Frequently asked questions:

Immunization Regulation

Public Health Act - Immunization Regulation

Which vaccines fall under the *Immunization Regulation*?

The *Immunization Regulation* applies to both provincially funded and privately purchased vaccines.

Who is responsible under the *Immunization Regulation*?

Individual health practitioners are responsible under the *Immunization Regulation*, except for Section 6, which only applies to Alberta Health Services.

Part 1: Assessment and Immunization Reporting

What must be reported under Part 1 of the *Immunization Regulation*?

An assessment with the intention of immunizing, an immunization event, or a past unreported immunization for both publicly funded and privately purchased vaccine must be reported to the Chief Medical Officer.

Who must report?

A health practitioner who conducts an assessment with the intention of immunizing a patient must report the assessment.

How do health practitioners report? What platform holds this information?

Health practitioners will report electronically to the provincial immunization repository (Imm/ARI). This is the existing reporting method for those health practitioners who currently report and it will continue to be the reporting method under this regulation.

How do I interface with Imm/ARI?

As part of implementation of this regulation, all immunizers are expected to obtain submission access to Imm/ARI through a vendor.

The electronic submission requirements will be available in early 2019.

Is there a timeframe for reporting?

The report must be submitted electronically **within 7 days.**

Why must assessments be reported? What assessments must be reported?

Immunization cannot be offered without a health practitioner first assessing the patient to determine if the immunization is appropriate and to obtain consent. Therefore, an immunization always has a preceding assessment. Certain assessments must be reported because Alberta Health would like to understand the reasons for which immunization does not occur.

The assessment must be reported if either of the following conditions exist: (a) the health practitioner recommends immunization but does not receive consent for the immunization; or (b) the health practitioner determines that immunization is contraindicated.

Why must immunization events be reported?

Under the *Public Health Act*, the Chief Medical Officer is responsible for monitoring the health of Albertans and making recommendations to the Minister of Health. To carry out this mandate, Alberta Health requires a comprehensive and timely source of immunization data. Reporting immunization events ensures client records are complete. Immunization data is then used to calculate immunization coverage rates and to manage vaccine preventable outbreaks.

Why must past unreported immunization events be reported?

In order to determine vaccine eligibility, it is essential to review the immunization history. When past unreported immunization events are reported, all health practitioners will have access to the patient's complete immunization history.

It is also advantageous from a health surveillance perspective to ensure that a patient's immunization information is as up-to-date as possible. Immunization administration data provides a more accurate picture of immunity in the population. This is necessary for outbreak management, and provides accurate information about general immunization rates. Health practitioners conducting immunization assessments, or health practitioners providing immunizations, will electronically submit past immunizations from a written record that were previously unreported to Imm/ARI.

When must past unreported immunization events be reported?

Past unreported immunization events are only required to be reported in the context of an assessment with the intention of immunizing.

When does Part 1 come into force?

Part 1 of the *Immunization Regulation* comes into force January 1, 2021.

Part 2: Reporting of Adverse Event Following Immunization

What is an adverse event following immunization (AEFI)?

An adverse event following immunization is an unfavourable health occurrence experienced by a patient that:

- follows immunization,
- cannot be attributed to a pre-existing condition, and
- meets one or more of the following criteria, as determined by a health practitioner:
  - 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;
  - is unusual or unexpected, or
  - cannot be explained by anything in the patient's medical history.

Who has a duty to report an AEFI?

ANY health practitioner who becomes aware of an AEFI as defined above must report it. They do not have to be the one who administered the vaccine. Netcare can be used to determine if an AEFI has previously been reported.

How are AEFIs reported?

Health practitioners will be required to report AEFIs to Alberta Health Services (AHS). AHS will have a central intake process for health practitioners to report AEFIs via phone, fax number and/or email. More details will be provided once processes have been established.

Is there a timeframe for reporting AEFIs?

AEFIs must be reported to AHS central intake within 3 days of the health practitioner determining or being informed that a patient has experienced an AEFI that has not already been reported to AHS.

The phone number for the AEFI Reporting Line is 1-855-444-2324 (1-855-444-CDCI).

What does AHS do with the information that is provided?

AHS will follow up with the patient to provide advice and recommendations, and to determine if the AEFI meets the criteria set out in the Schedule of the *Immunization Regulation* to be reported to Alberta Health.

