



PLEASE NOTE

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This document is *not* the official version of these regulations. The regulations and the amendments printed in the [Royal Gazette](#) should be consulted to determine the authoritative text of these regulations.

For more information concerning the history of these regulations, please see the [Table of Regulations](#).

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CHAPTER P-5.2

PHARMACEUTICAL INFORMATION ACT

GENERAL REGULATIONS

Pursuant to subsections 2(3), 3(2) and 4(6) and section 6 of the *Pharmaceutical Information Act* Stats. P.E.I. 2000, c.18, Council made the following regulations:

1. (1) In these regulations
- (a) “Act” means the *Pharmaceutical Information Act* Stats. P.E.I. 2000, c.18; Act
- (b) “billing number” means a billing number held by a health professional which authorizes the health professional to claim compensation payments under the *Health Services Payment Act* R.S.P.E.I. 1988, Cap. H-2 for basic health services provided by the health professional to his or her patients; billing number
- (c) “capacity” means, in respect of a person, the ability of the person to understand the medication information maintained in the Program pertaining to the person, and includes capacity
- (i) an understanding of how the information applies to that person,
- (ii) the ability to communicate that understanding,
- (iii) the ability to make decisions relevant to the use of and access to the information, and
- (iv) an understanding of the consequences of those decisions;
- (d) “Committee” means the Advisory Committee appointed under section 4 of the Act; Committee
- (e) “participating prescriber” means a prescriber who is registered under section 14 as a participating prescriber. participating prescriber
- (2) In these regulations, a reference to a third party who is acting on a person’s behalf does not include a parent or a guardian of the person. (EC211/07) Third party

ADVISORY COMMITTEE

2. (1) Subject to subsection (2), the Committee shall meet three times each calendar year. Meetings
- (2) Where the Minister or the Director urgently requires the advice of the Committee on a matter, the Committee shall, subject to subsection (4) Special meetings

and as soon as possible after the referral of the matter, meet to review the matter and provide advice to the Minister or Director, as the case may be, in respect of the matter.

Duties	<p>(3) In addition to the duties set out in the Act, the Committee shall</p> <ul style="list-style-type: none"> (a) subject to subsection (4), review and provide advice on matters referred to the Committee by the Minister or the Director; and (b) keep a record of <ul style="list-style-type: none"> (i) its observations while monitoring the Program as required by the Act, and (ii) any advice it provides in accordance with the Act and these regulations.
Referral to professional body	<p>(4) On the referral of a matter by the Minister or the Director to the Committee for its review and advice, the Committee</p> <ul style="list-style-type: none"> (a) may refer the matter to the professional body that the Committee considers appropriate to conduct such review and provide such advice, if the Committee is satisfied that the professional body is better qualified or more able to conduct the review and provide the advice required; and (b) shall subsequently review and provide advice on the matter, if the Minister or the Director advises the Committee that he or she has not received advice from the professional body within 90 days of the date that the matter was referred to the professional body. (EC211/07)
Chairperson	<p>3. (1) The Committee shall, at its first meeting in each calendar year, elect a chairperson, from among its members, who shall preside at its meetings.</p>
Expenses and remuneration	<p>(2) A member of the Committee shall, when attending to the business of the Committee, be</p> <ul style="list-style-type: none"> (a) reimbursed for such expenses incurred by the member; and (b) paid such remuneration for the member's services, <p>as the Minister considers appropriate.</p>
Executive secretary	<p>(3) The Director shall act as executive secretary to the Committee and carry out such duties as the Committee may establish.</p>
Meetings	<p>(4) Five members of the Committee shall constitute a quorum at a meeting of the Committee.</p>
Minutes	<p>(5) The Committee shall keep minutes of its meetings, which shall be signed by the chairperson after the minutes have been approved by the Committee. (EC211/07)</p>

