints process posters are available at no cost from ACP.

It is no longer necessary for pharmacists to display their Certificate of Registration, but they must have their Practice Permits available to show if asked.

Prescribing

When is only an electronic signature on a prescription acceptable?

Never, at the moment. ACP, the College of Physicians & Surgeons of Alberta, and Alberta Health and Wellness continue to work together to find secure eprescribing solutions. However, until requirements for securing patient confidentiality, verifying authenticity, and preventing diversion are defined, e-prescribing is not acceptable.

NOT acceptable

Prescriptions emailed to you.

Prescriptions produced by computer but not signed by the prescriber, or has an electronic signature and is not initialed by the prescriber.

There are insufficient security measures in place to ensure the validity of prescriptions sent electronically.

Acceptable

Prescriptions produced by computer and hand-signed by the prescriber or with an electronic signature that is then initialed by the prescriber and delivered by the patient are acceptable. However, it is your responsibility to ensure the prescription is authentic, just as you would for a prescription which is handwritten.

Prescriptions that are produced by computer and hand-signed by the prescriber, or with an electronic signature and initialed by the prescriber, that are then faxed to the pharmacy as per the Guideline for facsimile (Fax) transmission of prescriptions.

For best practices, refer to *Ensuring Safe* & *Efficient Communication of Medication Prescriptions* available on ACP's website under *Pharmacist Resources/ACP practice guidelines*.

Are there quantity or time restrictions pharmacists must abide by when adapting to extend therapy?

No. One of the main goals of pharmacist adapting is to improve continuity of treatment for patients and reduce stress on the health system. If your assessment indicates that there is no need for any changes to a patient's treatment regime, it is appropriate to provide a quantity of medication that is at least equivalent to the amount previously received (i.e., if they typically receive a 90-day fill, provide the same). When providing the medication, remind the patient to see their original prescriber before the next fill will be needed.

Prescribing continued from page 11

If a pharmacist just makes a minor change to a prescription, it can still be under physician's signature, right?

Wrong. If you adapt the prescription, you must sign your name as the prescriber and fulfill all the requirements of prescribing.

For example, if a doctor sends you a note saying she is going away for several weeks, and tells you that you may refill her patients' prescriptions while she is away, the prescriptions should be you. Why? A prescription, as defined by the Food and Drug Regulations means "an order given by a practitioner directing that a stated amount of any drug or mixture of drugs specified therein be dispensed for the person named in the order."

Although the doctor has communicated her intentions, her notification does not meet the definition of a prescription. When you adapt a prescription by extending refills, you are responsible for assessing the patient and the appropriateness of extending the prescription.

Take responsibility for this prescription by signing your name; then notify the prescriber that in her absence, you used your judgment and modified the following prescriptions.

How do I determine what's appropriate for generic substitution and therapeutic interchange?

All clinical pharmacists may perform generic substitution and therapeutic interchange. Pharmacists must use their professional judgment, supported by clinical evidence, to determine the appropriateness of both types of interchangeability. They must also limit their practice to their personal competence.

The responsibility for the decision on equivalence always lies with the pharmacist who makes the decision. Most pharmacists rely upon third party payer formularies to assist them in making the decision, but any reputable reference may be used. You should document the reference(s) used to support your decision in case your judgment is called into question at a later date.

You must notify the original prescriber if you adapt a prescription by therapeutic interchange. (Refer to Standard 12.9 for the required components.) You do not have to notify the original prescriber of the drug when you perform generic substitution.

For example, you do not have to notify the original prescriber when you dispense ratio-Pantoprazole when Pantoloc® is prescribed (a generic substitution), but do if prescribing Pantaloc® when Nexium® is prescribed (could be considered a therapeutic interchange if expected to have similar therapeutic effect for the particular patient).

What documentation must pharmacists complete when they adapt?

When adapting a prescription, the pharmacist must:

- reduce their prescription to writing,
- include a reference to the original prescription,
- retain a copy of both prescriptions,
- sign and enter the prescription with the pharmacist as the prescriber, and
- notify the original prescriber.

Refer to Standard 12 of the *Standards for Pharmacist Practice* for full details.

Can a pharmacist adapt or write a prescription for an animal?

