



PRINCE EDWARD ISLAND
ÎLE-DU-PRINCE-ÉDOUARD

IMMUNIZATION REGULATIONS

PLEASE NOTE

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For more information concerning the history of this Act, please see the *Table of Public Acts* on the Prince Edward Island Government web site (www.princeedwardisland.ca).

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PUBLIC HEALTH ACT CHAPTER P-30.1

IMMUNIZATION REGULATIONS

Pursuant to section 72 of the *Public Health Act* R.S.P.E.I. 1988, Cap. P-30.1, Council made the following regulations:

1. Definitions

In these regulations,

- (a) “**authorized user**” means
 - (i) the Minister,
 - (ii) the Chief Public Health Officer,
 - (iii) the Deputy Chief Public Health Officer, or
 - (iv) a health practitioner, pharmacist or pharmacy technician who has authorized access to the immunization registry pursuant to section 6;
- (b) “**immunization registry**” means the registry established pursuant to subsection 5(1);
- (c) “**pharmacist**” means a pharmacist as defined in the *Regulated Health Professions Act* Pharmacist and Pharmacy Technician Profession Regulations (EC532/14);
- (d) “**pharmacy technician**” means a pharmacy technician as defined in the Pharmacist and Pharmacy Technician Profession Regulations;
- (e) “**vaccine**” means a biological preparation that is designed to induce a protective immune response to a particular disease. (EC529/14; 520/17)

2. Vaccination reports

- (1) A health practitioner or a pharmacist who administers a vaccine other than an influenza vaccine to a patient shall report to the Chief Public Health Officer the following information in respect of each vaccination:
 - (a) the name of the patient;
 - (b) the date of birth of the patient;
 - (c) the sex of the patient;
 - (d) the patient’s civic address;
 - (e) the patient’s provincial health number;
 - (f) the product name of the vaccine administered to the patient;
 - (g) the date on which the vaccine was administered;
 - (h) the name and location of the clinic or other place where the vaccine was administered.

Idem, influenza vaccinations

- (1.1) A health practitioner or a pharmacist who administers an influenza vaccine to a patient shall report to the Chief Public Health Officer the following information in respect of each influenza vaccination:
- (a) the age of the patient, stated, if the patient is less than 2 years old, in months;
 - (b) the sex of the patient;
 - (c) the postal code used by the patient or, if the patient is a child, the postal code used by the parent or other person with whom the child normally resides.

Quarterly submission

- (2) The reports created under subsections (1) and (1.1) shall be submitted to the Chief Public Health Officer in an electronic form acceptable to the Chief Public Health Officer or in paper form quarterly or within a time period otherwise directed by the Chief Public Health Officer. *(EC529/14; 415/15; 520/17)*

3. Vaccination records

- (1) A person referred to in subsections 2(1) and (1.1) who administers a vaccine to a patient shall record the following information in respect of each vaccination:
- (a) the patient's name, address, provincial health number, date of birth and sex;
 - (b) the name of the vaccine and the dose administered;
 - (c) identification of the manufacturer and lot number of the vaccine;
 - (d) the route of administration and the location on the patient's body where the vaccine was administered;
 - (e) the name of the medical practitioner, nurse practitioner, nurse or pharmacist who administered the vaccine;
 - (f) the date on which the vaccine was administered.

Retention of record

- (2) A record created pursuant to subsection (1) shall be retained by the health practitioner or pharmacist, as the case may be, for a period of not less than 10 years from the date of administration of the vaccine, and the record shall be provided to the Chief Public Health Officer upon request. *(EC529/14; 415/15; 478/15; 520/17)*

4. Adverse events

An occurrence of an adverse event following immunization (AEFI) shall be reported by the health practitioner or pharmacist who observes the adverse event following a vaccination administered by that person, or to whom the patient presents himself or herself, as soon as observed and, in any case, not later than 24 hours after observation, to the Chief Public Health Officer. *(EC529/14; 520/17)*

5. Immunization registry may be established

- (1) The Chief Public Health Officer may establish and maintain, in the form of a computerized network and database, an immunization registry of information reported in accordance with these regulations.

Purposes of immunization registry

- (2) The purposes of the immunization registry are



- (a) to provide authorized users with access to immunization records of patients to assist in patient care;
- (b) to provide for the monitoring of information respecting immunizations for the purpose of establishing and administering immunization programs;
- (c) to act as a repository of information for health planning, research and the evaluation of the beneficial and adverse effects of vaccines; and
- (d) to provide for the monitoring of immunization rates in the province. (EC520/17)

6. Application for access

- (1) A health practitioner, pharmacist or pharmacy technician may apply to the Chief Public Health Officer, in the form required by the Chief Public Health Officer, for access to the immunization registry.

Requirements for access

- (2) The Chief Public Health Officer may grant access to an applicant who applies in accordance with subsection (1), if the applicant is
 - (a) employed or engaged in the provision of health care in his or her professional capacity; and
 - (b) in good standing with the professional regulatory body governing his or her profession in the province.

Register

- (3) The Chief Public Health Officer shall keep a register of authorized users granted access pursuant to this section.

Requirements no longer met

- (4) An authorized user granted access pursuant to this section shall cease to have access to the immunization registry if
 - (a) the authorized user ceases to be employed or engaged in the provision of health care in his or her professional capacity; or
 - (b) the authorized user's registration or license expires or is suspended or revoked.