**DISCLOSURE OF INFORMATION
IN THE PROGRAM IDENTIFYING A PERSON**

- 4.** (1) An application for the disclosure of information in the Program that identifies a person may be made to the Director Application for disclosure to the person identified
- (a) by the person, if the person is 18 years of age or older and has capacity; or
- (b) on behalf of the person, by a parent or guardian of the person, if the person is a minor or lacks capacity.
- (2) An application for disclosure must be made by completing a copy of Form 1 of Schedule A and by submitting it to the Director, together with the prescribed fee. Form of application
- (3) The Director shall, on receipt of an application made in accordance with this section, disclose to the applicant the information in the Program that identifies the person in respect of whom the application is made. (EC211/07) Disclosure
- 5.** (1) Where information in the Program that is disclosed to an applicant under section 4 is found by the applicant to be inaccurate or incomplete, the applicant may request a correction by completing a copy of Form 2 of Schedule A and by submitting it to the Director. Application to correct inaccuracies
- (2) Following a review of a request made in accordance with subsection (1), and of any evidence submitted pertaining to it, the Director shall, as the Director considers appropriate, Decision
- (a) correct or complete the information in the Program; or
- (b) add to the information a statement of disagreement regarding the request to correct the information.
- (3) A correction or completion of the information in the Program or a statement of disagreement added to the information shall remain part of the information in the Program from that time forward. (EC211/07) Amended information
- 6.** (1) For the purposes of clause 5(2)(b) of the Act and subsection 11(2) of these regulations, a person is deemed to consent to the disclosure of information in the Program identifying the person to a pharmacist, participating prescriber or other health professional where Consent to disclosure
- (a) the person, or a parent or guardian of the person acting on the person's behalf, requests
- (i) that a prescription be filled for the person, or
- (ii) that the person be given treatment;
- (b) the person, or a third party acting on the person's behalf, provides the pharmacist or participating prescriber with the person's personalized password; or

(c) a prescriber, acting on the request of the person, asks for a prescription to be filled for the person.

Third party requests
for prescriptions

(2) Where

- (a) a person does not have a personalized password; and
- (b) a third party acting on behalf of the person requests a prescription to be filled at a pharmacy,

a pharmacist shall, before filling the prescription,

- (c) obtain from the third party a written consent completed by the person; or
- (d) attempt to contact the person by telephone to obtain the person's verbal consent. (EC211/07)

Application for
personalized
password

7. (1) Where information in the Program identifies a person, an application for a personalized password that may be given to pharmacists and participating prescribers to allow them to access that information may be made

- (a) by the person, if the person is 18 years of age or older and has the capacity to decide whether or not to provide the personalized password to a pharmacist or participating prescriber; or
- (b) on behalf of the person, by a parent or guardian if the person is a minor or lacks the capacity to make the decision referred to in clause (a).

Form of application

(2) An application for a personalized password must be made by completing a copy of Form 3 of Schedule A and by submitting it to the Director.

Issuance of
password

(3) The Director shall, on receipt of an application made in accordance with this section, issue to the applicant the personalized password requested. (EC211/07)

Sign

8. Every pharmacist and participating prescriber shall post a sign, or ensure that a sign is posted, in the pharmacy or place of business in which the pharmacist or participating prescriber works that advises the public of

- (a) the existence and purpose of the Program;
- (b) the requirement for consent to disclosure;
- (c) the circumstances described in subsection 6(1) under which a person is deemed to consent to sharing of information;
- (d) the person's right to disclosure of information from the Program identifying the person and to apply for and obtain a personalized password; and
- (e) the duty of the pharmacist or participating prescriber, when dispensing any drug, to record with the Program all prescribed information. (EC211/07)

PHARMACISTS AND PARTICIPATING PRESCRIBERS

9. Pharmacists shall, when dispensing any drug, record with the Program the following information: Information to be recorded

