Province of Alberta

PUBLIC HEALTH ACT

IMMUNIZATION REGULATION

Alberta Regulation 182/2018

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Public Health Act

IMMUNIZATION REGULATION

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Interpretation

1(1) In this Regulation, "Act" means the *Public Health Act*.

(2) For the purposes of this Regulation and section 18.4 of the Act, "adverse event following immunization" means an unfavourable health occurrence experienced by a patient that

(a) follows immunization,

(b) cannot be attributed to a pre-existing condition, and

(c) meets one or more of the following criteria, as determined by a health practitioner:

(i) the health occurrence is life-threatening, could result in permanent disability, requires hospitalization or urgent medical attention, or for any other reason is considered to be of a serious nature;

(ii) the health occurrence is unusual or unexpected, including, without limitation, an occurrence that

(A) has not previously been identified, or

(B) has previously been identified but is being reported at increased frequency;

(iii) the health occurrence cannot be explained by anything in the patient's medical history, including, without limitation, a recent disease or illness, or consumption of medication.

Part 1
Assessment and Immunization Reporting

Assessment reporting

2(1) A health practitioner who conducts an assessment with the intention of immunizing the patient following the assessment shall ensure that a report is submitted to the Chief Medical Officer respecting the assessment if either of the following conditions exist:

(a) the health practitioner recommends immunization but does not receive consent for the immunization;

(b) the health practitioner determines that immunization is contraindicated.

(2) The health practitioner shall ensure that the report respecting the assessment is submitted by electronic means specified by the Chief Medical Officer as soon as possible and no later than 7 days after the assessment.

(3) The report respecting the assessment must contain the following information:

(a) patient first name and last name;

(b) patient personal health number or unique lifetime identifier;

(c) patient date of birth;

(d) patient sex at birth;

(e) vaccine code for the intended immunization;

(f) antigen code for the intended immunization;

(g) delivery management site code;

(h) date of the assessment;

(i) reason the vaccine was not administered.

Immunization reporting

3(1) A health practitioner who immunizes a patient shall ensure that a report respecting the immunization is submitted to the Chief Medical Officer by electronic means specified by the Chief Medical Officer.

(2) The health practitioner shall ensure that the report respecting the immunization is submitted as soon as possible and no later than 7 days after the immunization.

(3) The report respecting the immunization must contain the following information:

(a) patient first name and last name;

(b) patient personal health number or unique lifetime identifier;

(c) patient date of birth;

(d) patient sex at birth;

(e) vaccine code for the immunization;

(f) antigen code for the immunization;

(g) antigen dose count for the immunization;

(h) lot number of the vaccine, if available;

(i) manufacturer of the vaccine;

(j) date of the immunization;

(k) delivery management site code;

(l) reason the vaccine was administered.

Reporting re past unreported immunization

4(1) A health practitioner who, in the course of an immunization or an assessment conducted with the intention of immunizing the patient following the assessment, receives a complete written record respecting a past unreported immunization shall ensure that a report respecting the past unreported immunization is submitted to the Chief Medical Officer by electronic means specified by the Chief Medical Officer.

(2) The health practitioner shall ensure that the report respecting the past unreported immunization is submitted as soon as possible and no later than 7 days after the health practitioner receives the written record respecting the past unreported immunization.

(3) The report respecting the past unreported immunization must contain the following information:

(a) patient first name and last name;

(b) patient personal health number or unique lifetime identifier;

(c) patient date of birth;

(d) patient sex at birth;

(e) vaccine code for the immunization;

(f) antigen code for the immunization;

(g) antigen dose count, if available;

(h) lot number of the vaccine, if available;

(i) manufacturer of the vaccine, if available;

(j) date of the immunization;

(k) delivery management site code for the immunization, if available;

(l) reason the vaccine was administered, if available.

Part 2
Reporting of Adverse Event Following Immunization

Health practitioner reporting re adverse event following immunization

5(1) A health practitioner shall ensure that an adverse event following immunization is reported to a regional health authority within 3 days of the health practitioner determining or being informed that a patient of the health practitioner has experienced an adverse event following immunization that has not been reported to a regional health authority.

(2) The health practitioner shall ensure that the adverse event following immunization is reported by a method of immediate transmission, including, without limitation, telephone, facsimile or e-mail.

