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Canadian International Pharmacy Association

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International Pharmacy Practice In Canada

Patient safety and over all patient health should be the priority of any pharmacist regardless of the type of pharmacy practiced, be it hospital, retail, or innovative delivery such as distance based.

In a national poll the Canadian population ranked pharmacists as the most trusted health professionals. Canadian pharmacy practice is recognized internationally as a leader in innovation and focus on patient health and safety. Pharmacy is a highly regulated profession in Canada and pharmacists must adhere to strict guidelines administered by federal and provincial regulatory organizations.

The Health Protection Branch (HPB) is a department of Health Canada responsible for approving and regulating all medications, supplements, and herbs that are for resale. The Health Protection Branch has a similar role to the FDA in the United States. Canada is seen internationally as having some of the most advanced regulatory systems for the approval of medications. Medications that are approved to be sold in Canada are listed in the Food and Drug Act. The process of approving drugs in Canada is similar to the process in the United States resulting in a product that is safe for consumer consumption. In part this process is facilitated by a high degree of collaboration between HPB and the FDA as well by the fact that a vast majority of prescription pharmaceuticals are manufactured in the United States and are bio-equivalent or identical in both countries.

The distribution of medications from drug manufactures to pharmacies is a highly controlled process in Canada. Pharmacies can only purchase medication directly from a drug manufactures or through a wholesaler that is licensed by Health Canada to sell pharmaceuticals. Only pharmacies licensed by their provincial regulatory authorities can purchase prescription medications that are to be dispensed to the public. There are approximately twelve wholesalers in Canada that pharmacies have the ability to purchase through.

In Canada provincial pharmacy regulatory organizations (colleges or associations) regulate the practice of pharmacy. A pharmacy must obtain a license from the provincial pharmacy regulatory organizations to be able to dispense prescription medications to the public. Each province and territory has a legislative pharmacy act in addition to the standards of practice and code of ethics that all pharmacies and pharmacists must abide by.

The Canadian International Pharmacy Association (CIPA) was created in November 2002, to promote the growth and viability of the Canadian pharmacies that provide international services, as well as to provide a unified voice to address the challenges facing the industry at large**.** The Role and Mission of the Association is to support Canadian International Pharmacies in their delivery of high quality, affordable medications to patients around the world by doing all things necessary to attain these objects including, without limitation:

a) Developing creative solutions for superior patient access to affordable medications and health care products, while continuing to offer high quality professional patient care and services.
b) Working in conjunction with regulatory bodies and government agencies to establish standards and protocols to be followed by pharmacies providing international services to ensure the safe delivery of products and services to patients worldwide.
c) Supporting members in their efforts to meet and exceed existing professional standards of care and to develop standards of care unique to the international pharmacy industry.
d) Protecting the economic foundation of the international pharmacy sector to ensure continued access to high quality, affordable products and services to patients worldwide.
e) Promoting the satisfaction and health of patients by enhancing their relationships with international pharmacies.
f) Ensuring that all members develop policies and procedures that are in compliance with provincial and federal laws designed to protect the privacy and personal health information of patients in their care and be supportive of HIPAA compliance.
g) Ensuring members develop information technology and information management systems that ensure the security of the patient health information in their custody and control.

To ensure that CIPA pharmacies adhere to the above role and mission one of the criteria for membership is to sign a licensing agreement. By signing the agreement the pharmacy recognizes it must adhere to the following criteria:

Licensing

1. Provide the Licensor with verification of all required licensing of the Licensee within the jurisdiction in which its physical operation exists;

2. Provide the Licensor with verification that all persons in charge of the physical operation during its business hours are appropriately licensed and in good standing.

3. Appropriate verification shall include providing copies of all licenses and an affidavit of compliance on an annual basis.

Policies and Procedures
(these must be in writing and be available to the Licensor on request)

General

4. Maintain and enforce acceptable comprehensive policies and procedures in respect of the operation of the international prescription service;

5. Comply with all applicable statutes and regulations governing the practice of pharmacy within the jurisdiction where licensed.

