Arch A. Moore, Jr.
Governor

David K. Heydinger, M.D.
Director

State of West Virginia

DEPARTMENT OF HEALTH
CHARLESTON 25305

NOTICE OF PUBLIC HEARING OR COMMENT PERIOD ON PROPOSED RULE

COMMENT PERIOD

AGENCY: Health Department

NEW RULE: X AMENDMENT TO EXISTING RULE: _____

RULE TYPE: Interpretive

RULE TITLE: Pertussis Guidelines

A comment period on the above rule has been scheduled and will end on July 7, 1986 at 4:30 p.m. Written comments are to be mailed to the following address: Regulatory Services Division, West Virginia Department of Health, 1800 Washington Street, East, Charleston, West Virginia 25305.

Written comments may be delivered in person to: Room 7, Second Floor, P & G Building, 2019 Washington Street, East, Charleston, West Virginia not later than 4:30 p.m., July 7, 1986.

BRIEF SUMMARY OF PROPOSED RULE: This rule identifies circumstances under which pertussis vaccine should not be administered, circumstances under which administration should be delayed and categories of individuals significantly more vulnerable to major adverse reactions than the general public. The rule also describes a system for collecting and reporting information on the incidence of pertussis and of major adverse reactions to the vaccine.

TO OBTAIN COPIES: Write the Regulatory Services Division at the above address or call (304) 348-3223 or contact the Administrative Law Division, Office of the Secretary of State, Capitol Complex, Charleston, West Virginia, 25305, telephone (304) 345-4000.

FILED
1986 MAY 28 PM
OFFICE OF SECRETARY OF STATE

David K. Heydinger, M.D.
David K. Heydinger, M.D.
Director of Health

FISCAL NOTE FOR PROPOSED RULES

Rule Title: West Virginia Director of Health Interpretive Rules Chapter 16-3B, Series 52, 1986, Pertussis Guidelines

Type of Rule: X Legislative _____ Interpretive _____ Procedural

Agency HEALTH DEPARTMENT Address 1800 Washington St., E.
Charleston, WV 25305

1. Effect of Proposed Rule	ANNUAL Increase	ANNUAL Decrease	FISCAL YEAR Current	FISCAL YEAR Next	FISCAL YEAR Thereafter
Estimated Total Cost	$	$	$ 0	$ 0	$ 0
Personal Services					
Current Expense					
Repairs and Alterations					
Equipment					
Other					

2. Explanation of above estimates:

The pertussis guidelines will be integrated into the overall Immunization Program with slight increase in the cost of postage and printing. These minor additional costs will be paid out of federal funds. No increase in state funding will be needed.

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3. Objectives of these rules:

This rule identifies circumstances under which pertussis vaccine should not be administered, circumstances under which administration should be delayed and categories of individuals significantly more vulnerable to major adverse reactions than the general public. The rule also describes a system for collecting and reporting information on the incidence of pertussis and of major adverse reactions to the vaccine.

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

NONE

B. Economic Impact on Political Subdivisions; Specific Industries; Specific groups of citizens.

NONE

C. Economic Impact on Citizens/Public at Large.

NONE

Date: May 5, 1986

Signature of Agency Head or Authorized Representative

David K. Heydinger, M.D.

David K. Heydinger, M.D.
Director of Health

WEST VIRGINIA DIRECTOR OF HEALTH
RULE ABSTRACT

TITLE: Pertussis Guidelines

NUMBER: Chapter 16-3B, Series 52

TYPE: Interpretive

AUTHORIZING CODE: 16-3B

RELATED CODE: 16-3B

APPLICATION: Applies to any licensed health care professional, organization or institution, whether public or private, under whose authority pertussis vaccine is administered.

ABSTRACT: This rule identifies circumstances under which pertussis vaccine should not be administered, circumstances under which administration should be delayed and categories of individuals significantly more vulnerable to major adverse reactions than the general public. The rule also describes a system for collecting and reporting information on the incidence of pertussis and of major adverse reactions to the vaccine.

CONTACT PERSON: Joan Rutledge, Research Analyst, Regulatory Services Division, 348-3223

RESPONSIBLE DIVISION: James D. Farris, Director, Immunization Program, 348-2188

[PROPOSED]

WEST VIRGINIA DIRECTOR OF HEALTH

INTERPRETIVE RULES

Chapter 16-3B
Series 52
1986

Pertussis Guidelines

(For Public Comment)

[PROPOSED]

WEST VIRGINIA DIRECTOR OF HEALTH
INTERPRETIVE RULES

Chapter 16-3B
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1986

Pertussis Guidelines

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[PROPOSED]

WEST VIRGINIA DIRECTOR OF HEALTH
INTERPRETIVE RULES

Chapter 16-3B
Series 52
1986

Title: Pertussis Guidelines

Section 1. General

1.1. Scope - This interpretive rule establishes guidelines relating to the administration of pertussis vaccine, procedures for notification of health care providers of the guidelines and procedures for data collection and reporting.

