Establishes Children’s Vaccine Adverse Event Reporting System.

As introduced.
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.1983, 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.