

26:2N-1

12/30/86

LEGISLATIVE HISTORY CHECKLIST

NJSA: 26:2N-1

(Pertussis<sup>s</sup> vaccine-- associated health problems--require Dept. of Health to compile data)

LAWS OF: 1986

CHAPTER 134

BILL NO: S1696

Sponsor(s): Bassano and McNamera

Date Introduced: February 24, 1986

Committee: Assembly: Health and Human Services

Senate: Institutions, Health and Welfare

Amended during passage: No

Date of Passage: Assembly: Sept. 15, 1986

Senate: May 5, 1986

Date of Approval: Oct. 21, 1986

Following statements are attached if available:

Sponsor statement: Yes

Committee statement: Assembly Yes

Senate Yes

Fiscal Note: No

Veto Message: No

Message on Signing: No

Following were printed:

Reports: No

Hearings: No

(over)

DO NOT WRITE IN THESE SPACES

95

S294, vetoed by Governor during 1984-85.

Committee statement and original bill--attached. Legislative session-- OCR, Senate Maryland statute, referred to in sponsor's statement to S2954--attached.

SENATE, No. 1696  
STATE OF NEW JERSEY

INTRODUCED FEBRUARY 24, 1986

By Senators BASSANO and McNAMARA

Referred to Committee on Institutions, Health and Welfare

AN ACT concerning pertussis vaccine, supplementing Title 26 of the Revised Statutes, and making an appropriation.

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

1 i. For the purposes of this act:

2 a. "Commissioner" means the Commissioner of Health.

3 b. "Department" means the State Department of Health.

4 c. "Health care provider" means any licensed health care pro-  
5 fessional or public or private health care facility in this State that  
6 administers pertussis vaccine.

7 d. "Major adverse reaction" means collapse or shock, high pitched  
8 screaming, persistent crying for three or more hours, excessive  
9 somnolence (sleepiness), temperature of 105°, convulsions with or  
10 without accompanying fever or severe alterations of consciousness  
11 or any serious illness, disability or impairment of mental, emo-  
12 tional, behavioral or physical functioning or development, the first  
13 manifestation of which appears within 30 days of the date of ad-  
14 ministration of pertussis vaccine, and for which there is reasonable  
15 scientific or medical evidence that pertussis vaccine causes or  
16 significantly contributes to the illness, disability or impairment;  
17 or any other reaction which the department determines, by regula-  
18 tion, is a basis for not administering pertussis vaccine.

19 e. "Pertussis vaccine" means any vaccine containing a substance  
20 intended to prevent the occurrence of pertussis, which is adminis-  
21 tered separately or in conjunction with other substances intended  
22 to prevent the occurrence of other diseases.

1 2. The commissioner shall prepare and make available to all  
2 health care providers in the State and parents and guardians, upon  
3 request, a pamphlet which explains the benefits and possible ad-  
4 verse reactions to immunizations for pertussis. This pamphlet may  
5 contain any information which the commissioner deems necessary  
6 and may be revised by the department whenever new information  
7 concerning these immunizations becomes available. The pamphlet  
8 shall include the following information:

9 a. A list of the immunizations required for admission to a public  
10 or private school in the State;

11 b. Specific information regarding the pertussis vaccine which  
12 includes:

13 (1) The circumstances under which pertussis vaccine should not  
14 be administered or should be delayed, including the categories of  
15 persons who are significantly more vulnerable to major adverse  
16 reactions than are members of the general population;

17 (2) Possible adverse reactions to pertussis vaccine and the  
18 early warning signs or symptoms that may be precursors to a  
19 major adverse reaction which, upon occurrence, should be brought  
20 to the immediate attention of the health care provider who  
21 administered the vaccine;

22 (3) A form that the parent or guardian may use to monitor  
23 symptoms of a possible adverse reaction and which includes places  
24 where the parent or guardian can record information about the  
25 symptoms that will assist the health care provider; and

26 (4) Measures that a parent or guardian should take to reduce  
27 the risk of, or to respond to, a major adverse reaction including  
28 identification of who should be notified of the reaction and when  
29 the notification should be made.