No. Pharmacists are not allowed to prescribe for animals. This includes prescribing via adapting a prescription from a vet.

Pharmacist's authority to prescribe comes from the *Health Professions Act*. This Act and the *Government Organization Act*, which outlines restricted activities in Alberta, both include a definition of a health service as follows:

*health service means a service provided to people**

- *(i) to protect, promote or maintain their health,*
- (ii) to prevent illness,
- (iii) to diagnose, treat or rehabilitate them, or
- (iv) to take care of the health needs of the ill, disabled, injured or dying;

* emphasis added

Can a pharmacist write a prescription for a Schedule 2 or 3 drug? What about medical devices, e.g., syringes, blood testing strips?

Yes. Prescriptions are not required for Schedule 2 and 3 drugs and medical devices; therefore, writing prescriptions for them is not a restricted activity. Often these prescriptions are written to obtain third party coverage, but a prescription does not guarantee coverage. Third party payers may establish policies regarding whether or not they will cover the costs of these drugs of devices based upon a prescription from a pharmacist.

Standards 7 and 8 of the *Standards for Pharmacist Practice* outline pharmacist responsibilities when selling either Schedule 2 or 3 drugs. In the case of Schedule 2 drugs, this includes assessing the patient to determine whether any drug-related problems might be apparent and recording the sale of the drug on the patient record. It is not mandatory to notify other relevant members of the patient's health care team; however, you should use your discretion to determine when it is appropriate to do so.

Can staff in a doctor's office phone in prescriptions?

The document Ensuring Safe & Efficient Communication of Medication Prescriptions in Community and Ambulatory Settings has the answer to this question. You can find the complete guide under Pharmacist Resources/ACP practice guidelines on the ACP website. Here's a summary:

The use of an intermediary to communicate verbal prescriptions between a prescriber and a pharmacist **must be a last resort**¹. Patient safety and well-being is of utmost importance in making a decision to use an intermediary. When filling a medication prescription on an urgent basis, the benefit to the patient must be weighed along with the recognition of the legal risk incurred by the intermediary and the prescriber. If a decision to use an intermediary is made, the use of the intermediary must be done according to the guidelines outlined below.

1. Communication of verbal prescriptions through intermediaries does not diminish

the prescriber's responsibility for accuracy and appropriateness of prescribing or the responsibility to be available if the pharmacist requires direct communication with the prescriber.

- 2. New prescriptions may be transmitted to a pharmacist through an intermediary only:
 - a. in unusual or urgent situations.²
 - b. by a regulated health professional intermediary who speaks directly with a pharmacist. Under no circumstances may two intermediaries be used.
- 3. A prescriber's authorization to refill an existing prescription may be transmitted through an intermediary only:
 - *a. following approval and documentation by the prescriber.*
 - *b. if there are no changes to the prescription.*
- 4. Communication via an intermediary should include the indication for which the medication is being prescribed as well as the name and credential of the intermediary.



- 5. Intermediaries must not communicate verbal prescriptions for narcotics or controlled drugs, including benzodiazepines and other Targeted Substances as defined in the Controlled Drugs and Substances Act and its Regulations.
- 6. A new prescription that is communicated verbally to a pharmacist through an intermediary must be confirmed as soon as possible through direct communication between the prescriber and the pharmacist or via fax. Recommended time is within 24 hours.

A prescription that is communicated verbally must be documented by the prescriber issuing the order and the person receiving the order as per their professions' standards of practice.

How can I find out if a pharmacist has additional prescribing authorization?

To verify prescriber status quickly and accurately:

- log onto the ACP website (pharmacists.ab.ca),
- 2. click the Prescriber Lists tab,
- 3. log in using your registrant number and password, and
- 4. click the *Pharmacists* menu item on the left of the screen.

You can now search by the pharmacist's first name, last name, and/or registration number.

Note: Pharmacists with additional prescribing authorization may prescribe any drugs except narcotics and controlled substances. There are no restrictions on the quantity of drug they can prescribe.

1 For the purpose of these principles, intermediary refers to any individual "third party" or "agent" who communicates a medication prescription on behalf of a prescriber to a pharmacist. Intermediaries also refer to electronic devices such as voice messaging systems and telephone answering devices used to receive medication prescriptions.