1.2. Authority - This rule is issued under the authority of and is related to Chapter 16, Article 3B of the West Virginia Code.

1.3. Filing Date -

1.4. Effective Date -

Section 2. Application and Administration

2.1. Application - This rule applies to any health care provider (see §3.4).

2.2. Administration - The administration of this rule is vested with the director of the West Virginia department of health.

Section 3. Definitions

3.1. Any Other Adverse Reaction - Any reaction which the department, after consultation with the medical and pharmacy facilities of West Virginia's teaching hospitals, determines by guidelines is a basis for not continuing with pertussis vaccine administration (see §4).

3.2. Department - The West Virginia department of health.

3.3. Director - The director of the West Virginia department of health or his or her lawful designee.

3.4. Health Care Provider - Any licensed health care professional, organization or institution, whether public or private, under whose authority pertussis vaccine is administered.

3.5. Major Adverse Reaction - Any serious illness, disability or impairment of mental, emotional, behavioral or physical functioning or development, the first manifestation of which appears within four weeks after the date of administration of pertussis vaccine and for which there is reasonable scientific or medical evidence that pertussis vaccine causes, or significantly contributed to, such effect.

3.6. Pertussis Vaccine - 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.

Section 4. Circumstances Under Which Pertussis Vaccine Should Not Be Administered

4.1. Pertussis vaccine should not be administered to an individual who is less than six to eight weeks of age or who is seven or more years old.

4.2. If pertussis vaccine is to be administered to an individual who is between the ages of six to eight weeks and six years (through and including the sixth year), general use guidelines (a recommended immunization schedule based on data collected by the Advisory Committee on Immunization Practices of the United States Public Health Service and the Committee on Infectious Diseases of the American Academy of Pediatrics) provided by the department to local and county health departments should be consulted.

4.3. Pertussis vaccine should not be administered to an individual who has an evolving neurologic disorder.

4.4. If an individual has experienced any of the following major adverse reactions, additional doses of pertussis vaccine should not be administered:

(a) collapse or shock;

(b) crying persisting for three or more hours or an unusual high-pitched cry occurring within forty-eight hours;

(c) temperature of 105° F or greater;

(d) a convulsion or an episode of limpness and paleness with or without accompanying fever;

(e) severe alteration of consciousness;

(f) generalized and/or local neurologic signs;

(g) systemic (severe) allergic reactions;

(h) excessive somnolence; or

(i) an evolving neurologic disorder.

If additional specific major adverse reactions to the pertussis vaccine become known by the scientific community, the department will review the above list to determine whether amendment is warranted.

4.5. A family history of convulsion or other neurologic disorders is not

considered to be a contraindication to giving pertussis vaccine.

4.6. The administration of pertussis vaccine to an individual is not required if, in the written, signed opinion of the health care provider, the risk to the potential recipient outweighs the benefits both to the potential recipient and to the public, taking into account: a) the information provided in §§4, 5 and 6 of this rule; b) incidence, complications and cost, both actual and potential, of pertussis disease; c) incidence, severity and cost, both actual and potential, of adverse reactions to pertussis vaccine; and d) national and local levels of immunization and vaccine efficacy rates.

Section 5. Circumstances Under Which Administration of Pertussis Vaccine Should Be Delayed

5.1 Administration of the pertussis vaccine should be delayed under any of the following circumstances:

(a) an individual exhibits a severe febrile illness;

(b) an individual is receiving immunosuppressive therapy, including irradiation, antimetabolites, corticosteroids, alkylating agents, or cytotoxic drugs;

(c) an individual has a history of seizure and it has not been determined that there is not an evolving neurologic disorder present; or

(d) it is suspected, although not confirmed, that an individual has experienced a major adverse reaction.

5.2. General or special use guidelines (a recommended immunization schedule based on data collected by the Advisory Committee on Immunization Practices of the United States Public Health Service and the Committee on Infectious Diseases of the American Academy of Pediatrics) provided by the department to local and county health departments should be consulted when a health care provider is considering the administration of pertussis vaccine to individuals in the circumstances described in §5.1.

