

SENATE, No. 996

STATE OF NEW JERSEY
219th LEGISLATURE

INTRODUCED JANUARY 30, 2020

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.

3
4 **BE IT ENACTED** *by the Senate and General Assembly of the State*
5 *of New Jersey:*

6
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.

31

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.

46

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
6 Vaccine Injury Act of 1986” (42 U.S.C. ss.300aa-1 et seq.) is
7 reported to the Vaccine Adverse Event Reporting System (VAERS)
8 operated by the federal Centers for Disease Control and Prevention
9 and the 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.1986, 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.

43 44 45 STATEMENT

46
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.