ASSEMBLY, No. 400

STATE OF NEW JERSEY

219th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2020 SESSION

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SYNOPSIS

Establishes Children's Vaccine Adverse Event Reporting System.

CURRENT VERSION OF TEXT

Introduced Pending Technical Review by Legislative Counsel.

AN ACT establishing a vaccine adverse event reporting system and supplementing Title 26 of the Revised Statutes.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. This act shall be known and may be cited as the "Children's Vaccine Adverse Event Reporting Act."

2. The Legislature finds and declares that:

a. The use of vaccines has greatly reduced the incidence of many infectious diseases, disability, and death, has resulted in the eradication of smallpox, and has dramatically decreased the transmission of certain types of polio globally.

b. Routine immunization of children in the United States targets numerous vaccine-preventable diseases, and children receive multiple doses of some vaccines between birth and age six, with certain boosters required through the pre-teen and teenage years to ensure efficacy.

c. Generally, vaccines have an excellent safety record, and pharmaceutical research has spurred the development of less reactogenic vaccines, however vaccines can, like most medical procedures and medications, have side effects.

d. Newly approved vaccines, such as that for human papilloma virus, have resulted in an increase in the number of vaccines that are recommended during childhood and adolescence.

e. In order to contribute to the scientific knowledge and pharmacovigilance of vaccines in children, it is appropriate that the State provide a means by which health care professionals report suspected adverse reactions to vaccines in children.

3. As used in this act:

"Adverse Event" means any unfavorable or unintended medical occurrence, including any sign, laboratory finding, symptom, or disease that the child experiences within eight weeks following the administration of a vaccine.

"Child" means an individual who is under 19 years of age.

"Commissioner" means the Commissioner of Health.

"Department" means the Department of Health.

"Health care provider" means a physician, physician assistant, advanced practice nurse, registered nurse, pharmacist, or other professional licensed pursuant to Title 45 of the Revised Statutes and authorized to administer vaccines.

"System" means the Children's Vaccine Adverse Event Reporting System established pursuant to this act.

4. a. The commissioner shall establish and maintain a Children's Vaccine Adverse Event Reporting System in the Department to receive and maintain all adverse event information that is reported pursuant to this act, and any other information that the commissioner deems relevant and appropriate to effectuate the purposes of this act. The commissioner shall also ensure that an adverse event report received pursuant to this act that is not subject to mandatory reporting pursuant to the "National Childhood Vaccine Injury Act of 1986" (42 U.S.C. ss.300aa-1 et seq.) is reported to the Vaccine Adverse Event Reporting System (VAERS) operated by the federal Centers for Disease Control and Prevention and the United States Food and Drug Administration.

b. A health care provider shall report to the system an adverse event experienced by a child in the provider's care or to whom the health care provider administered a vaccine, and occurring within eight weeks following the administration of a vaccine to the child, regardless of whether the vaccine is deemed, in the professional opinion of the health care provider, to be the cause of the adverse event. A health care provider who treats a child in the emergency department of a hospital or an urgent care center in the State shall be subject to the reporting requirements of this act.

c. The report shall be in a form and manner to be determined by the commissioner and shall include the name and address of the health care provider submitting the report, the name, age, and address of the child, the adverse event or events experienced by the child, the date of administration of the child's most recent vaccine, the vaccine or vaccines that were administered, any product inserts that were packaged with the vaccine, and any other pertinent information as may be required by the commissioner.

d. A health care provider that provides information to the department pursuant to this act shall not be deemed to be, or held liable for, divulging confidential information.

e. The commissioner may share the information in the system solely: (1) with recognized public health entities that analyze data on vaccines and adverse events, except that the identity of any child or health care provider shall not be disclosed or made public; and, (2) as required pursuant to subsection a. of this section.

f. Nothing in this act shall be deemed to supercede or abrogate the provisions of P.L.1986, c.134 (C.26:2N-1 et seq.) concerning the reporting of adverse reactions to pertussis vaccines.

5. This act shall take effect on the first day of the sixth month next following the date of enactment but the commissioner may take such anticipatory administrative action in advance as is necessary for the implementation of this act.

STATEMENT

This bill requires the establishment of a Children's Vaccine Adverse Event Reporting System in the Department of Health to receive and maintain reports of adverse events experienced by a child under 19 years of age, in the eight weeks following the administration of a vaccine. The bill requires that health care providers report any adverse event experienced by a child in the provider's care or to whom the health care provider administered a vaccine(s), regardless of whether the vaccine(s) is deemed, in the professional opinion of the health care provider, to be the cause of the adverse event. The reporting requirements would apply to a physician, physician assistant, advanced practice nurse, registered nurse, pharmacist, or other professional licensed pursuant to Title 45 of the Revised Statutes and authorized to administer vaccines, including those who provide care to a child in the emergency department of a hospital or an urgent care center in the State.

The bill provides that the Commissioner of Health is to determine the form and manner of reports made to the system and that such reports include the name and address of the health care provider submitting the report, the name, age, and address of the child, the adverse event or events experienced by the child, the date of administration of the child's most recent vaccine, the vaccine or vaccines that were administered, any product inserts that were packaged with the vaccine, and any other pertinent information as may be required by the commissioner.

The bill authorizes the commissioner to share the adverse event reports only with: (1) recognized public health entities that analyze data on vaccines and adverse events, except that the identity of any child or health care provider shall not be disclosed or made public; and, (2) with the Vaccine Adverse Event Reporting System (VAERS) operated by the federal Centers for Disease Control and Prevention and the United States Food and Drug Administration, in the event that the healthcare provider was not required to report the particular adverse event to VAERS under the provisions of federal law.

The bill would take effect on the first day of the sixth month next following enactment.