- (a) the pharmacist's ID number;
- (b) the pharmacy's ID number;
- (c) the date the drug is dispensed;
- (c.1) the date the drug is retrieved from the pharmacy by the patient or a person acting on the patient's behalf;
- (d) the prescription number or transaction number;
- (e) the date the prescription is submitted;
- (f) the group code of the Provincial Drug Program;
- (g) the patient's ID number (provincial health number or other);
- (h) the patient's date of birth;
- (i) the patient's gender;
- (j) the code indicating a new or refill prescription;
- (k) the number of prescription refills authorized;
- (l) the drug identification number;
- (m) the quantity dispensed;
- (n) the estimated number of days the prescription is to last;
- (o) the prescriber's ID;
- (p) the intervention or exception code, if used;
- (q) the directions for use. (EC211/07; 78/10)

10. Participating prescribers may record the following information with the Program: Information that may be recorded

- (a) new prescriptions;
- (b) dosage changes;
- (c) prescriptions on hold or discontinued;
- (d) resumed prescriptions. (EC211/07)

11. (1) A pharmacist or a participating prescriber shall not access information in the Program for any purpose other than to Purposes of access to information permitted

- (a) dispense a drug;
- (b) counsel a patient with regard to the patient's drug therapy;
- (c) consult with a pharmacist or a prescriber with regard to the patient's drug therapy;
- (d) conduct a drug usage evaluation;
- (e) check for any of the following problems
 - (i) unintended or adverse drug interactions,
 - (ii) medication duplication, or
 - (iii) unusual dosages; or
- (f) determine whether a drug usage or prescription is inconsistent with accepted pharmacy or medical practice.

- Consultation (2) When carrying out a review of information in the Program that identifies a person, a pharmacist or a participating prescriber may, with the consent of the person, consult with other health professionals.
- Notice of problems (3) Where, on receipt of a request to fill a prescription or before issuing a prescription, a pharmacist or participating prescriber discovers a problem referred to in clause 11(1)(e) or (f) during a review of information in the Program that identifies the person, the pharmacist or participating prescriber shall, as soon as possible,
- (a) take such action as is consistent with the best practice of pharmacy or medicine, including altering the dose, changing the drug or refusing to fill the prescription; and
 - (b) advise the person of the problem
 - (i) verbally, where the person is present,
 - (ii) by telephone or registered letter, or
 - (iii) by a sealed, written disclosure provided with any prescription filled for the person. (EC211/07)
- Security measures **12.** (1) Every pharmacist in charge of a pharmacy and every participating prescriber shall ensure that the pharmacy or the place of business of the participating prescriber has security measures sufficient to prevent the unauthorized collection, retention, maintenance, alteration, use or disclosure of information in the Program, including ensuring that
- (a) the computer terminal capable of accessing and displaying information in the Program is installed in such a way as to be inaccessible to anyone other than a pharmacist or participating prescriber and designated support staff;
 - (b) the terminal is under the supervision of a pharmacist or participating prescriber; and
 - (c) confidentiality undertakings, as set out in Form 4 of Schedule A, are completed and signed by
 - (i) any support staff in the pharmacy or place of business who are permitted to have access to the Program,
 - (ii) any software vendor representative who does business with the pharmacy or place of business, and
 - (iii) the owner or chief signing officer of the pharmacy or place of business.
- Submission of Form **5** (2) Every pharmacist in charge of a pharmacy and every participating prescriber shall, before he or she first accesses information in the Program, complete and submit a copy of Form 5 of Schedule A to the Director. (EC211/07)
- Emergency access to Program information **13.** (1) Nothing in these regulations is to be construed as limiting or prohibiting access to information in the Program by a health practitioner acting in an emergency situation pursuant to clause 5(4)(a) of the Act.

(2) Pursuant to clauses 2(2)(c) and 5(4)(b) of the Act, information in the Program is accessible by government employees in administering government drug-benefit plans and programs, only to the extent that the information accessed pertains to those plans or programs.

Government
employees

(3) Pursuant to clause 5(4)(c) of the Act, information in the Program may also be accessed by employees and contractors responsible for the technical support and maintenance of the information systems used in the Program, only where the access pertains to work being carried out on the Program. (EC211/07)

Information systems
staff

PARTICIPATING PRESCRIBERS

14. (1) The Minister may, on application by a prescriber, approve the registration of the prescriber as a participating prescriber if

- (a) the application is made in a form acceptable to the Minister; and
- (b) the Minister is satisfied that the prescriber
 - (i) has an active billing number, and
 - (ii) is a member in good standing of the prescriber's professional body.