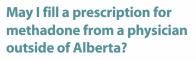
2 Unusual situations are circumstances that are not typical or that are out of the ordinary. Urgent/Emergent situations are circumstances that call for immediate action or attention.



If I receive a prescription from out of province, may I fill it?

If the prescriber is authorized to write the prescription in their province of employment, then you may fill it. Which medications various health professionals are permitted to prescribe varies by province. To confirm prescription validity, check with the prescriber's college in their province of employment.

This answer applies to both TPP and non-TPP prescriptions.



Health Canada has indicated that a physician licensed in one province cannot legally prescribe methadone in another province. However, Health Canada recognizes that it may be necessary for the physician in the patient's home province to continue managing their care for a short period to allow transition to an Alberta physician.

If you are filling a methadone prescription, you must ensure that:

- 1. the prescription is current, authentic, complete and appropriate (*Standard 5* of *Standards for Pharmacist Practice*).
- the prescriber has the required exemption. Methadone may only be prescribed by a physician with an exemption under section 56 of the *Controlled Drugs and Substances Act*. You may check with Health Canada's Methadone Program (toll free 1-866-358-0453) if the physician holds an exemption and if so, for which indication (treatment of opiate dependence and/or analgesia).

Note: Many provinces in Canada do not have a triplicate prescription program. Although methadone is on the triplicate list in Alberta, you cannot ask a physician from another province to comply with Alberta's triplicate prescription program.

Having an authentic, valid prescription from an authorized prescriber fulfills a pharmacist's obligation in determining the appropriateness of that prescription, right?

Wrong. Pharmacists must not rely on assumptions or defer to another practitioner's judgment in determining the appropriateness of a patient's medication. In particular, Standard 5.6 of the Standards for Pharmacist Practice states:

A pharmacist must determine the appropriateness of a prescription for the condition being treated by considering relevant factors that a reasonable pharmacist would consider in the circumstances including, but not limited to, whether:

- (a) the prescription is accurate;
- (b) the prescription orders a drug or blood product 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 or blood product;
- (i) the results of laboratory or other tests, if applicable, support that prescription; and

 (j) other patient-specific characteristics such as age; pregnancy or lactation status; cognitive, mental and physical challenges; lifestyle; cultural beliefs or living environment may negatively affect the appropriateness of the drug or blood product.

The information available on the patient's electronic health record through Netcare can also help you determine the appropriateness of a new prescription or refill request.

Under the *Health Information Act*, pharmacists, as custodians, may access (i.e., use) patient-specific health information such as drugs dispensed and lab values to provide health services (*Section 27(1*)).

Are prescriptions and refills valid if they were written by a physician who has since died or retired?

Officially, if the prescription was written by a physician who was licensed to practise medicine in Canada at the time the prescription was written, the prescription is still valid.

You must still ensure that the prescription is appropriate for the patient at the time you dispense. Particularly in the case of refills, consider whether it is appropriate to fill refills on a prescription when the patient is not being monitored by a physician and, if appropriate, for how long.

Your decision may have to take into account factors such as the difficulty the patient may have in finding a new family physician and the risk of going without a prescription medication. Remember that prescription refills are valid for a maximum of 18 months after the prescription was first filled.

In all cases, encourage the patient to find a new physician.

Questions about ACP

What's the difference between ACP and RxA?

ACP's primary responsibility is the safety of the public. The Alberta College of Pharmacists governs the pharmacy profession in Alberta to support and protect the public's health and well-being. ACP takes responsibility for pharmacy practice by setting and enforcing high standards of competence and ethical conduct. To fulfill its mandate, the college:

- registers pharmacists and licenses pharmacies,
- measures and supports the competence of pharmacists, and
- resolves complaints about pharmacists' practices and pharmacies' operations.

Once pharmacy technicians are regulated, ACP will perform the same roles for that profession.

RxA supports and advances the professional and economic well-being of its members to enhance the health of all Albertans. Its primary responsibility is to advocate for pharmacists. RxA advocates for and provides services to members by:

- promoting quality pharmacy practice,
- negotiating agreements related to pharmacist services,
- strategic partnerships with key organizations to support member interests,
- programs and benefits, and
- promoting professional recognition.

