

HEALTH INFORMATION ACT HEALTH INFORMATION REGULATIONS

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 on the Prince Edward Island Government web site to determine the authoritative text of these regulations.

For more information concerning the history of these regulations, please see the *Table of Regulations* on the Prince Edward Island Government web site (www.princeedwardisland.ca).

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HEALTH INFORMATION REGULATIONS

Pursuant to section 81 of the *Health Information Act* R.S.P.E.I. 1988, Cap. H-1.41, the Lieutenant Governor in Council made the following regulations:

Interpretation and Application

1. Definition, "Act"

In these regulations, "**Act**" means the *Health Information Act* R.S.P.E.I. 1988, Cap. H-1.41. (*EC359/17*)

2. Health care facility

- (1) For the purpose of clause 1(l) of the Act, the following facilities are designated as health care facilities:
 - (a) a nursing home operated by Health PEI;
 - (b) a nursing home operated under a licence issued pursuant to the *Community Care Facilities and Nursing Homes Act* R.S.P.E.I. 1988, Cap. C-13;
 - (c) a surgical facility.

Research ethics board

(2) For the purpose of clause 1(aa) of the Act, the Prince Edward Island Research Ethics Board is designated as a research ethics board. (EC359/17; 1120/24)

3. Act does not apply

- (1) For the purpose of clause 4(1)(c) of the Act, for greater certainty the following are prescribed
 - (a) the Children's Lawyer;
 - (b) the Prince Edward Island Workers Compensation Board.

Idem

- (2) For the purpose of subsection 4(2) of the Act, the following enactments are prescribed:
 - (a) the Occupational Health and Safety Act R.S.P.E.I. 1988, Cap. O-1.01;
 - (b) the Workers Compensation Act R.S.P.E.I. 1988, Cap. W-7.1. (EC359/17)

Consent

4. Refusal or withdrawal of consent in writing

Where an individual refuses to grant consent or withdraws consent to the collection, use or disclosure of his or her personal health information in accordance with section 13, the refusal or withdrawal shall be in writing, signed and dated by the individual. (EC359/17)

Research Plan

5. Contents of research plan

In addition to the matters set out in clauses 30(2)(a) and (b) of the Act, a research plan shall include

- (a) a research protocol, including a description of the specific information or variables required for the research;
- (b) a plan for the de-identification of data, including a data flow diagram, if applicable; and
- (c) any information known to the person submitting the research plan relevant to the consideration of the research ethics board under clause 30(3)(a) of the Act. (EC359/17)

Disclosure Outside Province

5.1 Disclosure outside province

For the purpose of section 35 of the Act, a custodian may disclose personal health information relating to an individual, without the consent of the individual, to a person outside the province for the purpose of conducting an accreditation, an audit or a peer review, or providing legal services, error management services, risk management services or quality improvement services, in respect of a person who provides health care to the individual. (EC598/22)

Electronic Health Record System

5.2 Prescribed personal health information

- (1) For the purposes of Part 7 of the Act, the following classes or types of personal health information are prescribed personal health information:
 - (a) personal demographic information;
 - (b) health care facility or location where health care is provided;
 - (c) information about clinical events;
 - (d) known allergies and intolerances;
 - (e) immunization records;
 - (f) prescriptions and dispensing records;
 - (g) drug-to-drug interaction alerts;
 - (h) referral and scheduling information;
 - (i) communications between the individual and the health care provider;

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(j) laboratory test results;

- (k) diagnostic imaging results, reports, and digital images;
- (l) other medical reports.

Social worker

(2) For the purposes of Part 7 of the Act, a person who is certified as a social worker under the *Social Work Act* R.S.P.E.I. 1988, Cap. S-5, is designated as a health care provider. (*EC598/22*)

5.3 Eligible custodians

- (1) Subject to subsection (2), the following custodians are eligible to be authorized custodians under Part 7 of the Act:
 - (a) health care facilities;
 - (b) health care providers;
 - (c) Health PEI.

Requirements

- (2) To become an authorized custodian, a custodian shall
 - (a) where the custodian is a health care facility or health care provider, apply in the form required by the Minister to be an authorized custodian;
 - (b) where the custodian is a health care provider, have successfully completed a system privacy and security course approved by the Minister; and
 - (c) enter into an agreement with the Minister in respect of access to and the use of the PEI EHR, including the suspension or revocation of such access and use. (EC598/22)

5.4 Duty of authorized custodian

Where an authorized custodian under Part 7 of the Act provides health care to an individual, the authorized custodian shall collect and record any prescribed personal health information about the individual that is generated or becomes known during the provision of health care, or ensure the information is collected and recorded, in the PEI EHR. (EC598/22)

Drug Information System

6. DIS information, prescription

(1) In accordance with subsection 73.3(2) of the Act, the following information shall be collected and recorded in the DIS when a drug is dispensed in a pharmacy, other than in a hospital, for a patient pursuant to a prescription:

- (a) the pharmacist's DIS identification number;
- (b) the pharmacy's DIS identification number;
- (c) the prescriber's DIS identification number;
- (d) the patient's name, date of birth and provincial health number; (e) the date the prescription is submitted at the pharmacy;
- (f) the date the drug is dispensed;
- (g) the date the drug is retrieved from the pharmacy;
- (h) the drug identification number;
- (i) the prescription number or transaction number;
- (j) the code indicating a new prescription or refill;

- (k) the group code of the provincial drug program, if applicable;
- (l) any intervention or exception code used;
- (m) the quantity of the drug dispensed;
- (n) the directions for use of the drug;
- (o) the estimated number of days of use based on the quantity of the drug dispensed and the directions for use of the drug;
- (p) the number of prescription refills authorized, if applicable.