30 The commissioner shall prepare the pamphlet in consultation  
31 with the Medical Society of New Jersey and the University of  
32 Medicine and Dentistry of New Jersey and shall adopt by regula-  
33 tion the information contained in the pamphlet, pursuant to the  
34 "Administrative Procedure Act," P. L. 1968, c. 410 (C. 52:14B-1  
35 et seq.).

1 3. Prior to administering a pertussis vaccine to a child in this  
2 State, a health care provider shall give the child's parent or guard-  
3 ian a copy of the pamphlet prepared pursuant to section 2 of this  
4 act and provide the parent or guardian with a reasonable oppor-  
5 tunity to read the contents of the pamphlet.

1 4. A child shall not be required to receive a pertussis vaccine as  
2 a condition for admission to a public or private school if the child's

3 health care provider states in writing that the vaccine is medically  
4 contraindicated pursuant to subsection b. (1) of section 2 of this  
5 act and the reasons for the medical contradictions.

1 5. a. Upon administering a pertussis vaccine to a child in this  
2 State, a health care provider shall record and retain as part of the  
3 child's permanent health record the date the vaccine was admin-  
4 istered, the manufacturer, a lot number and any other available  
5 identifying information of the vaccine that was administered, and  
6 the name and title of the health care provider who administered  
7 the vaccine.

8 b. The health care provider shall make the information concern-  
9 ing the vaccine available to the child's parent or guardian, upon  
10 request.

1 6. a. If, within seven days of administering a pertussis vaccine  
2 the health care provider has reason to believe that the recipient of  
3 the vaccine has had a major adverse reaction, the health care pro-  
4 vider shall record all relevant information in the child's permanent  
5 medical record and report the information, including the manu-  
6 facturer and the lot number, to the department.

7 b. Upon receipt of the information, the department shall im-  
8 mediately notify the manufacturer of the vaccine and the Center  
9 for Disease Control of the adverse reaction.

1 7. The commissioner shall periodically report information re-  
2 ceived regarding major adverse reactions to the United States  
3 Center for Disease Control.

1 8. There is appropriated \$75,000.00 from the General Fund to  
2 the Department of Health to carry out the purposes of this act.

1 9. This act shall take effect on the 180th day following enactment.

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#### STATEMENT

This bill requires the Department of Health to prepare and make available to health care providers for distribution to parents a pamphlet concerning the benefits of, and possible adverse reactions associated with, administration of the pertussis (whooping cough) vaccine.

Also, the bill requires that a health care provider give the pamphlet to a parent or guardian before the pertussis vaccine is administered. The health care provider is required to record in the child's permanent medical record identifying information about the pertussis vaccine. If a major adverse reaction to the pertussis vaccine occurs, the health care provider is directed to report this information to the department, which is then required to report

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the information immediately to the manufacturer of the vaccine and to the Center for Disease Control.

The bill exempts a child from the pertussis vaccine, which is required as a condition for admission to school, if the child's health care provider states in writing that the vaccine is medically contraindicated for that child.

The bill appropriates \$75,000.00 to the Department of Health.

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HEALTH—GENERAL

Requires the Department of Health to disseminate and record certain information about the health problems associated with pertussis vaccine; appropriates \$75,000.00.

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ASSEMBLY HEALTH AND HUMAN RESOURCES  
COMMITTEE

STATEMENT TO

**SENATE, No. 1696**

**STATE OF NEW JERSEY**

DATED: SEPTEMBER 8, 1986

The Assembly Health and Human Resources Committee reports favorably Senate Bill No. 1696.

This bill requires the Department of Health to prepare and make available to health care providers for distribution to parents a pamphlet which explains the benefits of, and possible adverse reactions associated with, administration of the pertussis (whooping cough) vaccine. The bill appropriates \$75,000.00 to the Department of Health for this purpose.

