

**SENATE, No. 2828**

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**STATE OF NEW JERSEY**  
**218th LEGISLATURE**

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INTRODUCED JULY 23, 2018

**Sponsored by:**

**Senator ROBERT W. SINGER**

**District 30 (Monmouth and Ocean)**

**SYNOPSIS**

Establishes Children's Vaccine Adverse Event Reporting System.

**CURRENT VERSION OF TEXT**

As introduced.



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

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

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7 1. This act shall be known and may be cited as the “Children’s  
8 Vaccine Adverse Event Reporting Act.”

9

10 2. The Legislature finds and declares that:

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

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

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

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

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

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32 3. As used in this act:

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

37 “Child” means an individual who is under 19 years of age.

38 “Commissioner” means the Commissioner of Health.

39 “Department” means the Department of Health.

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

44 “System” means the Children’s Vaccine Adverse Event  
45 Reporting System established pursuant to this act.

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47 4. a. The commissioner shall establish and maintain a  
48 Children’s Vaccine Adverse Event Reporting System in the  
49 Department to receive and maintain all adverse event information

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

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

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

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

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

35 f. Nothing in this act shall be deemed to supercede or abrogate  
36 the provisions of P.L.1983, c.134 (C.26:2N-1 et seq.) concerning  
37 the reporting of adverse reactions to pertussis vaccines.

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

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#### STATEMENT

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47 This bill requires the establishment of a Children's Vaccine  
48 Adverse Event Reporting System in the Department of Health to  
49 receive and maintain reports of adverse events experienced by a

1 child under 19 years of age, in the eight weeks following the  
2 administration of a vaccine. The bill requires that health care  
3 providers report any adverse event experienced by a child in the  
4 provider's care or to whom the health care provider administered a  
5 vaccine(s), regardless of whether the vaccine(s) is deemed, in the  
6 professional opinion of the health care provider, to be the cause of  
7 the adverse event. The reporting requirements would apply to a  
8 physician, physician assistant, advanced practice nurse, registered  
9 nurse, pharmacist, or other professional licensed pursuant to Title  
10 45 of the Revised Statutes and authorized to administer vaccines,  
11 including those who provide care to a child in the emergency  
12 department of a hospital or an urgent care center in the State.

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

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

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