

HEALTH

HE301

HEALTH ACT 1911

**HEALTH (NOTIFICATION OF ADVERSE EVENT AFTER
IMMUNIZATION) REGULATIONS 1995**

Made by the deputy of the Governor in Executive Council.

Citation

1. These regulations may be cited as the *Health (Notification of Adverse Event After Immunization) Regulations 1995*.

Interpretation

2. In these regulations —

“adverse event after immunization” means —

- (a) any one or more of the following conditions suffered by a person within 48 hours of immunization —
 - (i) screaming that continues for more than 3 hours;
 - (ii) a temperature of 40.5°C that cannot reasonably be attributed to any other cause;
 - (iii) anaphylaxis;
 - (iv) shock; or
 - (v) a hypotonic or hyporesponsive episode;

- (b) any one or more of the following conditions suffered by a person within 30 days of immunization —
 - (i) encephalopathy;
 - (ii) convulsions;
 - (iii) aseptic meningitis;
 - (iv) thrombocytopenia; or
 - (v) acute flaccid paralysis;
- (c) the death of a person that occurs within 30 days of immunization; or
- (d) any other serious condition suffered by a person within 30 days of immunization if the condition is —
 - (i) not reasonably attributable to any other cause; and
 - (ii) suspected of being associated with immunization;

“immunization”, in relation to a person, means the administration to the person of a vaccine for the purpose of protecting the person against a disease.

Adverse event after immunization prescribed as condition of health

3. An adverse event after immunization is prescribed as a condition of health to which Part IXA of the Act applies.

Notification by medical practitioner

4. (1) A medical practitioner must notify the Executive Director, Public Health of an adverse event after immunization within 14 days of becoming aware of that adverse event.

- (2) A notification under subregulation (1) must —
 - (a) be in writing in a form approved by the Executive Director, Public Health; and
 - (b) include the following information —
 - (i) a full description of the adverse event after immunization;
 - (ii) the full name of the person who suffered the adverse event after immunization and that person's address or telephone number;
 - (iii) where the adverse event after immunization is the death of a person, the full name, and the address or telephone number, of the next of kin or personal representative of the deceased person (if known);
 - (iv) the name, dose and batch number of the vaccine administered;
 - (v) the date on which the vaccine was administered;
 - (vi) the name and address of the place where the vaccine was administered; and
 - (vii) the full name, address and telephone number of the medical practitioner giving the notification.

(3) A medical practitioner who contravenes subregulation (1) commits an offence and is liable to a penalty which is not more than \$1 000 and not less than —

- (a) in the case of a first offence, \$100;
- (b) in the case of a second offence, \$200; and
- (c) in the case of a third or subsequent offence, \$500.

Fee for notification

5. A fee of \$5 is payable to a medical practitioner who gives notification under regulation 4 but this regulation does not apply to a medical practitioner who is employed in the Public Service of the State or the Commonwealth, or is employed by an agency or instrumentality of the State or the Commonwealth.

Executive Director, Public Health may request provision of information

6. (1) Where the Executive Director, Public Health —
- (a) is notified of an adverse event after immunization; and
 - (b) has reasonable grounds to believe that a person is able to provide information relating to the adverse event,

the Executive Director, Public Health may request the person to provide such information relating to the adverse event as the Executive Director, Public Health considers necessary for the purpose of achieving the objects of Part IXA of the Act.

(2) A person to whom a request is made under subregulation (1) must comply with the request within 14 days of receiving the request.

(3) A person who, without reasonable excuse, contravenes subregulation (2) commits an offence and is liable to a penalty which is not more than \$1 000 and not less than —

- (a) in the case of a first offence, \$100;
- (b) in the case of a second offence, \$200; and
- (c) in the case of a third or subsequent offence, \$500.

By Command of the deputy of the Governor,

J. PRITCHARD, Clerk of the Council.