The bill requires that a health care provider give the pamphlet to a parent or guardian before the pertussis vaccine is administered. The health care provider is also required to record in the child's permanent medical record identifying information about the pertussis vaccine. If a major adverse reaction to the pertussis vaccine occurs, the health care provider is directed to report this information to the department, which is then required to report this information immediately to the manufacturer of the vaccine and the United States Center for Disease Control.

The bill exempts a child from the requirement of receiving the pertussis vaccine as a condition for admission to school if the child's health care provider states in writing that the vaccine is medically contraindicated for that child.

SENATE INSTITUTIONS, HEALTH AND WELFARE  
COMMITTEE

STATEMENT TO

**SENATE, No. 1696**

**STATE OF NEW JERSEY**

DATED: MARCH 24, 1986

The Senate Institutions, Health and Welfare Committee favorably reports Senate Bill No. 1696.

This bill requires the Department of Health to prepare and make available to health care providers for distribution to parents a pamphlet which explains the benefits of, and possible adverse reactions associated with, administration of the pertussis (whooping cough) vaccine. The bill appropriates \$75,000.00 to the Department of Health to carry out its purposes.

The bill requires that a health care provider give the pamphlet to a parent or guardian before the pertussis vaccine is administered. The health care provider is also required to record in the child's permanent medical record identifying information about the pertussis vaccine. If a major adverse reaction to the pertussis vaccine occurs, the health care provider is directed to report this information to the department, which is then required to report this information immediately to the manufacturer of the vaccine.

The bill exempts a child from receiving the pertussis vaccine, which is required as a condition for admission to school, if the child's health care provider states in writing that the vaccine is medically contraindicated for that child.

This bill is similar to Senate Bill No. 2954 of 1985 which the committee reported with amendments in June 1985. Senate Bill No. 1696 includes the amendments adopted by the committee as well as amendments adopted by the General Assembly Corrections, Health and Human Services Committee. The 1985 bill passed in both Houses but was pocket vetoed by the Governor at the end of the last legislative session.



[SECOND OFFICIAL COPY REPRINT]

SENATE, No. 2954

STATE OF NEW JERSEY

INTRODUCED MAY 6, 1985

By Senator BASSANO

Referred to Committee on Institutions, Health and Welfare

AN Act concerning pertussis vaccine **\*\*[and]\*\*** **\*\***, **\*\*** supplementing Title 26 of the Revised Statutes **\*\***, and making an appropriation **\*\***.

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

1 1. For the purposes of this act:

2 a. "Commissioner" means the Commissioner of Health.

3 b. "Department" means the State Department of Health.

4 c. "Health care provider" means any licensed health care pro-  
5 fessional or public or private health care facility in this State that  
6 administers pertussis vaccine.

7 d. "Major adverse reaction" means **\*[any serious illness, dis-**  
8 **ability or impairment of mental, emotional, behavioral or physical**  
9 **functioning or development, the first manifestation of which**  
10 **appears within seven days of the date of administration of pertussis**  
11 **vaccine, and for which there is reasonable scientific or medical**  
12 **evidence that pertussis vaccine causes or significantly contributes**  
13 **to the illness, disability or impairment; or any other reaction which**  
14 **the department determines, by regulation, is a basis for not admin-**  
15 **istering]** *\*collapse or shock, **\*\*[persistent screaming episode]\*\****  
16 ***\*\*high pitched screaming, persistent crying for three or more hours,***  
17 ***excessive somnolence (sleepiness)\*\***, temperature of 105° **\*\*[or]\*\****  
18 ***\*\***, **\*\*convulsions with or without accompanying fever or severe***  
19 ***alterations of consciousness **\*\***or any serious illness, disability or***  
19A ***impairment of mental, emotional, behavioral or physical function-***  
19B ***ing or development\*\***, the first manifestation of which appears*

**EXPLANATION**—Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

Matter printed in italics thus is new matter.

Matter enclosed in asterisks or stars has been adopted as follows:

\*—Senate committee amendments adopted June 20, 1985.

\*\*—Assembly committee amendments adopted December 5, 1985.