Registration -
requirements

(2) The Director shall maintain a register of participating prescribers and shall

- (a) enter in the register the name and address of a prescriber whose registration has been approved by the Minister; and
- (b) remove from the register the name and address of a prescriber who is suspended or excluded by the Minister from participation in and access to the Program. (EC211/07)

Register

REPORTS, PLANNING AND RESEARCH

15. (1) Any person who wishes to make an application for the disclosure of information in the Program shall submit to the Director

- (a) a completed copy of
 - (i) Form 6 of Schedule A, if the disclosure is requested for the purpose of planning or the preparation of a report, or
 - (ii) Form 7 of Schedule A, if the disclosure is requested for the purpose of research; and
- (b) the prescribed fees.

Reports, planning or
research

(2) On receipt of the application for disclosure and the prescribed fees, the Director shall review the application and shall make recommendations to the Minister either for or against disclosure.

Recommendation

(3) The Minister may, when deciding whether to permit the disclosure requested, consider the Director's recommendations.

Consolidation of
recommendations

- Decisions (4) After making a decision in respect of a request for disclosure, the Minister shall give
- (a) the applicant a written notice of the decision; and
 - (b) the Director a copy of the notice. (EC211/07)

FEES

- Fees **16.** (1) The fees prescribed for the purposes of these regulations are those set out in Schedule C.
- Reduction (2) The Minister may reduce the fees referred to in subsection (1) where a reduction is requested by an applicant who is a federal, provincial or territorial government body, an academic institution, or a student. (EC211/07)

COMPLAINTS, SUSPENSIONS AND EXCLUSIONS

- Complaint inquiry **17.** The Minister is vested with the powers of a commission under the *Public Inquiries Act* R.S.P.E.I. 1988, Cap. P- 31 and shall be deemed to have been appointed under that Act and to have been commissioned to cause inquiry into those matters or complaints that concern the Program and those matters that are within the powers of the Minister under the Act. (EC211/07)
- Suspension or exclusion **18.** (1) After
- (a) causing inquiry into a matter or complaint pursuant to section 17; and
 - (b) considering the findings of the inquiry,
- the Minister may suspend or exclude a pharmacist or participating prescriber from participating in and having access to the Program, if the Minister is satisfied that there is just cause for either such action.
- Just cause (2) The following constitute just cause for suspending or excluding, under subsection (1), a pharmacist or participating prescriber from participating in and having access to the Program:
- (a) any access to information in the Program sought for a purpose other than those permitted under subsection 11(1);
 - (b) any use of information in the Program for advertising;
 - (c) any intentional input into the Program of false or incorrect information;
 - (d) any improper prescribing or dispensing practice for which a pharmacist or participating prescriber is disciplined by his or her professional regulating body;
 - (e) any illegal act involving the prescribing or use of pharmaceuticals;
 - (f) anything else deemed as just cause by the Minister.

(3) A suspension or exclusion imposed under subsection (1) may be temporary or permanent.

Temporary or
permanent
suspension or
exclusion

(4) The Minister shall, before imposing a suspension or exclusion on a pharmacist or participating prescriber, *Idem*


(a) advise the professional body of the pharmacist or participating prescriber of the findings of the inquiry conducted in respect of the pharmacist or participating prescriber; and

(b) request and consider any recommendation made by the professional body of the pharmacist or participating prescriber respecting the duration of the suspension or exclusion. (EC211/07)

19. (1) Subject to subsection (2), these regulations come into force on March 31, 2007. *Commencement*


(2) Sections 8 and 9 of these regulations come into force on January 1, 2008.