Who runs ACP?

The college is governed by a 12-member council (9 pharmacists and 3 public members). The Dean of the U of A Faculty of Pharmacy and Pharmaceutical Sciences, an undergraduate student from the Faculty, and two technician observers also participate as non-voting members of council. Council drafts policy and sets the direction for ACP. The day-to-day operations of the college are administered by the registrar and college staff.

Who gets to be on ACP council?

One of the responsibilities and privileges of belonging to a self-regulated profession is participation. This is most clearly put into practice in the election of council members. Nine pharmacists, representing five regional districts, are elected for three-year terms. All ACP registrants are eligible to vote in their district's elections.

Public members of council are appointed by the Lieutenant Governor under Section 13 of the *Health Professions* *Act.* The Act specifies that 25% of the voting members of council must be public members. All ex officio (non-voting) members are appointed by council.

A consultation is currently underway regarding amendments allowing for the election



of pharmacy technicians to council. The discussion paper and consultation details are available at https://pharmacists.ab.ca/Content_File s/Files/ElectionDiscussionPaper.pdf.

All feedback is due to ACP by Monday, September 13.

Questions continued from page 15

Where can I find back issues of newsletters?

Issues of acp*news*, The Link, Transition Times, heads up! and DUE Quarterly are all archived on the ACP website under the *News & Events* tab.

How do I update my email address with ACP?

Just follow these steps.

- 1. Click on *Registrant profile login* on the blue menu on the left of the ACP homepage.
- 2. Click on Login/Logout and then enter your user User ID (registrant number) and your password.*
- 3. Click on *View Profile*. Click on the *Edit* button in the appropriate section and update your information.
- 4. Click Save.
- 5. Your record is now updated.

Forgot your password? To reset your password online:

- 1. Click on *Registration profile login*. This will take you to the login screen.
- 2. Click on the *Click here if you forgot your password* link found below the login screen.
- 3. Follow the prompts to reset your password.



Remember that The Link, ACP's e-newsletter, is an

official college publication and college registrants are responsible for reviewing all information contained within all college newsletters.

Can I get ACP newsletters electronically?

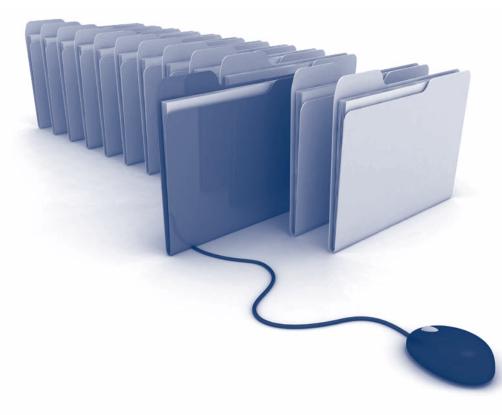
Yes! Clean up the environment and your post office box. To receive acpnews and Transition Times electronically:

- 1. go to the ACP homepage (pharmacists.ab.ca),
- 2. click on the Registrant Profile icon,
- 3. log in and then click on View Profile,
- click the "edit" icon in the Contact Information box (second from the top), and
- 5. for your newsletter preference, select email.

The Link, ACP's electronic newsletter, is published every second Tuesday. Make sure that

acp_communications@pharmacists.ab.ca is not being blocked by your email program's filters. Otherwise, you'll miss news that's important to your practice.

Record keeping



Keeping prescription and patient records – How long is long enough?

The retention of information is controlled by federal legislation, our provincial standards of practice, and the Health Information Act. An overview of the major requirements is on page 17.

Why do patient records have to be retained for so long?

The 10-year requirement is consistent with retention of medical records by all other health professionals and health care facilities.

Does the patient record need to be active in my software system for the whole time?

No, the records may be archived. However, you do need to be able to access the record if necessary for 10 years past the last date of service, or until the patient's twentieth birthday if the patient is a child.