19C *within* **\*\*[48 hours]\*\*** *\*\*30 days\*\** of the date of administration  
 19D of\* pertussis vaccine\*\*, and for which there is reasonable scientific  
 19E or medical evidence that pertussis vaccine causes or significantly  
 19F contributes to the illness, disability or impairment; or any other  
 19G reaction which the department determines, by regulation, is a basis  
 19H for not administering pertussis vaccine\*\*.

20 e. "Pertussis vaccine" means any vaccine containing a substance  
 21 intended to prevent the occurrence of pertussis, which is adminis-  
 22 tered separately or in conjunction with other substances intended  
 23 to prevent the occurrence of other diseases.

1 2. The commissioner shall prepare and make available to all  
 2 health care providers in the State and parents and guardians, upon  
 3 request, a pamphlet which **\*[contains]\*** *\*explains the benefits and*  
 3A *possible adverse reactions to immunizations for pertussis\*\** **[, polio**  
 3B *and measles, mumps and rubella]\*\*. This pamphlet may contain  
 3C any information which the commissioner deems necessary and may  
 3D be revised by the department whenever new information concerning  
 3E these immunizations becomes available. The pamphlet shall in-  
 3F clude\* the following information:*

4 a. A list of the immunizations required for admission to a public  
 5 or private school in the State;

6 b. Specific information regarding the pertussis vaccine which  
 7 includes:

8 (1) The circumstances under which pertussis vaccine should not  
 9 be administered or should be delayed, including the categories of  
 10 persons who are significantly more vulnerable to major adverse  
 11 reactions than are members of the general population;

12 **\*[(2)]\*** *\*2.\** Possible adverse reactions to pertussis vaccine and  
 13 the early warning signs or symptoms that may be precursors to a

14 major adverse reaction which, upon occurrence, should be brought  
 15 to the immediate attention of the health care provider who  
 16 administered the vaccine;

19 **\*[(4)]\*** *\*3.\** A form that the parent or guardian may use to  
 20 monitor symptoms of a possible adverse reaction and which includes  
 21 places where the parent or guardian can record information about  
 22 the symptoms that will assist the health care provider; and

23 **\*[(5)]\*** *\*4.\** Measures that a parent or guardian should take to  
 24 reduce the risk of, or to respond to, a major adverse reaction includ-  
 25 ing identification of who should be notified of the reaction and when  
 26 the notification should be made.

27 The commissioner shall prepare the pamphlet in consultation

28 with the Medical Society of New Jersey and the University of  
 29 Medicine and Dentistry of New Jersey and shall adopt by regula-  
 30 tion the information contained in the pamphlet, pursuant to the  
 31 "Administrative Procedure Act," P. L. 1968, c. 410 (C. 52:14B-1  
 32 et seq.).

1 3. Prior to administering a pertussis vaccine to a child in this  
 2 State, a health care provider shall give the child's parent or guard-  
 3 ian a copy of the pamphlet prepared pursuant to section 2 of this  
 4 act and provide the parent or guardian with a reasonable oppor-  
 5 tunity to read the contents of the pamphlet.

1 4. A child shall not be required to receive a pertussis vaccine as  
 2 a condition for admission to a public or private school if the child's  
 3 health care provider states in writing that the vaccine is medically  
 4 contraindicated pursuant to subsection b. (1) of section 2 of this  
 5 act and the reasons for the medical contradictions.

1 5. a. Upon administering a pertussis vaccine to a child in this  
 2 State, a health care provider shall record and retain as part of the  
 3 child's permanent health record the date the vaccine was adminis-  
 4 tered, the manufacturer, a lot number and any other available  
 5 identifying information of the vaccine that was administered, and  
 6 the name and title of the health care provider who administered  
 7 the vaccine.

8 b. The health care provider shall make the information concern-  
 9 ing the vaccine available to the child's parent or guardian, upon  
 10 request.

1 6. a. If, within seven days of administering a pertussis vaccine  
 2 the health care provider has reason to believe that the recipient of  
 3 the vaccine has had a major adverse reaction, the health care pro-  
 4 vider shall record all relevant information in the child's permanent  
 5 medical record and report the information, including the manu-  
 6 facturer and the lot number, to the department.