Suspension or revocation of access

- (5) The Chief Public Health Officer may suspend or revoke the access of an authorized user granted access pursuant to this section if the Chief Public Health Officer has reasonable grounds to believe that the authorized user
 - (a) contravened subsection 9(3); or
 - (b) facilitated access to the immunization registry by a person who is not an authorized user.

Due process

- (6) Before suspending or revoking the access of an authorized user pursuant to subsection (5), the Chief Public Health Officer shall:
 - (a) serve notice in writing of the Chief Public Health Officer's intention to suspend or revoke the authorized user's access, including reasons, on the authorized user and the authorized user's employer or the operator of any health facility where the authorized user is engaged in the provision of health care, as the case may be;
 - (b) give the authorized user 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 user, if any; and
- (d) serve notice in writing of the Chief Public Health Officer's decision, including reasons, and the suspension or revocation, if applicable, on the authorized user and the authorized user's employer or the operator of any health facility where the authorized user is engaged in the provision of health care, as the case may be. *(EC520/17)*

7. User identification

- (1) The Chief Public Health Officer shall assign unique user identification to each authorized user.

Record of access

- (2) The Chief Public Health Officer shall ensure that an electronic record of the following information is automatically created each time information is accessed in the immunization registry:
 - (a) the user identification of the authorized user accessing the information;
 - (b) the date and time the information is accessed;
 - (c) a description of the information that the authorized user accesses.

Retention of record

- (3) The Chief Public Health Officer shall ensure that an electronic record created pursuant to subsection (2) is retained for at least 10 years following the date of the access. *(EC520/17)*

8. Copy of information, patient

- (1) A patient may request, and an authorized user shall provide, a copy of information respecting the patient recorded in the immunization registry.

Copy of access record, patient

- (2) A patient may request, and the Chief Public Health Officer shall provide, a copy of an electronic record created pursuant to subsection 7(2) in respect of access to information respecting the patient recorded in the immunization registry. *(EC520/17)*

9. Prohibition, access

- (1) No person shall access the immunization registry except
 - (a) an authorized user, whose access has not been suspended or revoked; or
 - (b) a person who is providing technical support in respect of the immunization registry.

Prohibition, use or disclosure

- (2) No person other than an authorized user shall use or disclose information recorded in the immunization registry.

Prohibition, authorized user

- (3) No authorized user, other than the Chief Public Health Officer, shall use or disclose information respecting a patient recorded in the immunization registry unless the use or disclosure is
 - (a) authorized by the patient or the patient's substitute decision-maker in accordance with subsection (6); or
 - (b) necessary for the provision of health care to the patient.



Use by Chief Public Health Officer

- (4) In addition to the circumstances described in clauses (3)(a) and (b), the Chief Public Health Officer may use information respecting a patient recorded in the immunization registry in the following circumstances:
- (a) the information is de-identified;
 - (b) the use is for the purpose of
 - (i) delivering, evaluating or monitoring an immunization program,
 - (ii) health planning, research, and the evaluation of the beneficial and adverse effects of vaccines,
 - (iii) monitoring immunization rates in the province,
 - (iv) evaluating and monitoring the health and safety of the general public.

Disclosure by Chief Public Health Officer

- (5) In addition to the circumstances described in clauses (3)(a) and (b), the Chief Public Health Officer may disclose information respecting a patient recorded in the immunization registry in the following circumstances:
- (a) the information is de-identified;
 - (b) the disclosure is for the purpose of
 - (i) delivering, evaluating or monitoring an immunization program,
 - (ii) health planning, research, and evaluating the beneficial and adverse effects of vaccines,
 - (iii) monitoring immunization rates in the province,
 - (iv) evaluating and monitoring the health and safety of the general public,
 - (v) complying with a summons, subpoena, warrant, order or similar requirement issued by a court, person or entity with jurisdiction to compel the production of personal health information, or
 - (vi) complying with the rules of court concerning the production of evidence in a proceeding;
 - (c) the disclosure is to
 - (i) a public health authority established under an Act of the Parliament of Canada, another province or other jurisdiction, if the disclosure is for a public health purpose, or
 - (ii) a professional regulatory body with statutory authority over persons practising a health profession, including for the purpose of an investigation by that body;
 - (d) the disclosure is required by an enactment or an Act of the Parliament of Canada.

Substitute decision-maker

- (6) For the purpose of clause (3)(a), where a patient is incapable of consenting, or of communicating that consent, to the use or disclosure of information respecting the patient recorded in the immunization registry, one of the following persons may, in descending order of priority, on the patient's behalf and in the place of the patient, act as a substitute decision-maker for that patient by giving, not giving, withholding or withdrawing the consent, provided the person is capable of doing so:
- (a) a person who has been authorized, in writing, by the patient to provide consent;
 - (b) the patient's guardian;
 - (c) the patient's spouse;

- (d) the patient's adult child;
- (e) the patient's parent;
- (f) the patient's adult sibling;
- (g) any other adult next of kin of the patient;
- (h) a person who is authorized under an enactment to practise a health profession in the province and is providing health care to the patient;
- (i) the Public Guardian;
- (j) where the patient is deceased,
 - (i) the patient's personal representative as defined in the *Probate Act* R.S.P.E.I. 1988, Cap. P-21, or
 - (ii) the patient's
 - (A) spouse,
 - (B) adult child, or
 - (C) parent. (EC520/17)

