

6. This Regulation comes into force on the 45th day following the date of its publication in the *Gazette officielle du Québec*.

Despite the foregoing, section 414 comes into force on 1 April 2016.

3341

M.O., 2014

Order number 2014 005 of the Minister of Health and Social Services and the Minister for Rehabilitation, Youth Protection and Public Health dated 16 May 2014

Public Health Act
(chapter S-2.2)

Regulation respecting the vaccination registry and unusual clinical manifestations temporarily associated with vaccination

THE MINISTER OF HEALTH AND SOCIAL SERVICES
AND THE MINISTER FOR REHABILITATION, YOUTH
PROTECTION AND PUBLIC HEALTH,

CONSIDERING section 64 of the Public Health Act (chapter S-2.2), which provides that the information prescribed therein on each vaccination is released to the operations manager of the vaccination registry for registration, under the conditions and in the manner prescribed by regulation of the Minister;

CONSIDERING section 69 of the Act concerning the reporting to the appropriate public health director by a health professional of unusual clinical manifestations temporarily associated with vaccination, which provides in particular that the health professional must provide the information prescribed therein and any other information prescribed by regulation of the Minister;

CONSIDERING paragraph 8 of section 136 of the Act, which provides in particular that the Minister may make regulations to determine the means of communication to be used whenever information is transmitted under the Act;

CONSIDERING the publication in Part 2 of the *Gazette officielle du Québec* of 19 February 2014, in accordance with sections 10 and 11 of the Regulations Act (chapter R-18.1), of a draft Regulation respecting the vaccination registry and unusual clinical manifestations temporarily associated with vaccination, with a notice that it could be made on the expiry of 45 days following that publication;

CONSIDERING section 17 of the Regulations Act, which provides that a regulation comes into force 15 days after the date of its publication in the *Gazette officielle du Québec* or on any later date indicated in the regulation or in the Act under which it is made;

CONSIDERING that it is expedient to make the Regulation with amendments to take into account certain comments received;

ORDER AS FOLLOWS:

The Regulation respecting the vaccination registry and unusual clinical manifestations temporarily associated with vaccination, appearing below, is hereby made.

| | |
|---|---|
| GAÉTAN BARRETTE, <i>Minister of Health and Social Services</i> | LUCIE CHARLEBOIS, <i>Minister for Rehabilitation, Youth Protection and Public Health</i> |
|---|---|

Regulation respecting the vaccination registry and unusual clinical manifestations temporarily associated with vaccination

Public Health Act
(chapter S-2.2, ss. 64, 69, 136, par. 8)

DIVISION I VACCINATION REGISTRY

CHAPTER I CONDITIONS FOR RELEASING INFORMATION TO THE OPERATIONS MANAGER OF THE VACCINATION REGISTRY

1. An institution within the meaning of the Act respecting health services and social services (chapter S-4.2) or the Act respecting health services and social services for Cree Native persons (chapter S-5) that operates a centre where a professional administers a vaccine must, within 2 business days of the administration of the vaccine, release the following information to the operations manager of the vaccination registry for registration:

(1) the information referred to in section 64 of the Public Health Act (chapter S-2.2), except the information provided for in subparagraphs *d*, *f* and *g* of paragraph 1, subparagraphs *f* and *i* of paragraph 2, subparagraphs *i*, *k* and *l* of paragraph 3, the vaccinator's unique provider number and the unique identification number of the location providing health services and social services to which the vaccinator is attached;

(2) the information referred to in section 4.

An institution that operates a centre where a health professional has, in accordance with the second paragraph of section 61 of the Act, validated a vaccination received by a person outside Québec must, within 2 business days of the validation, release the information referred to in the first paragraph, insofar as it is available, to the operations manager of the vaccination registry for registration in the vaccination registry.

The information to be released by an institution is released by means of an information asset that allows for the safe transmission of the information. The Minister informs each institution in writing of the information asset allowing for such transmission, of the centre or facility where the asset is available to the institution and of the date on which the transmission is to begin.

An institution that does not have access to an information asset as provided for in the third paragraph must release the information prescribed by the first and second paragraphs in a manner that ensures the information's protection.

2. A vaccinator not acting within the scope of the mission of a centre operated by an institution must, within 2 business days of the administration of a vaccine, release the information referred to in the first paragraph of section 1 to the operations manager of the vaccination registry for registration.

The information to be released by the vaccinator is released in a manner that ensures the protection of the information released.

3. A health professional who does not act within the scope of the mission of a centre operated by an institution and who has, in accordance with the second paragraph of section 61 of the Act, validated a vaccination received by a person outside Québec must, within 2 business days of the validation, release the information referred to in the first paragraph of section 1, insofar as it is available, to the operations manager of the vaccination registry for registration in the vaccination registry.

The information to be released by the professional is released in a manner that ensures the protection of the information released.