7 b. Upon receipt of the information, the department shall im-  
 8 mediately notify the manufacturer of the vaccine *\*\*and the Center*  
 9 *for Disease Control\*\** of the adverse reaction.

1 7. The commissioner shall periodically report information re-  
 2 ceived regarding major adverse reactions to the United States  
 3 Center for Disease Control.

1 *\*\*8. There is appropriated \$75,000.00 from the General Fund to*  
 2 *the Department of Health to carry out the purposes of this act.\*\**

1 *\*\*[8.]\*\* \*\*9.\*\** This act shall take effect on the 180th day follow-  
 2 ing enactment.

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SENATE, No. 2954

STATE OF NEW JERSEY

INTRODUCED MAY 6, 1985

By Senator BASSANO

Referred to Committee on Institutions, Health and Welfare

AN ACT concerning pertussis vaccine and supplementing Title 26  
of the Revised Statutes.

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

1 1. For the purposes of this act:

2 a. "Commissioner" means the Commissioner of Health.

3 b. "Department" means the State Department of Health.

4 c. "Health care provider" means any licensed health care pro-  
5 fessional or public or private health care facility in this State that  
6 administers pertussis vaccine.

7 d. "Major adverse reaction" means any serious illness, disability  
8 or impairment of mental, emotional, behavioral or physical func-  
9 tioning or development, the first manifestation of which appears  
10 within seven days of the date of administration of pertussis vac-  
11 cine, and for which there is reasonable scientific or medical evidence  
12 that pertussis vaccine causes or significantly contributes to the ill-  
13 ness, disability or impairment; or any other reaction which the  
14 department determines, by regulation, is a basis for not adminis-  
15 tering pertussis vaccine.

16 e. "Pertussis vaccine" means any vaccine containing a substance  
17 intended to prevent the occurrence of pertussis, which is adminis-  
18 tered separately or in conjunction with other substances intended  
19 to prevent the occurrence of other diseases.

1 2. The commissioner shall prepare and make available to all  
2 health care providers in the State and parents and guardians, upon  
3 request, a pamphlet which contains the following information:

4 a. A list of the immunizations required for admission to a public  
5 or private school in the State;

6 b. Specific information regarding the pertussis vaccine which  
7 includes:

8 (1) The circumstances under which pertussis vaccine should not  
9 be administered or should be delayed, including the categories of  
10 persons who are significantly more vulnerable to major adverse  
11 reactions than are members of the general population;

12 (2) The frequency, severity and potential long-term effects of  
13 pertussis;

14 (3) Possible adverse reactions to pertussis vaccine and the early  
15 warning signs or symptoms that may be precursors to a major  
16 adverse reaction which, upon occurrence, should be brought to the  
17 immediate attention of the health care provider who administered  
18 the vaccine;

19 (4) A form that the parent or guardian may use to monitor  
20 symptoms of a possible adverse reaction and which includes places  
21 where the parent or guardian can record information about the  
22 symptoms that will assist the health care provider; and

23 (5) Measures that a parent or guardian should take to reduce  
24 the risk of, or to respond to, a major adverse reaction including  
25 identification of who should be notified of the reaction and when  
26 the notification should be made.

27 The commissioner shall prepare the pamphlet in consultation  
28 with the Medical Society of New Jersey and the University of  
29 Medicine and Dentistry of New Jersey and shall adopt by regula-  
30 tion the information contained in the pamphlet, pursuant to the  
31 "Administrative Procedure Act," P. L. 1968, c. 410 (C. 52:14B-1  
32 et seq.).

1 3. Prior to administering a pertussis vaccine to a child in this  
2 State, a health care provider shall give the child's parent or guard-  
3 ian a copy of the pamphlet prepared pursuant to section 2 of this  
4 act and provide the parent or guardian with a reasonable oppor-  
5 tunity to read the contents of the pamphlet.