(3) The following information must be reported in respect of the adverse event following immunization:

(a) patient first name and last name;

(b) patient personal health number or unique lifetime identifier;

(c) patient date of birth;

(d) patient sex at birth;

(e) description of the adverse event, including, without limitation, any applicable symptom or diagnosis listed in the Schedule as reported by the patient or observed or diagnosed by the health practitioner, as the case may be, and the onset and duration of the adverse event;

(f) vaccine code of the vaccine used in the immunization preceding the adverse event following immunization, if available;

(g) lot number of the vaccine used in the immunization preceding the adverse event following immunization, if available;

(h) manufacturer of the vaccine used in the immunization preceding the adverse event following immunization, if available;

(i) date of the immunization preceding the adverse event following immunization;

(j) delivery management site code for the immunization preceding the adverse event following immunization, if available;

(k) first name, last name and telephone number of the person reporting.

Regional health authority reporting re adverse event following immunization

6(1) Within 4 days of determining that a patient has experienced an adverse event following immunization that is listed in the Schedule, a regional health authority shall submit a report respecting the adverse event following immunization to the Chief Medical Officer by electronic means specified by the Chief Medical Officer.

(2) The report of the regional health authority in respect of an adverse event following immunization must contain the following information:

(a) patient first name and last name;

(b) patient personal health number or unique lifetime identifier;

(c) patient date of birth;

(d) patient sex at birth;

(e) vaccine code of the vaccine used in the immunization preceding the adverse event following immunization;

(f) lot number of the vaccine used in the immunization preceding the adverse event following immunization, if available;

(g) manufacturer of the vaccine used in the immunization preceding the adverse event following immunization, if available;

(h) date of the immunization preceding the adverse event following immunization;

(i) recommendation, if any, provided by the regional health authority in respect of a patient's future immunization or in respect of follow-up action;

(j) delivery management site code for the immunization preceding the adverse event following immunization, if available.

(3) In addition to the information listed in subsection (2), a report submitted by a regional health authority to the Chief Medical Officer must refer to one or more of the following events:

(a) an event listed in the Schedule in item (a), (d), (g), (h), (j), (k), (l), (o), (p), (q), (t), (u), (v), (aa) or (cc), only if diagnosed by a physician;

(b) an event listed in the Schedule in item (b), (c), (e), (f), (i), (m), (n), (r), (s), (w), (x), (y), (z), (bb) or (dd).

Part 3
Maintenance of Vaccine Viability

Interpretation

7 In this Part,

(a) "handle", in respect of vaccine, means to manipulate, in the course of one's employment duties, a package of vaccine, including, without limitation, for the purposes of preparing the vaccine for transportation or for administration to a patient;

(b) "vaccine" means a biological agent intended for use in immunization.

Transportation requirements

8(1) A person who directs the transportation of a package of vaccine shall provide instructions to the persons who have duties in the transportation of the package of vaccine for the purpose of ensuring that the temperature conditions, as specified in the monograph for the vaccine posted on the Health Canada website, are complied with during transportation.

(2) A person who accepts delivery of a transported package of vaccine shall, immediately on delivery,

(a) review the condition of the package of vaccine and make best efforts to determine if the temperature conditions as specified in the monograph for the vaccine, posted on the Health Canada website, have been complied with during transportation, and

(b) ensure that, after the review, the vaccine is stored in compliance with the temperature conditions as specified in the monograph for the vaccine posted on the Health Canada website.

Storage requirements

9(1) A person who directs or has employment duties respecting the storage of vaccine shall ensure that the temperature conditions, as specified in the monograph for the vaccine posted on the Health Canada website, are complied with during storage.

(2) A person who directs the storage of vaccine shall ensure that the temperature of the storage unit is monitored continuously by a method that is capable of displaying or recording the minimum and maximum temperatures in the storage unit for the purposes of compliance with subsection (3).

(3) A person who directs the storage of vaccine shall ensure that, for the days that the site of the storage operates or is open for business, the maximum and minimum temperatures in the storage unit

(a) are checked at least twice daily, and

(b) are recorded in a log at least twice daily, to show the maximum and minimum temperatures since the last recording, with 2 of the recordings for each day being separated by at least 8 hours.

(4) A person who directs the storage of vaccine shall retain a recording referred to in subsection (3) for at least one year after the recording is made.

Handling requirements

10 A person who handles vaccine shall ensure that the temperature conditions, as specified in the monograph for the vaccine posted on the Health Canada website, are complied with during handling.