Requirements for record keeping

Record	What is it?	Retention period?	Reference
Prescription	A written record (hard copy) of a prescription from any authorized prescriber. For example, a prescription from a physician, pharmacist, or nurse practitioner.	Generally 42 months (3.5 years). However, the more precise answer is 2 years past the completion of therapy with regard to the prescription or 42 months, whichever is greater.	Standard 73 of Standards for Operating Licensed Pharmacies; Food and Drug Act
Patient record	 A patient record must contain: demographic information about the patient, a profile of drugs provided, and a record of care provided. 	10 years past the last date of pharmacy service provided or for 2 years past the age of majority of the patient if the patient is a child, whichever is greater	Standard 78 of Standards for Operating Licensed Pharmacies; Standard 18.3 and Appendix A of Standards for Pharmacist Practice
Record of care	 Part of the patient record. Includes: records of drug-related problems identified and the actions taken or monitoring plans created to deal with them, 		
	 a record of any prescriptions adapted and other drugs prescribed, a record of drugs administered by injection, and other information such as prescriptions that were not filled or summaries of consultations with the patient or other health care providers. 		
Drug error ¹	 A drug error means: drug incident (any preventable event that may cause or lead to inappropriate drug use or patient harm) where the drug was released to the patient, or an adverse drug event (an unexpected or undesired incident that results in patient injury or death or an adverse outcome for a patient including injury or complication). 	10 years after the error is discovered	Standards 60(c & 64(c) of Standards for Operating Licensed Pharmacies
Disclosure of health information without [signed] consent of the patient	A record of the disclosed diagnostic, treatment and care information which is provided to another health care provider. ² For example, faxing a patient's drug profile to a physician's office.	10 years following the date of disclosure	Section 41(2) o the <i>Health</i> Information Act

1 A licensee must ensure that a quality assurance process is implemented and maintained in a licensed pharmacy. The quality assurance process must provide for reporting, investigating, and evaluating drug errors.

Do I have to retain a copy of all faxes sent to doctor's offices?

No, you do not have to keep a copy of the fax, but you must keep a record that you have disclosed the information. You may keep a copy of the fax or you may make a note in the patient's profile or create a written "disclosure log." Regardless of the method or recording the disclosure, the record must be kept for 10 years.

Why is the patient's personal health number required as part of patient demographics?

The personal health number (PHN) is the unique identifier that is used by other health professionals to identify the patient. In addition to allowing the pharmacist to identify the patient, collection and use of the PHN will allow for sharing of information in the Alberta electronic health record.

What if the patient refuses to provide their personal health number?

If an individual is apprehensive about providing their PHN, explain to them:

- the importance of this number in uniquely identifying their record within the pharmacy and the health system;
- how important it is for you, as a significant member of their health team, to have this number to ensure that their drug therapy information is entered only on their record;
- the importance of having their drug therapy information accessible to other healthcare professionals, through their EHR, if they become ill and cannot speak (e.g., stroke or unconscious from an auto accident); and
- that collecting their PHN is one more step you are taking to keep them safe.

If the individual refuses to provide their PHN, despite your explanation, DO NOT refuse professional services. Proceed to provide the services as you normally would, and do your best to ensure that their drug therapy information is entered on the correct record. (Sections 1(1)(f)(xi) and Part 3, Section 21 of *Health Information Act*)

² When a custodian discloses a record containing individually identifying diagnostic, treatment and care information without consent, the disclosing custodian must make a notation of the name of the recipient, the date and purpose of the disclosure and a description of the information disclosed. The disclosure notation may be in paper or electronic form, may be put on the individual's health or drug record or in a book or "disclosure log."



Refusing services

Can a pharmacist refuse to sell a product (e.g., Tylenol #1) or dispense a prescription?

Yes, if you believe it is in the patient's best interests and you have evidencebased support for your reasoning. The primary job of a pharmacist is to ensure patients receive the most appropriate therapy. In some situations, no medication is the best therapy.

Standard 4.2 of the Standards for Pharmacist Practice includes a list of appropriate responses if you suspect a patient has or is likely to have a drugrelated problem; one response is refusing to dispense or sell the drug or blood product to the patient.

Can a pharmacist "discharge" a patient?