1 4. A child shall not be required to receive a pertussis vaccine as  
2 a condition for admission to a public or private school if the child's  
3 health care provider states in writing that the vaccine is medically  
4 contraindicated pursuant to subsection b. (1) of section 2 of this  
5 act and the reasons for the medical contradictions.

1 5. a. Upon administering a pertussis vaccine to a child in this  
2 State, a health care provider shall record and retain as part of the  
3 child's permanent health record the date the vaccine was adminis-  
4 tered, the manufacturer, a lot number and any other available  
5 identifying information of the vaccine that was administered, and

6 the name and title of the health care provider who administered  
7 the vaccine.

8 b. The health care provider shall make the information concern-  
9 ing the vaccine available to the child's parent or guardian, upon  
10 request.

1 6. a. If, within seven days of administering a pertussis vaccine  
2 the health care provider has reason to believe that the recipient of  
3 the vaccine has had a major adverse reaction, the health care pro-  
4 vider shall record all relevant information in the child's permanent  
5 medical record and report the information, including the manu-  
6 facturer and the lot number, to the department.

7 b. Upon receipt of the information, the department shall im-  
8 mediately notify the manufacturer of the vaccine of the adverse  
9 reaction.

1 7. The commissioner shall periodically report information re-  
2 ceived regarding major adverse reactions to the United States  
3 Center for Disease Control.

1 8. This act shall take effect on the 180th day following enactment.

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#### STATEMENT

Recently there has been increasing concern about the safety of pertussis vaccine as more cases of children who were injured or who died as a result of receiving the vaccine have been reported. The vaccine has been known to cause death, brain damage, mental retardation, paralysis and other serious permanent disorders.

In order to address this concern, this bill requires the Department of Health to prepare and make available to health care providers for distribution to parents a pamphlet concerning the benefits for and possible health problems associated with administration of the pertussis (whooping cough) vaccine.

Further, the bill requires that a health care provider give the pamphlet to a parent or guardian before the pertussis vaccine is administered. The health care provider also is required to record in the child's permanent medical record identifying information about the vaccine. If a major adverse reaction to the vaccine occurs, the health care provider is directed to report this information to the department, which is then required to report this information immediately to the manufacturer of the vaccine.

The bill exempts a child from the pertussis vaccine, which is required as a condition for admission to school, if the child's health care provider states in writing that the vaccine is medically contraindicated for that child.

This bill is based on a statute recently enacted in Maryland.

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SENATE INSTITUTIONS, HEALTH AND WELFARE  
COMMITTEE

STATEMENT TO

**SENATE, No. 2954**

with Senate committee amendments

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**STATE OF NEW JERSEY**

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DATED: JUNE 20, 1985

As amended by committee, this bill requires the Department of Health to prepare and make available to health care providers for distribution to parents a pamphlet concerning the benefits for and possible adverse reactions associated with administration of the pertussis (whooping cough) vaccine. The booklet may also contain the information about the polio, and measles, mumps and rubella vaccines.

Also, the bill requires that a health care provider give the pamphlet to a parent or guardian before the pertussis vaccine is administered. The health care provider is also required to record in the child's permanent medical record identifying information about the pertussis vaccine. If a major adverse reaction to the pertussis vaccine occurs, the health care provider is directed to report this information to the department, which is then required to report this information immediately to the manufacturer of the vaccine.

The bill exempts a child from the pertussis vaccine, which is required as a condition for admission to school, if the child's health care provider states in writing that the vaccine is medically contraindicated for that child.

The committee amended the bill at the request of the Department of Human Services. The amendments make the definition of "major adverse reaction" more specific and authorize the Commissioner of Health to include information about the polio and measles, mumps and rubella vaccine in the booklet on pertussis.

- (1) In good faith relies on spiritual means through prayer for healing; and
- (2) Complies with the laws, rules, and regulations that relate to sanitation for and quarantine of infectious, contagious, and communicable diseases. (An. Code 1957, art. 43, § 98; 1982, ch. 21, § 2; ch. 568.)