Form 4

 Pharmaceutical Information Program PO Box 2000, Charlottetown, PEI C1A 7N8		Confidentiality Undertaking Form 4
Personal information on this form is collected under the <i>Pharmaceutical Information Act</i> and Regulations. This information is required to fulfill the confidentiality requirements of the Act and regulations. If you have any questions about this collection of personal information, you may contact the Director of the Pharmaceutical Information Program.		
Name (Last name, given name)		Position:
Mailing address		
Province	Postal code	Telephone number
I will not access or use any clinical or patient information in PhIP for any purpose other than those authorized by the <i>Pharmaceutical Information Act</i> and its regulations. I agree at all times to treat as confidential the information in PhIP and will not participate in or permit the unauthorized release or disclosure of this information. I agree to adhere to all legislation, policies, procedures and standards issued by PhIP related to the confidentiality, privacy and security of PhIP information. I understand that the penalty upon conviction for any violation of the <i>Pharmaceutical Information Act</i> or regulations is a fine which may range from a minimum of \$15,000.00 to a maximum of \$50,000.00.		
Date	Signature	


(EC211/07)


Form 5

 Pharmaceutical Information Program PO Box 2000, Charlottetown, PEI C1A 7N8		Confirmation of Confidentiality Undertaking		Form 5
Personal information on this form is collected under the <i>Pharmaceutical Information Act</i> and Regulations. This information is required to fulfill the confidentiality requirements of the Act and regulations. If you have any questions about this collection of personal information, you may contact the Director of the Pharmaceutical Information Program.				
Name (Last name, given name)			Position:	
Mailing Address				
Province		Postal code		Telephone number
I have implemented security measures sufficient to prevent the unauthorized collection, retention, maintenance, alteration, use or disclosure of Program information, including ensuring that the computer terminal capable of accessing and displaying Program information is inaccessible to anyone other than myself and designated support staff. I will not access or use any clinical or patient information in PhIP for any purpose other than those authorized by the <i>Pharmaceutical Information Act</i> and the regulations. I agree at all times to treat as confidential information in PhIP and will not participate in or permit the unauthorized release or disclosure of this information. I agree to adhere to all legislation, policies, procedures and standards issued by PhIP related to the confidentiality, privacy and security of PhIP information.				
<input type="checkbox"/> As Pharmacist in charge, I have retained in my office confidentiality undertakings signed by all of the following: <ul style="list-style-type: none"> ● designated support staff ● software vendor representative ● Pharmacy owner/Chief Signing Officer The computer terminal(s) capable of displaying Program information is/are under the supervision of a pharmacist.		<input type="checkbox"/> As Participating Prescriber, I have retained in my office confidentiality undertakings signed by all of the following: <ul style="list-style-type: none"> ● designated support staff ● software vendor representative The computer terminal(s) capable of displaying Program information is/are under my supervision.		
Date			Signature	


(EC211/07)


Form 6

 Pharmaceutical Information Program PO Box 2000, Charlottetown, PEI C1A 7N8		Application for Release of Information for Purpose of Reports or Planning Form 6	
Personal information on this form is collected under the <i>Pharmaceutical Information Act</i> and Regulations. This information is required in order to process your application for release of information for purposes of reports or planning. If you have any questions about this collection of personal information, you may contact the Director of the Pharmaceutical Information Program.			
Individual(s) preparing report:			
Name	Position	Department	Institution
Mailing address of principal applicant:		Tel:	
Province Postal code		Fax:	
		Email:	
Title of project:		Type of project:	
		<input type="checkbox"/> standard report <input type="checkbox"/> planning	
Start date for project:		Completion date for project:	
Summary of project:			
<input type="checkbox"/> proposal attached (max. 10 pages) Frequency of report: ____ reports per ____ (example: week / month / year)			