Yes, but the pharmacist must assist the patient to obtain appropriate pharmacy services from another pharmacist or health professional within a timeframe fitting the patient's needs. (Code of Ethics, Principle 4.3)

Note that Standard 2 of the proposed Standard of Practice for Pharmacists and Pharmacy Technicians includes specific parameters for terminating a patient relationship. A consultation on the



proposed amendments is underway now. You can access all the documents via the Bulletin Board section on the ACP website

homepage. All feedback is due to the ACP office by Sept. 13.

Registration renewal

Registrants must renew before June 1 each year. Pharmacies must renew before June 16. (ACP Bylaws 48 and 43.1)

What is needed for renewal?

For *clinical pharmacists*, a complete practice permit renewal means the submission of:

- a Continuing Professional Development (CPD) Log indicating completion of a minimum of 15 CEUs between June 1 of the previous year and May 31 of the current year,
- a completed declaration of compliance with insurance requirements, and
- the applicable fees for permit renewal.

A complete *pharmacy licence* renewal includes:

an undertaking statement signed by the licensee;

- an undertaking statement signed by the proprietor's agent;
- a statutory declaration sworn and signed by the licensee;
- a statutory declaration sworn and signed by the proprietor's agent;
- completion of a review of the ownership and pharmacy staffing information;
- provision of the pharmacy's hours of operation;
- responses to questions regarding methadone dispensing, lock and leave, sterile compounding and practical training sites; and
- submission of applicable fees for the pharmacy licence category selected.



Tax questions

What pharmacy-related expenditures can patients claim?

According to the Canada Revenue Agency (CRA), drug costs can be claimed only if prescribed by a medical practitioner and recorded by a pharmacist. Over-the-counter medications, vitamins, and supplements, even if prescribed by a medical practitioner, cannot be claimed.

It is still appropriate to provide a receipt for unprescribed medications; however, the receipt should not be labeled as an official receipt for tax purposes.

For more information, see the CRA website (www.cra-arc.gc.ca).

To whom can you issue a receipt?

The *Health Information Act* provides guidance for pharmacists when issuing receipts. Prescription receipts for income tax purposes contain individually identifying diagnostic, treatment and care information (DIN)

and registration information. The Act permits disclosure of individually identifying health information beyond the controlled arena to:

- the individual who is the subject of the information (Section 33),
- the authorized representative of the individual (Sections 33 and 104), and
- third parties with the individual's consent.

This consent must be provided in writing or electronically and must include:

- an authorization for the custodian to disclose the health information specified in the consent,
- the purpose for which the health information may be disclosed,
- the identity of the person to whom the health information may be disclosed,
- an acknowledgment that the individual providing the consent has been made aware of the reasons why the health information is needed and the risks and benefits to the individual of consenting or refusing to consent,
- the date the consent is effective and the date, if any, on which the consent expires, and
- a statement that the consent may be revoked at any time by the individual providing it.

If all of the disclosures are to the individual or their authorized representative, a disclosure notation (Section 41) and notice to recipient (Section 42) is not required. If a disclosure is done with the individual's consent, a notice to recipient (Section 42) would be required.



Wholesaling? Manufacturing?

When does selling drugs to other pharmacies become wholesaling?

According to the Food and Drug Regulations *C.01A.004.* (1), wholesaling is the activity of selling any prescription drug other than at retail (prescription) sale, where the seller's name does not appear on the label of the drug.

Subject to subsection (2), no person shall, except in accordance with an establishment licence,

(a) fabricate, package/label, distribute as set out in section C.01A.003, import or wholesale a drug.

Buying groups where one pharmacy purchases drugs in bulk on behalf of a number of pharmacies are considered to be wholesaling and require an Establishment Licence. Similarly, a pharmacist who frequently purchases a quantity of pharmaceuticals and then resells or distributes either divided into portions or the entire quantity to one or more pharmacies is considered to be wholesaling.

Pharmacies engaging in the practice of the wholesale of Schedule F drugs require an Establishment Licence. An Establishment Licence is required by any site involved in manufacturing, importing, wholesaling, distributing, packaging/labeling or testing of drug products.

The Food and Drug Regulations *C.01.041*. (*1.1*) also say that a pharmacist may only sell a Schedule F drug if a prescription has been received for that drug.