**Effect of amendment.** — Chapter 568, Acts 1982, effective July 1, 1982, repealed former subsection (c) and redesignated former subsection (d) to be present subsection (c).

**§ 18-325. Prohibited acts; penalty.**

(a) *Refusal to enter health facility.* — An individual may not refuse to enter a health facility if the individual has been ordered taken to the health facility under § 18-324 of this subtitle.

(b) *Disorderly behavior; leaving before proper discharge.* — While an individual is in any health facility for tuberculosis treatment, the individual may not:

- (1) Behave in a disorderly manner; or
- (2) Leave the health facility before being discharged properly.

(c) *Penalty.* — An individual who violates any provision of this section is guilty of a misdemeanor and on conviction shall be imprisoned in a penal institution with facilities for tuberculosis treatment until the Secretary or the Health Department of Baltimore City finds that the condition of the individual no longer endangers the health of the community. (1982, ch. 568.)

**Editor's note.** — Section 2, ch. 568, Acts 1982, provides that the act shall take effect July 1, 1982.

Part V. Pertussis.

**§ 18-328. Definitions.**

(a) *In general.* — In Part V of this subtitle, the following words have the meanings indicated.

(b) *Health care provider.* — "Health care provider" means any licensed health care professional, organization, or institution, whether public or private, under whose authority pertussis vaccine is administered.

(c) *Pertussis vaccine.* — "Pertussis vaccine" means any vaccine that contains materials intended to prevent the occurrence of pertussis, whether or not the materials are administered separately or in conjunction with other materials intended to prevent the occurrence of other diseases.

(d) *Major adverse reaction.* — "Major adverse reaction" means:

- (1) Any serious illness, disability, or impairment of mental, emotional, behavioral, or physical functioning or development, the first manifestation of which appears within 7 days after the date of administration of pertussis vaccine and for which there is reasonable scientific or medical evidence that pertussis vaccine causes, or significantly contributes to, such effect; and

(2) At the Medic... a basis for 578, 785.

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§ 18-32

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(2) Any other reaction, which the Department, after consultation with the Medical and Chirurgical Faculty of Maryland, determines by guideline is a basis for not continuing with pertussis vaccine administration. (1984, chs. 578, 785.)

**Editor's note.** — Section 2, ch. 578, and § 2, ch. 785, Acts 1984, provide that the "act shall take effect Jan. 1, 1985, and that all guidelines authorized or required to be promulgated under §§ 18-328 through 18-332 of the Health-General Article, as enacted by this act, shall be promulgated no later than Jan. 1, 1985."

### § 18-329. Required information.

(a) *Duty to provide information.* — (1) Prior to the administration of pertussis vaccine, the health care provider shall provide to the individual's parent or guardian written information, satisfying the requirements of this subsection, and by appropriate inquiries attempt to elicit the information necessary to make the determinations required by § 18-332 (b) of this subtitle.

(2) The information required under § 4-204 (c) of this article, as to pertussis vaccine, and under paragraph (1) of this subsection shall include:

- (i) The frequency, severity, and potential long-term effects of pertussis;
- (ii) Possible adverse reactions to pertussis vaccine which, if they occur, should be brought to the immediate attention of the health care provider;
- (iii) A form listing symptoms to be monitored and containing places where information can be recorded to assist in reporting to the health care provider, local health officer, and the Department;
- (iv) Measures parents should take to reduce the risk of, or to respond to, any major adverse reaction;
- (v) Early warning signs or symptoms to which parents should be alert as possible precursors to a major adverse reaction;
- (vi) When and to whom parents should report any major adverse reaction;
- (vii) A summary of the immunization requirements adopted under § 7-402 (a) of the Education Article, including those related to pertussis vaccine; and

(viii) The information required under § 18-332 (a) (1) through (3) of this subtitle.

(b) *Form and content of information provided.* — The Department by guideline and consistent with § 18-331 (b) of this subtitle shall prescribe the form and content of the information provided to parents in accordance with this section. (1984, chs. 578, 785.)

§ 18-330. Records.