Prescriptions

6. Maintain and enforce policies and procedures in accordance with statutes and regulations within the jurisdiction where licensed regarding the integrity, legitimacy and authenticity of any prescription received by the Licensee.

Patient Information

7. In jurisdictions where it is necessary for the originating U.S. prescription to be converted to a Canadian prescription, the Licensee shall ensure that the Canadian physician reviewing the patient's personal health information conducts an independent review to determine whether a Canadian prescription should be issued;

8. Maintain and enforce policies and procedures in accordance with statutes and regulations within the jurisdiction where licensed regarding retention and storage of patient records, reasonable verification of the identity of the patient, the prescriber and, where appropriate, the caregiver;

9. Maintain and enforce policies and procedures in accordance with statutes and regulations within the jurisdiction where licensed regarding the protection of the personal health information of patients (for example, the Health Information Act in Alberta; or the Personal Health Information Act in Manitoba and Federal legislation such as the Personal Information Protection and Electronic Documents Act) and ensuring that there are appropriate safeguards in place to prevent inappropriate or non-essential access or use of a patient's personal health information.

Communication

10. Maintain and enforce policies and procedures that mandate professional staff to offer meaningful consultation to the patients or caregivers, where required;

11. Maintain and enforce policies and procedures establishing a mechanism for:

i) patients to report suspected drug related problems and errors and for the Licensee then to take appropriate action;

ii) contacting patients and, if necessary, the prescriber, if an undue delay is encountered in delivering the prescribed drug or device;

iii) advising patients or caregivers of drug or device recalls;

iv) educating patients and caregivers about the appropriate means to dispose of expired, damaged or unusable medications in accordance with statutes and regulations within the jurisdiction where licensed.

Storage and Shipment of Products

12. Maintain and enforce policies and procedures regarding the shipping of drugs and devices via a secure and traceable means and within appropriate temperature, light and humidity standards applicable to the item being shipped in compliance with the latest pertinent data.

CIPA supports the ability for the US patient to file a complaint against a CIPA certified pharmacy. Therefore, in the licensing agreement a consumer complaint process is incorporated:

CONSUMER COMPLAINTS PROCESS
(excerpted from the by-laws of the Licensor)

1. A Complaint from a consumer about a Certified Member must be in writing addressed to the Executive Director or his/her designate ("ED") of CIPA.

2. All complaints received by the ED will be forwarded to the Complaints Investigation Committee ("CIC") within 3 days of receipt of the complaint. The CIC shall have the authority to rule on the complaint as set out in this process.

3. The CIC will assign the complaint to one or more of its members who will assess and deal with the complaint within 14 days of the complaint being received from the ED as follows:

a) if the complaint is deemed not appropriate or is without merit, the CIC shall respond directly to the consumer in writing that the complaint is dismissed.

b) if the complaint is deemed appropriate or has merit, the CIC shall acknowledge receipt of the complaint to the consumer and shall send a copy of the complaint to the Certified Member.

4. The Certified Member receiving the complaint shall respond to the CIC in writing within 7 days of receiving the copy of the complaint from the CIC.

5. The CIC will:

a) review the Certified Member's response, if any;

b) seek additional information, if needed, from the ED, the consumer or the Certified Member;

c) prepare and provide a report to the consumer, within 10 days after the deadline for receiving the Certified member's response, with a copy to the Certified Member and the ED, which report shall include:

1) if the Certified Member has provided no response, a ruling that the membership of the Certified member in the corporation shall be revoked;

2) if the complaint, based on the initial or additional information received, is found to be without merit, a ruling that the complaint be dismissed and that no further action is required;

3) if the complaint, based on the initial or additional information received, is found to have merit, a referral of the complaint to the Certified Members Review Committee for adjudication.