Action following contravention of temperature conditions

11 A person having employment duties respecting the storage, handling or transportation of vaccine who determines or becomes aware that the temperature conditions, as specified in the monograph for the vaccine posted on the Health Canada website, have been contravened shall, as soon as possible,

(a) quarantine the vaccine from other vaccines to prevent it from being administered,

(b) clearly mark the vaccine as quarantined and not to be used for immunization,

(c) ensure that the vaccine is stored under the temperature conditions, as specified in the monograph for the vaccine posted on the Health Canada website, and

(d) notify a health practitioner who has responsibility for action after a quarantine.

Action after quarantine

12(1) A health practitioner who is notified under section 11(d) or otherwise becomes aware of a contravention of the temperature conditions, as specified in the monograph for the vaccine posted on the Health Canada website, shall, as soon as possible and no later than 5 days after being notified or becoming aware, contact the manufacturer of the vaccine to request a viability assessment and determination respecting that vaccine.

(2) The health practitioner shall ensure that vaccine determined by the manufacturer to be non-viable is not administered to a patient and is disposed of or returned to the manufacturer.

(3) If the manufacturer determines that the vaccine is non-viable, and the vaccine was administered to a patient, the health practitioner shall, as soon as possible and no later than 5 days after the manufacturer's notification of non-viability, ensure that the delivery management site at which the vaccine was administered is notified of the non-viability.

(4) Within 5 days after a notification of the non-viability of a vaccine under subsection (3), a designated health practitioner at the delivery management site shall make reasonable attempts to notify all patients who were administered the non-viable vaccine.

(5) Vaccine that has been determined by the manufacturer after an assessment requested under subsection (1) to be viable may be removed from quarantine and administered to a patient.

Record keeping re temperature conditions contravention

13(1) A person referred to in section 11 or 12(1) shall ensure that the following information is recorded:

(a) the date and time that the temperature conditions contravention was identified (format: 2018July24, 0900);

(b) the date and time the vaccine was quarantined (format: 2018July24, 1000);

(c) the maximum and minimum temperatures recorded during the temperature conditions contravention (for example, -4˚C and +22˚C);

(d) the duration of the contravention or the maximum possible duration if the actual duration is unknown (for example, approximately 22 hours);

(e) the date that the viability assessment and determination were provided (format: 2018July25);

(f) the vaccine viability determination (that is, viable or non-viable);

(g) a statement of whether any non-viable vaccines were administered to patients;

(h) the vaccine code of the vaccine that was exposed to conditions contravening the temperature conditions;

(i) the manufacturer of the vaccine that was exposed to conditions contravening the temperature conditions;

(j) the lot number of the vaccine that was exposed to conditions contravening the temperature conditions.

(2) The person referred to in section 11 or 12(1) shall ensure that a copy of the information recorded under subsection (1)(a), (c), (d) and (f) is kept with the vaccine that is determined by the manufacturer to be viable.

(3) The information recorded under subsection (1) must be retained for at least 7 years.

Coming into force

14(1) This Regulation, except sections 2, 3 and 4, comes into force on the coming into force of section 23(a)(ii) and (b) of the *Public Health Amendment Act, 2016*.

(2) Sections 2, 3 and 4 come into force on January 1, 2021.

Schedule

Adverse Event Following Immunization to be Reported by a Regional Health Authority

(a) acute disseminated encephalomyelitis;

(b) adenopathy;

(c) allergic reaction;

(d) anaesthesia or paraesthesia;

(e) anaphylaxis;

(f) arthralgia or arthritis;

(g) Bell's palsy;

(h) cellulitis;

(i) convulsion (febrile or afebrile);

(j) encephalitis;

(k) erythema multiforme;

(l) Guillain-Barré syndrome;

(m) hypotonic-hyporesponsive episode (HHE);

(n) infected abscess;

(o) intussusception;

(p) meningitis;

(q) myelitis;

(r) nodule;

(s) oculo-respiratory syndrome (ORS);

(t) orchitis;

(u) paralysis;

(v) parotitis;

(w) rash;

(x) screaming episode or persistent crying;

(y) severe diarrhea or vomiting;

(z) sterile abscess;

(aa) subacute sclerosing panencephalitis;

(bb) swelling or pain;

(cc) thrombocytopenia;

(dd) other severe or unusual events.

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