(a) *Duty of health care provider.* — At the time of administration of pertussis vaccine to an individual, the health care provider shall record in a permanent record to which the patient or the patient's parent or guardian shall have access on request:

- (1) The date of each vaccination;
- (2) The manufacturer and lot number of the vaccine used for each;
- (3) Any other identifying information on the vaccine used; and
- (4) The name and title of the health care provider.

(b) *Major adverse reactions to vaccine.* — Within 24 hours any health care provider who has administered pertussis vaccine to an individual and has reason to believe that the individual has had a major adverse reaction to the vaccine shall:

- (1) Record all relevant information in the individual's permanent medical record; and
- (2) Report the information, including the manufacturer's name and lot number, to the local health officer who shall immediately forward the information to the Department. On receipt of the information, the Department shall immediately notify the vaccine manufacturer. (1984, chs. 578, 785.)

§ 18-331. Collection of data.

(a) *Department to establish system.* — By guideline, the Department shall establish a system, sufficient for the purposes of subsections (b) and (c) of this section, to collect data from the local health officers, from public and private health care providers, and from parents on the incidence of pertussis and major adverse reactions to pertussis vaccine.

(b) *Revision and updating of required information.* — On the basis of information collected under this subsection and of other information available, the Department shall periodically revise and update the information required by § 18-329 and the guidelines adopted under § 18-332 of this subtitle.

(c) *Reports.* — (1) The Department shall report to the United States Centers for Disease Control all information collected under subsection (a) of this section, including that received under § 18-330 (b) of this subtitle.

(2) Subject to § 2-1312 of the State Government Article, the Department shall report annually to the General Assembly on the incidence of pertussis and of major adverse reactions to pertussis vaccine. (1984, chs. 578, 785; 1985, ch. 10, § 3.)

**Effect of amendment.** — The 1985 amendment, effective July 1, 1985, substituted "subsection (a) of this section" for "§ 18-331 (a)" in paragraph (1) of subsection (c).

§ 18-332.

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### § 18-332. Adoption of guidelines.

(a) *Contents.* — The Department shall adopt guidelines, after notice and public hearing in accordance with the Administrative Procedure Act, setting forth:

- (1) The circumstances under which pertussis vaccine should not be administered;
- (2) The circumstances under which administration of the vaccine should be delayed;
- (3) Any categories of potential recipients who are significantly more vulnerable to major adverse reactions than is the general population; and
- (4) Procedures to notify all physicians of the content of the final guidelines and all updates issued thereafter.

(b) *Exceptions.* — The administration of pertussis vaccine to an individual may not be required by any provision of law if, in the physician's medical judgment:

- (1) The circumstances specified under subsection (a) (1) or (2) of this section are present; or
- (2) Taking into account the information specified under subsection (a) (3) of this section as well as all other relevant information, and the risk to the potential recipient outweighs the benefits both to the potential recipient and to the public in administering the vaccine.

(c) *Emergency authority of Secretary.* — Nothing in this section shall be construed to affect any emergency authority of the Secretary under any other provision of law to protect the public health. (1984, chs. 578, 785.)

*Cross references.* — For Administrative Procedure Act, see Subtitles 1 through 4, Title 10 of the State Government Article.

See Editor's note to § 18-328 of this article.

### Part VI. Acquired Immune Deficiency Syndrome (AIDS).

### § 18-333. Acquired Immune Deficiency Syndrome (AIDS) Research and Information Program.

(a) *Establishment; contents of Program.* — (1) The Secretary shall establish and promote a statewide public information program on Acquired Immune Deficiency Syndrome (AIDS).

(2) The public information program shall:

- (i) Attempt to reach individuals at risk for contracting AIDS;
- (ii) Encourage those individuals at risk for contracting AIDS to take the necessary precautions to prevent transmission of the HTLV-III virus; and
- (iii) Include any other aspects that the Secretary considers appropriate.

(b) *Training programs.* — The Secretary shall establish a program to train physicians, physician's assistants, nurses, and other health professionals in:

- (1) Diagnosing and treating AIDS or other conditions associated with AIDS; and