PLEASE NOTE

This document, prepared by the ***Legislative Counsel Office***, is an office consolidation of this regulation, current to July 1, 2017. It is intended for information and reference purposes only.

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***.

If you find any errors or omissions in this consolidation, please contact:

Legislative Counsel Office
Tel: (902) 368-4292
Email: legislation@gov.pe.ca

CHAPTER H-1.41

HEALTH INFORMATION ACT

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

Definition, "Act"

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

Health care facility

2. (1) For the purpose of clause 1(l) of the Act, a nursing home operated by Health PEI or under a license issued pursuant to the *Community Care Facilities and Nursing Homes Act* R.S.P.E.I. 1988, Cap. C-13, is designated as a health care 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)

Act does not apply

3. (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

Refusal or withdrawal of consent in writing

4. 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

Contents of research plan

5. 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)

Drug Information System

DIS information, prescription

6. (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, exempted codeine product without prescription

(2) In accordance with subsection 73.3(2) of the Act, the following information shall be collected and recorded in the DIS when an exempted codeine product, as defined in the *Pharmacy Act* General Regulations (EC527/14), 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 use of the drug. (EC359/17)

Access granted by manager

7. (1) Access to the DIS may only be granted pursuant to section 73.4 of the Act to

(a) an employee of Health PEI who is responsible for the administration of a provincial drug benefit plan;
(b) a person referred to in section 1 of the *Regulated Health Professions Act* Exemption Regulations (EC754/14), until December 31, 2018; or
(c) one of the following health care providers who is employed or engaged at a health care facility in that capacity:
(i) a licensed practical nurse,
(ii) a medical practitioner,
(iii) a nurse practitioner,
(iv) a pharmacist,
(v) a pharmacy technician,
(vi) a registered nurse.

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 he or she ceases to be an employee of Health PEI responsible for the administration of a provincial drug benefit plan.

Idem

(3) An authorized custodian who is granted access to the DIS in accordance with clause (1)(b) shall cease to have access after December 31, 2018, or if he or she ceases to be employed in a dispensary in a hospital or health facility operated by the Government or Health PEI, whichever occurs sooner.

Idem

(4) An authorized custodian who is granted access to the DIS in accordance with clause (1)(c) shall cease to have access if his or her registration or license expires or is suspended or cancelled or the authorized custodian ceases to be employed or engaged at a health care facility as a health care provider referred to in clause (1)(c).

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)

General

Fees **8.** 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)

Revocation **9.** 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”	$11.00
(c) 11” x 14”	$25.00
(d) 16” x 20”	$40.00
(e) 20” x 24”	$100.00
4. Microfilm	
(a) 16 mm roll	$29.95
(b) 35 mm roll	$32.95
5. Slide, colour 35 mm	$8.50 per slide
6. Audio cassette	
(a) applicant supplies cassette	$5.00
(b) custodian supplies cassette	$10.00
7. Video cassette	
(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
10. Shipping	Cost to custodian

(EC359/17)