DIS information, drug preparation without prescription

- (1.1) In accordance with subsection 73.3(2) of the Act, the following information shall be collected and recorded in the DIS when a drug preparation referred to in subsection 36(1) of the *Narcotic Control Regulations*, C.R.C., c. 1041, is supplied in a pharmacy, other than in a hospital, for a patient without a prescription:
 - (a) the pharmacist's DIS identification number;
 - (b) the pharmacy's DIS identification number;
 - (c) the patient's name, date of birth and provincial health number;
 - (d) the date the drug is supplied;
 - (e) the drug identification number;
 - (f) the quantity of the drug supplied;
 - (g) the directions for use of the drug;
 - (h) the estimated number of days of use based on the quantity of the drug supplied and the directions for the use of the drug.

DIS information, exempted codeine product without prescription

(2) Revoked by (EC1120/24). (EC359/17; 1120/24; 146/25)

7. Access granted by manager

- (1) Access to the DIS may only be granted pursuant to section 73.4 of the Act to
 - (a) an employee of the Department of Health and Wellness who is responsible for the administration of a provincial drug benefit plan;
 - (b) a health care provider who requires access to the DIS to provide health care at a health care facility;
 - (c) a person employed at a health care facility to provide administrative support to a health care provider.

Social worker

(1.1) For the purposes of Part 7.1 of the Act and this section, a person who is certified as a social worker under the *Social Work Act* is designated as a health care provider.

Access revoked

(2) An authorized custodian who is granted access to the DIS in accordance with clause (1)(a) shall cease to have access if the authorized custodian ceases to be an employee of the Department of Health and Wellness responsible for the administration of a provincial drug benefit plan.

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Idem

(3) Revoked by EC1003/21.

Access revoked, member of regulated health profession

- (4) An authorized custodian who is granted access to the DIS in accordance with clause (1)(b) shall cease to have access if
 - (a) the authorized custodian ceases to be registered, licensed or designated as a health care provider; or
 - (b) the authorized custodian ceases to require access to the DIS to provide health care at a health care facility.

Access revoked, administrative support

(4.1) An authorized custodian who is granted access to the DIS in accordance with clause (1)(c) shall cease to have access if the authorized custodian ceases to be employed at a health care facility to provide administrative support services to a health care provider.

Access suspended or revoked

- (5) The Minister may suspend or revoke the access of an authorized custodian who is granted access to the DIS in accordance with subsection (1), if the Minister has reasonable grounds to believe that the authorized custodian
 - (a) knowingly recorded false or incorrect information in the DIS;
 - (b) collected, used or disclosed personal health information in the DIS for a purpose contrary to the Act; or
 - (c) facilitated access to the DIS by a person who is not an authorized custodian.

Idem

- (6) Before suspending or revoking the access of an authorized custodian in accordance with subsection (5), the Minister shall
 - (a) serve notice in writing of the Minister's intention to suspend or revoke the authorized custodian's access to the DIS, including reasons, on the authorized custodian and the authorized custodian's employer or the operator of the health care facility where the authorized custodian is engaged, as the case may be;
 - (b) give the authorized custodian an opportunity to make submissions orally or in writing within a specified time period respecting the proposed suspension or revocation;
 - (c) consider the submissions of the authorized custodian, if any; and
 - (d) serve notice in writing of the Minister's decision, including reasons, on the authorized custodian and the authorized custodian's employer or the operator of the health care facility where the authorized custodian is engaged, as the case may be.

Interim suspension

(7) Despite subsection (6), where the Minister has reasonable grounds to believe that access by an authorized custodian to the DIS poses a serious and demonstrable risk of harm to an individual, the Minister may immediately suspend the authorized custodian's access for a period of up to 90 days.

Notice

(8) The Minister shall serve notice in writing of a suspension applied under subsection (7), including reasons, on the authorized custodian and the authorized custodian's employer or the operator of the health care facility where the authorized custodian is engaged, as the case may be. (EC359/17; 1003/21; 598/22; 336/23; 1120/24; 146/25)

General

8. Fees

Pursuant to section 80 of the Act, a custodian may require an individual to pay to the custodian a fee up to the maximum amount set out in the Schedule to these regulations, but not exceeding the actual cost of the service, to copy or ship a record of the individual's personal health information, based on the format of the copy. (EC359/17)

9. Revocation

The *Pharmaceutical Information Act* General Regulations (EC211/07) are revoked. (EC359/17)

SCHEDULE

Fees

	Service Provided	Maximum Fee
	1. Paper copy (photocopy or computer printout)	25 cents per page
	2. Paper copy (from microfilm)	50 cents per exposure
	3. Photo print (from digital or negative, colour or black and white)	
	(a) 5" x 7"	\$9.00
	(b) 8" x 10" (c) 11" x 14" (d) 16" x 20" (e) 20" x 24"	\$11.00 \$25.00 \$40.00 \$100.00
	4. Microfilm	
	(a) 16 mm roll	\$29.95
	(b) 35 mm roll	\$32.95
	5. Slide, colour 35 mm 6. Audio cassette	\$8.50 per slide
	(a) applicant supplies cassette (b) custodian supplies cassette 7. Video cassette	\$5.00 \$10.00
	(a) applicant supplies cassette	\$5.00
	(b) custodian supplies cassette	\$10.00
	8. Other media format (DVD, USB, CD, etc.)	Cost to custodian
	9. Electronic copy	Cost to custodian
/E =	10. Shipping	Cost to custodian
(EC359/17)		