DIVISION II

OTHER INFORMATION TO BE RELEASED TO THE OPERATIONS MANAGER OF THE VACCINATION REGISTRY

4. The following information, insofar as it is available, must be released to the operations manager of the vaccination registry for registration in the vaccination registry:

(1) in respect of the vaccinated person:

(a) the criteria and the type of proof of immunity, if applicable;

(b) if the person is not registered with the Régie de l'assurance maladie du Québec, the number and title of the official document emanating from a State authority establishing the person's identity;

(2) the means of communication preferred by the vaccinated person in case of vaccine reminder, recall or promotion;

(3) an indication that the vaccination was performed under a public vaccination program, if applicable.

5. The following information must be released to the operations manager of the vaccination registry for registration in the vaccination registry, upon request by the manager or the Minister, by any person or organization in possession of the information:

(1) in respect of the vaccinated person:

(a) the person's language of correspondence;

(b) the name of each of the person's parents;

(c) an indication that the person works in an educational institution, if applicable;

(d) the date of death, if applicable;

(2) in respect of the vaccinated person attending an educational institution, the year of the school year corresponding to the school data contained in the register in the person's respect;

(3) in respect of the vaccinated person who works in an educational institution:

(a) the name of the educational institution where the person works, the person's educational level and the class number, if applicable, and the name of the school board and of the building where the person works, if applicable;

(b) the year of the school year corresponding to the school data contained in the register in the person's respect;

(4) from among the information provided for in section 64 of the Act:

(a) the information provided for in subparagraphs *d, f* and *g* of paragraph 1, subparagraphs *f* and *i* of paragraph 2, subparagraphs *i, k* and *l* of paragraph 3;

(b) the vaccinator's unique provider number and the unique identification number of the location providing health services and social services to which the vaccinator is attached.

CHAPTER II REPORTING OF UNUSUAL CLINICAL MANIFESTATIONS TEMPORARILY ASSOCIATED WITH VACCINATION

6. Every health professional referred to in section 69 of the Act must provide to the public health director of the professional's territory, in addition to the information provided for in that section, the following information, insofar as it is available:

(1) the date of birth, sex and estimated age at vaccination time of the person concerned;

(2) the vaccination date, the brand name of the vaccine administered or the name of the immunizing agent and the lot number of the vaccine administered;

(3) the dose number, the lot number of the adjuvant, the injection site and administration route of the vaccine administered, the quantity administered and the unit of measurement of the vaccine administered;

(4) the socio-sanitary region where the person concerned resides or, if vaccination did not take place in Québec, the Canadian province or country where vaccination took place;

(5) the time elapsed between vaccination and the beginning of the unusual clinical manifestation;

(6) identification of the unusual clinical manifestation;

(7) a description of the unusual clinical manifestation;

(8) the duration of the unusual clinical manifestation;

(9) immunization errors observed in connection with the unusual clinical manifestation, if applicable;

(10) the evolution of the incident at the time of reporting and at the time of the follow-up, if applicable;

(11) an indication that the person concerned is pregnant and the expected date of delivery, if applicable;

(12) the type of any medical consultation relating to the unusual clinical manifestation, if applicable;

(13) the date of any admission to a hospital centre in connection with the unusual clinical manifestation and the duration of hospitalization, if applicable;

(14) an indication that a current hospitalization is extended following the unusual clinical manifestation and the duration of that extension, if applicable;

(15) the severity of the case;

(16) a description of the treatment received, if applicable;

(17) the medication history of the person concerned at the time of vaccine administration, in connection with the unusual clinical manifestation;

(18) a description of the health problems, illnesses, allergies and acute lesions of the person concerned that are known at the time of vaccine administration, in connection with the unusual clinical manifestation;

(19) a description of the unusual clinical manifestations associated with vaccination that appeared previously in the person concerned, if applicable;

(20) the date of death of the person concerned, if applicable;

(21) the position of the person reporting the unusual clinical manifestation and the socio-sanitary region of the report;

(22) the date of the report.

CHAPTER III TRANSITIONAL

7. Despite the fourth paragraph of section 1, any institution operating a general and specialized hospital centre or local authority must keep the information prescribed by the first paragraph of that section until the date on which the transmission of information is to begin by means of an information asset, in accordance with the third paragraph of that section, or until 31 December 2016 at the latest.

Until the first of those dates, the information must be kept by such an institution so that it can be released to the operations manager of the vaccination registry, upon request by the manager or the Minister, for registration in the vaccination registry and so that it can be used or released in accordance with the Act.

8. Despite sections 2 and 3, any vaccinator or professional referred to in those sections must keep the information prescribed in the first paragraph of section 1 until 31 December 2016. The information must be kept by such a vaccinator or professional so that it can be released to the operations manager of the vaccination registry, upon request by the manager or the Minister, for registration in the vaccination registry and so that it can be used or released in accordance with the Act.

CHAPTER IV COMING INTO FORCE

9. This Regulation comes into force on the fifteenth day following the date of its publication in the *Gazette officielle du Québec*.