When does Part 2 of the *Immunization Regulation* come into force?

Part 2 of the *Immunization Regulation* came into force December 17, 2018.

Part 3: Maintenance of Vaccine Viability

What does "maintenance of vaccine viability" mean?

"Maintenance of vaccine viability" relates to the requirements for transportation, storage and handling of vaccines. Vaccines need to be maintained as per their respective product monographs, which are available on the Health Canada website.

If a vaccine is exposed to certain conditions (such as extremes of temperature), viability cannot be assured.

In order to protect vaccine from such conditions and protect patients from compromised vaccine, it is necessary to establish requirements in regulation throughout the process of vaccine storage, handling and transportation.

Who does Part 3 of the *Immunization Regulation* apply to?

Vaccine Storage

All persons who participate in and/or direct the storage of vaccine.

Vaccine Handling

Any person who is handling the vaccine, including but not limited to removing the vaccine from storage to administer to a patient or who is preparing the vaccine for transportation.

Vaccine Transportation

Any person who directs the transportation of vaccine is responsible for providing appropriate instructions for transportation to maintain vaccine temperature as per manufacturer's recommendation as specified in the product monograph on the Health Canada website.

What are the storage requirements?

The storage requirements include continuous monitoring, minimum/maximum temperature reporting, and temperature recording twice per day. These requirements are meant to ensure that the temperature conditions, as specified in the product monograph for the vaccine are complied with during storage.

What are the handling requirements?

The handling requirements stipulate that anyone who handles vaccine must ensure that the temperature conditions, as specified in the product monograph for the vaccine, are complied with.

What are the transportation requirements?

The transportation requirements stipulate that a person who directs the transportation of vaccine is responsible for providing appropriate instructions for transportation to maintain vaccine temperature as per the manufacturer's recommendation as specified in the product monograph on the Health Canada website.

The person who accepts delivery of a transported package is required to review the condition of the vaccine and make best efforts to determine that the temperature conditions have been maintained as specified in the product monograph. After the review, the vaccine must be stored in compliance with the temperature conditions specified in the product monograph.

What is required when a temperature condition contravention is discovered?

The *Immunization Regulation* requires that when any person who stores, handles or transports vaccine (or directs the storage, handling or transportation) becomes aware of a temperature contravention during storage, handling, or transport, they must ensure the vaccine is quarantined as soon as possible.

What does it mean to quarantine a vaccine?

To quarantine the vaccine is to isolate it from other products, clearly mark it as quarantined, label it with the date of quarantine and store it at the temperature conditions required by the manufacturer. It is important that this action be taken as soon as possible, as the product should be prevented from further exposure to extremes of temperature, and should be prevented from being administered until its viability is determined. There is no reason for a delay between discovering the contravention and quarantining it.

What do I do after vaccine has been quarantined?

The regulation requires that, once a vaccine has been quarantined, the person directing the storage of that vaccine ensures that a health practitioner contact the manufacturer of the vaccine (within 5 days) to obtain a viability determination respecting the contravention.

What occurs when the vaccine is determined to be viable?

If the viability determination is that the product remains viable, the product can be removed from quarantine and can be subsequently administered to a patient.

What occurs when the vaccine is determined to be not viable?

If the viability determination is that the product is no longer viable, the quarantined product must be disposed of or returned to the manufacturer.

What if a vaccine is found to be non-viable after administration to a patient?

The health practitioner who called the manufacturer must notify (within 5 days of receiving the viability assessment from the manufacturer) the site where the vaccine was administered. The health practitioner at the site where the vaccine was administered must then attempt to notify the patient within 5 days of becoming aware.

What records need to be kept for vaccine storage?

Temperature logs need to be kept for one year. A temperature log needs to include the type of monitoring device, monitoring, minimum/ maximum temperature reporting, and temperature recordings.

How long do records for temperature condition contraventions need to be kept?

Records for temperature condition contraventions need to be kept for 7 years. The information to be recorded is outlined in the *Immunization Regulation*. Some information related to the temperature excursion must be kept with the vaccine. This information is also outlined in the *Immunization Regulation*.

Who can I contact for more information?

Please contact your professional college or association for more information.