Section 6. Categories of Potential Recipients Significantly More Vulnerable to Major Adverse Reactions

6.1. Individuals who have an evolving neurologic disorder are significantly more vulnerable to major adverse reactions than is the general population.

6.2. Individuals who have or had a current or previous major or other adverse reaction are significantly more vulnerable to major adverse reactions than is the general public.

6.3. General or special use guidelines, as referenced in §§4.2 and 5.2, should be consulted when a health care provider is considering the administration of pertussis vaccine to individuals significantly more vulnerable to

major adverse reactions than the general population.

Section 7. Reviews; Procedures to Notify Health Care Providers of the Guidelines and Updates

7.1. Within thirty days of the effective date of this rule, the director shall notify by letter all health care providers, as defined in this rule, of these guidelines and of the provisions of Chapter 16, Article 3B of the West Virginia Code and shall enclose a copy of this rule.

7.2. Thereafter, the director shall annually give notice to all health care providers, as defined in this rule, by letter summarizing any revisions of this rule or Chapter 16, Article 3, Section 1 et seq. of the West Virginia Code.

7.3. The director shall review this rule annually, or more frequently, if indicated by new medical information. A report of the review shall be prepared no later than the thirtieth day of November, beginning in nineteen hundred and eight-six, and annually thereafter. The director shall undertake any revisions of this rule indicated by the report according to the procedures specified by Chapter 29A, Article 3 of the West Virginia Code.

7.4. In conducting annual reviews, the director will consult, among other things, the following: the medical and pharmacy departments of West Virginia's teaching hospitals; publications of the United States Center for Disease Control, the American Academy of Pediatrics, and other national recommending bodies with access to reasonable medical evidence concerning the administration of the pertussis vaccine.

Section 8. System to Collect and Report Data on the Incidence of Pertussis and Major Adverse Reactions to Pertussis Vaccine

8.1(a). Reporting of Adverse Reactions by Parents or Guardians - Chapter 16, Article 3B, Section 2 of the West Virginia Code requires that written information be provided by health care providers to parents or guardians of an individual advising them when and to whom any adverse reactions are to be reported.

8.1(b). Reporting the Incidence of Pertussis (Whooping Cough) - Public and private health care providers shall report the incidence of pertussis weekly to the county health officer in accordance with the West Virginia Board of Health's Legislative Rule on Reportable Diseases (Chapter 16-1, Series VII, 1985). In accordance with the Reportable Diseases Legislative Rule, the county health officer shall report the incidence of pertussis to the West Virginia department of health. Pursuant to Chapter 16, Article 3 , Section 1 et seq. of the West Virginia Code, the department shall report the incidence of pertussis to the United States Center for Disease Control. Pursuant to Chapter 16, Article 3, Section 1 et seq. of the West Virginia Code, the department shall report to the legislature annually, on the first of December, the incidence of pertussis, by sending copies of the report to the President of the Senate and the Speaker of the House of Delegates. A copy of this report

will also be placed on file with the West Virginia Secretary of State.

8.1(c). Reporting Major and Other Adverse Reactions to the Pertussis Vaccine - The parent or guardian of an individual to whom pertussis vaccine has been administered should report any suspected major or other adverse reaction to the health care provider who administered the vaccine. Within twenty-four hours after a major or other adverse reaction is recognized by 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, such health care provider shall record all relevant information in the individual's permanent medical record.

Public and private health care providers shall report the incidence of major adverse reaction(s) to the county health officer in accordance with the West Virginia Board of Health's Legislative Rule on Reportable Diseases (Chapter 16-1, Series VII, 1985). This report shall include the manufacturer's name and lot number. In accordance with the Reportable Diseases Rule, the county health officer shall immediately report the incidence of major adverse reaction(s) to the West Virginia department of health.

In accordance with Chapter 16, Article 3, Section 1 et seq. of the West Virginia Code, the department shall immediately notify the vaccine manufacturer of the incidence of any major adverse reaction. In addition, the department shall immediately notify the United States Center for Disease Control of the incidence of any major adverse reaction. Annually, on the first day of December, the department shall report the incidence of major adverse reactions to the West Virginia legislature by sending copies of the report to the President of the Senate and the Speaker of the House of Delegates. A copy of this report will also be placed on file with the West Virginia Secretary of State.

Section 9. Severability - The provisions of this rule are declared to be severable. If any provisions of this rule shall be held invalid, the remaining provisions of this rule shall remain in effect.