6. The Chair of the Certified Members Review Committee, within 3 days of the receipt of the report, shall select one of its members to act as adjudicator. The adjudication shall be a document only adjudication unless the Certified Member, within 3 days of being notified in writing of the name of the adjudicator, requests a hearing.

7. If no hearing is requested, the adjudicator shall request the consumer to provide any comments on the report in writing within 7 days. Those further comments, if any, shall be provided to the Certified Member who shall provide any further comments to the adjudicator within a further 7 days. The Certified Member's further comments shall be provided to the consumer for final comments within a further 3 days and the consumer shall have a further 7 days to make those final comments to the adjudicator in writing.

8. Upon receipt of the final comments, if any, from the consumer, the adjudicator, within 10 days, shall consider all of the information provided and shall make a written ruling, with or without reasons:

a) to dismiss the complaint; or

b) to issue a reprimand to the Certified Member together with an order for the Certified Member to take such remedial measures as the adjudicator deems appropriate in the circumstances; or

c) to revoke the membership of the Certified Member in the Corporation; and

d) in addition to any other ruling, to levy a fine (to a maximum of $5000.00) against the Certified Member and/or to order that the Certified Member pay such costs associated with the process that the adjudicator deems appropriate in the circumstances.

9. If the Certified Member requests a hearing, the Certified member shall be responsible for all costs associated therewith including travel, accommodation and meals of the adjudicator in traveling to a location for the hearing that is convenient for the consumer. The costs shall be estimated by the ED and the Certified Member shall pay those costs to the Corporation, in advance, within 3 days of the ED providing the reasonable estimate of costs. If the Certified Member does not pay such costs in advance, the right to a hearing will be lost and the matter will proceed on a documents only basis. If a hearing is to proceed it must be set at a time that is no later than 30 days from the request for a hearing unless the consumer consents to a longer period and the adjudicator shall render a written decision within 10 days after the hearing is completed in accordance with subparagraphs a) to d) of paragraph 34 hereof.

10. The decision of the CIC and the adjudicator shall be final and binding upon the consumer and the Certified Member and the Corporation.

Canadian pharmacies servicing US patients strive to achieve the same level of patient care as any other pharmacy providing services to the Canadian population. To ensure a high level of care to the US patient Canadian pharmacies have incorporated rigorous policies and procedure. The following is a general outline of the process for a US patient to obtaining medications from a Canadian International Pharmacy:

1. **Registration with a Canadian Pharmacy**; typically requires three documents.

    a. A detailed patient profile; this document provides both demographic and medical (medical conditions, medication history, allergies) information that is utilized by Canadian pharmacists and physicians to provide optimal patient care.

    b. A customer agreement; this document outlines the relationship between the patient and pharmacy.

    c. A physical prescription from a US licensed physician; this document ensures that a US patient is receiving care from a primary care physician in the United States. The original prescription is either mailed by the patient or faxed by the US physician.

    A pharmacy will not process a prescription for a US patient unless all three documents are provided.

2. **Verification of information;** pharmacy staff verify demographic and medication information to ensure that all information is accurate and correct so the right medication reaches the patient.

3. **Authorization by a Canadian Physician;** the patient medical history and the US prescription are made available to the Canadian physician. The Canadian physician assesses all the information and determines which prescription to authorize. Under Canadian pharmacy regulations Canadian pharmacies can only dispense a prescription that is issued by a Canadian licensed physician.

4. **Dispensing medications;** since pharmacy practice is regulated at the provincial level, a licensed Canadian pharmacy follows standards set out by provincial pharmacy regulatory organizations for dispensing medications.

5. **Billing;** pharmacies use secure billing procedures to ensure patient confidentially. Any information that passes through an online connection does so with the same levels of encryption and security that online banking transactions occur with.

6. **Shipping;** methods of shipping require secure and traceable means and within appropriate temperature, light and humidity standards applicable to the item being shipped in compliance with the latest pertinent data.