	Pharmaceutical Information Program PO Box 2000, Charlottetown, PEI C1A 7N8	Application for Release of Information for Purpose of Reports or Planning Form 6
Specific data required: (include data fields and date ranges)		
Measures to protect confidentiality of data: (include who will have access, where stored)		
Will PhIP data be linked or used in conjunction with data from other sources? <input type="checkbox"/> no <input type="checkbox"/> yes, source:		
<ul style="list-style-type: none"> • I understand the data can only be released in aggregate, non-identifiable format, with all data cells containing a minimum of 20 individuals. • I understand the data can only be used for the project described above. Any additional use will require a new application. • I agree at all times, to treat as confidential the PhIP information received. • I ensure that by the project's completion date all non-aggregated PhIP information will be destroyed, including shredding paper records, and deleting electronic files and backups. • I will provide PhIP with a copy of the study results by the project completion date. 		
Date	Signature	
For office use only: <input type="checkbox"/> administrative fee received <input type="checkbox"/> suitable for use of PhIP data		

Form 7

 Pharmaceutical Information Program PO Box 2000, Charlottetown, PEI C1A 7N8		Application for Release of Information for Research Purposes		Form 7
Personal information on this form is collected under the <i>Pharmaceutical Information Act</i> and Regulations. This information is required in order to process your application for release of information for research purposes. If you have any questions about this collection of personal information, you may contact the Director of the Pharmaceutical Information Program.				
Principal investigators:				
Name	Position	Department	Institution	
Mailing address of principal applicant:			Tel:	
Province Postal code			Fax:	
			Email:	
Title of project:				
Start date for project:		Completion date for project:		
Summary of project:				
<input type="checkbox"/> proposal attached (max. 10 pages)				
Research Ethics Board (REB)		REB name (see Schedule B):		
Submission date:				
Status of review: <input type="checkbox"/> pending <input type="checkbox"/> approved <input type="checkbox"/> denied				
Date		Signature		

	Pharmaceutical Information Program PO Box 2000, Charlottetown, PEI C1A 7N8	Application for Release of Information for Research Purposes	Form 7
Specific data required: (include data fields and date ranges)			
Measures to protect confidentiality of data: (include who will have access, where stored)			
Will PhIP data be linked or used in conjunction with data from other sources? <input type="checkbox"/> no <input type="checkbox"/> yes, source:			
<ul style="list-style-type: none"> ● I understand the data can only be released in aggregate, non-identifiable format, with all data cells containing a minimum of 20 individuals. ● I understand the data can only be used for the project described above. Any additional use will require a new application. ● I agree at all times, to treat as confidential the PhIP information received. ● I ensure that by the project's completion date all non-aggregated PhIP information will be destroyed, including shredding paper records, and deleting electronic files and backups. ● I will provide PhIP with a copy of the study results by the project completion date. 			
Date	Signature		
For office use only: <input type="checkbox"/> administrative fee received <input type="checkbox"/> suitable for use of PhIP data			

SCHEDULE B**Acceptable Research Ethics Boards
For Applications on Form 7**

Prince Edward Island Research Ethics Board
University of Prince Edward Island Research Ethics Board
Dalhousie Health Sciences Human Research Ethics Board
Capital Health Research Ethics Board (QEII Health Sciences Centre)
University of New Brunswick Research Ethics Board
Memorial University of Newfoundland Research Ethics Board
Comité d'éthique de l'Université de Laval
McGill University Health Centre Research Ethics Board
Queen's University General Research Ethics Board
McMaster University Medical Research Ethics Board
University of Toronto Health Sciences I Research Ethics Board
University of Waterloo Human Research Ethics Committee
University of Manitoba Health Research Ethics Board
University of Saskatchewan Biomedical Research Ethics Board
University of Alberta Health Research Ethics Board
University of British Columbia Research Ethics Board

(EC211/07; 78/10)

SCHEDULE C**Fees**

1. The fee payable for an application under section 4 for disclosure is \$10.00 per calendar year of information requested.
2. No fee is payable in respect of a request under section 5 to correct information.
3. No fee is payable for an application under section 7 for a personalized password.
4. The fees payable for an application under section 15 for the disclosure of information are as follows:
 - (a) a non-refundable \$400 administrative fee; and
 - (b) an analysis fee equal to the sum of
 - (i) the number of hours of staff time required to provide the information, multiplied by \$150, and
 - (ii) the number of records accessed, multiplied by 5 cents.

(EC211/07)