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S T A T E O F R H O D E I S L A N D

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2020

A N A C T

RELATING TO HEALTH AND SAFETY -- VACCINE ADVERSE EVENTS REPORTING ACT

Introduced By: Senator Elaine J. Morgan

Date Introduced: February 13, 2020

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

SECTION 1. Title 23 of the General Laws entitled "HEALTH AND SAFETY" is hereby amended by adding thereto the following chapter:

CHAPTER 6.6

VACCINE ADVERSE EVENTS REPORTING ACT

23-6.6-1. Short title.

This chapter shall be known and may be cited as the "Vaccine Adverse Events Reporting Act."

23-6.6-2. Legislative declarations.

The general assembly hereby declares that the United States Department of Health And Human Services reports that:

(1) Fewer than one percent (1%) of vaccine adverse events are reported.

(2) Low reporting rates preclude or slow the identification of "problem" drugs and vaccines that endanger public health.

(3) New surveillance methods for drug and vaccine adverse effects are needed.

(4) Barriers to reporting include a lack of clinician awareness, uncertainty about when and what to report, as well as the burdens of reporting as reporting is not part of clinicians' usual workflow, takes time, and is duplicative.

23-6.6-3. Definitions.

As used in this chapter:

(1) "Department" means the department of health;

(2) "Vaccine adverse event" means any adverse effect related to the administration of a vaccine sustained by a patient; and

(3) "Vaccine provider" means a hospital, medical practice, sole practitioner or medical organization that administers vaccinations to its patients by a licensed doctor or nurse.

23-6.6-4. Department of health - Collection of data and reporting requirements.

(a)(1) The department shall provide an internet-based software program (ESP VAERS) to facilitate vaccine provider's detection and clinical reporting of vaccine adverse events, in order to improve the safety of the Rhode Island vaccination program.

(2) The software program will provide standardized vaccine adverse events which will alert the vaccine provider to assess the need for a potential vaccine adverse event to be directly reported to the vaccine adverse event reporting system (VAERS) database.

(b) The department shall provide the software to be accessible and also provide guidance on implementation through written directives to vaccine providers that may be accessed on the department of health website.

(c) The department shall provide guidance and a training video reviewing adverse events listed on the reportable events table (RET). The RET reflects what is reportable by law pursuant to 42 U.S.C. 300aa-25 to the VAERS database including conditions found in the manufacturer package insert.

(d) The department shall provide a report of the potential vaccine adverse events reported to VAERS impacting Rhode Island residents and potential adverse events from vaccines administered in Rhode Island annually to the governor and the general assembly. Data points in the report shall include:

(1) Age of vaccinee;

(2) Sex of vaccinee;

(3) Date of vaccination;

(4) Date of onset of potential adverse event;

(5) Vaccine(s) type;

(6) Vaccine name and manufacturer; and

(7) Description of adverse event.

23-6.6-5. Vaccine providers - Reporting of data.

Vaccine providers shall be required to use Internet-based reporting of potential vaccine adverse events to the VAERS. Vaccine providers shall meet all of the following conditions:

(1) The vaccine provider is required to participate in post-marketing surveillance to improve on the safety and quality of the vaccination program; and

(2) The vaccine provider shall maintain appropriate security protocols to preserve the confidentiality of the reports submitted through the system.

SECTION 2. This act shall take effect upon passage.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

A N A C T

RELATING TO HEALTH AND SAFETY -- VACCINE ADVERSE EVENTS REPORTING ACT

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This act would establish a reporting system to detect and report vaccine adverse events to the department of health (DOH) from vaccine providers to improve the safety of the Rhode Island vaccination program.

This act would take effect upon passage.

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