Subject to sections C.01.043 and C.01.046, no person shall sell a substance containing a Schedule F Drug unless:

- (a) the sale is made pursuant to a verbal or written prescription received by the seller; and
- (b) where the prescription has been transferred to the seller under section C.01.041.1, the requirements of section C.01.041.2 have been complied with.

Pharmacies wishing to obtain an Establishment Licence should contact the Health Products and Food Branch Inspectorate Establishment Licensing Unit at (613) 954-6790 or visit the website at:

http://www.hc-sc.gc.ca/dhpmps/compli-conform/licences/index-en g.php for information regarding obtaining the required site licence.

Wholesaling? Manufacturing?

continued from page 19

References:

Lambert, J. (2004, November 16). Obligations of Pharmacists under the *Food and Drugs Act* and *Food and Drug Regulations*. Retrieved from Health Canada website: www.hc-sc.gc.ca/dhpmps/medeff/advisories-avis/prof/_200 4/distrib_distanc_dispens_ltp-lpeng.php)

Drug Compliance Verification & Investigation Unit (2004, November 16). Frequently Asked Questions -Compliance Inspections. Retrieved from Health Canada website: www.hcsc.gc.ca/dhp-mps/compli-conform/info -prod/drugs-drogues/internet_faqs_tctm-eng.php

When does compounding become manufacturing?

Manufacturing is a commercial activity that is regulated under the *Food and Drugs Act* and its Regulations, *Good Manufacturing Practices* (GMP) and other federal legislation. Manufacturers must have comprehensive risk management strategies in place and are subject to routine inspection by Health Canada. Manufacturers pay annual fees for Establishment Licenses, entitling them to fabricate, package, label, import, distribute or sell drug products to drug wholesalers, pharmacists and prescribers.

Compounding is a professional activity performed by pharmacists pursuant to or in anticipation of a prescription for individual patients.

The Manufacturing and Compounding Drug Products in Canada: A Policy Framework states that pharmacists may prepare "limited quantities ... in anticipation of receiving a prescription".

Compounding "inordinate" amounts (quantities in excess of prescriptions received or anticipated) is not permitted. Bulk compounding in anticipation of receiving prescriptions is permitted as long as the products are not commercially available and your pharmacy has a history of receiving valid prescriptions for the products.

The full text of the Policy Framework is available on the Health Canada website (www.hc.sc.gc.ca/hpb-dgps/therapeut). Use the search function to locate the document title: *Manufacturing and Compounding Drug Products in Canada: A Policy Framework (June 2000).*

Can a pharmacy sell prescription medications to ambulance operators?

A pharmacy is permitted to sell drugs to the ambulance authority if presented with a prescription. These prescriptions are issued from the medical director of the authority: the physician in charge. Unless your pharmacy has an establishment licence from Health Canada and may legally operate as a wholesale, you may not sell drugs to the ambulance authority without prescriptions for each drug order. In areas where the authority purchases sufficient volume, it may be prudent to suggest the authority set up a contract directly with a drug wholesale.

Bonus question

With the announcement of FluMist, we anticipate this will quickly rise to the top of our FAQ list. To quell your curiosity, here's the answer!

Can a pharmacist administer flu vaccine intra-nasally?

Yes. According to Alberta's *Government Organization Act* Section 7.1, administration of a vaccine is a restricted activity. Pharmacists do have this restricted activity named in their scope of practice in the *Health Professions Act*. Therefore, all clinical pharmacists may administer a vaccine that does not require injection if they are competent to do so. "Competent to do so" includes handling adverse reactions, which could potentially include being trained in CPR and first aid.

Do you have a question that isn't covered here?

Don't forget that there are several FAQ sections under different practice areas on the ACP website. If your search there still doesn't answer you question, let us know so we can include it in a future publication. Send your questions to Communications Leader, Karen Mills, at karen.mills@pharmacists.ab.ca.

alberta college of **pharmacists**



Suite 1200, 10303 Jasper Ave NW Edmonton, AB T5J 3N6 Telephone: 780-990-0321 Toll free: 1-877-227-3838 Fax: 780-990-0328 pharmacists.ab.ca



Mixed Sources Product group from well-managed forests, controlled sources and recycled wood or fiber www.fsc.org Cert no. SW-COC-002083 0 1996 Forest Stewardship Council