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State of West Virginia

DEPARTMENT OF HEALTH
CHARLESTON 25305

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SECRETARY OF STATE

NOTICE OF AGENCY ADOPTION OF AN INTERPRETIVE, PROCEDURAL
OR LEGISLATIVE RULE EXEMPT FROM REVIEW BY THE LEGISLATIVE
RULE-MAKING REVIEW COMMITTEE

AGENCY: Department of Health

NEW RULE: X AMENDMENT TO EXISTING RULE: _____

RULE TYPE: Interpretive

RULE TITLE: Pertussis Guidelines, Series 52, 1986

The above rule constitutes the official rule adopted by this agency and filed with the Secretary of State.

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

FILED

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SECRETARIAT OF THE

TITLE 64

WEST VIRGINIA DEPARTMENT OF HEALTH
INTERPRETIVE RULES

Pertussis Guidelines

Series 52

1986

WEST VIRGINIA DEPARTMENT OF HEALTH
INTERPRETIVE RULES

Pertussis Guidelines

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TITLE 64

WEST VIRGINIA DEPARTMENT OF HEALTH
INTERPRETIVE RULES

Series 52

FILED
1987 FEB 20 PM 12:59
SECRETARY OF HEALTH

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 - February 20, 1987

1.4. Effective Date - August 1, 1987

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 faculties 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 weeks of age or who is seven or more years old, except that in epidemic situations, immunization may be started as early as two weeks of age, and the first three doses can be given as frequently as four weeks apart.

4.2. If pertussis vaccine is to be administered to an individual between six weeks of age and the seventh birthday, 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. When an infant or child returns for a second or later dose of pertussis vaccine, the parent should be questioned about any adverse events occurring after the previous dose.

4.5. Pertussis Vaccine Contraindications - Major adverse reactions following pertussis immunization that constitute absolute contraindications to further administration of pertussis vaccine are as follows:

- (a) collapse or shock occurring within forty-eight hours;
- (b) crying persisting for three or more hours or an unusual high-pitched cry occurring within forty-eight hours;
- (c) temperature of 104.9° F or greater occurring within forty-eight hours;
- (d) a convulsion or seizure with or without accompanying fever occurring up to three days after receipt of pertussis vaccine;
- (e) severe alteration of consciousness within seven days;
- (f) generalized and/or focal neurologic signs within seven days;
- (g) systemic (severe) allergic reactions within seven days;
- (h) excessive somnolence within seven days;
- (i) an evolving neurologic disorder within seven days; or
- (j) an episode of limpness and paleness within seven days.

If additional circumstances under which pertussis vaccine should not be administered become known by the scientific community, the department will review the above list to determine whether amendment is warranted. Nothing in this section relieves a health care provider from responsibility for reporting all adverse reactions as required under section 8.1(c).

4.6. Pertussis vaccine should not be administered if the individual has had confirmed *Bordetella pertussis* infection.

4.7. Pertussis vaccine should not be administered if the individual is hypersensitive to the vaccine components.

4.8. 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.

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. Infants and young children who have had previous convulsions (whether febrile or nonfebrile) are more likely to have seizures following pertussis vaccine than those without such histories, but there is no evidence that such seizures induce permanent brain damage in children.

6.4. 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 Centers 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 - 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 Centers 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 Centers 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.

PUBLIC HEARING ON PROPOSED PERTUSSIS GUIDELINES
INTERPRETIVE RULE

COMMENTS RECEIVED

FILED
1987 FEB 23
SECRETARY OF HEALTH

Title, Type and Number: Proposed Pertussis Guidelines, Department of Health Interpretive Rules, Series 52, 1986.

Date and Location: December 11, 1986 (2:00 pm), Conference Room, P&G Building, 2019 Washington Street, East, Charleston, West Virginia 25305.

A public hearing regarding this rule was held on December 11, 1986. The hearing was attended by twelve persons, six of whom provided testimony. Following is a summary of comments received during the hearing:

Richard Hopkins, M.D. - West Virginia Department of Health: Dr. Hopkins gave an introduction regarding the purpose of the proposed Pertussis Guidelines Rule. The rule provides for notification to parents of the risks associated with the vaccine and should help prevent future reactions.

Robert Walker, M.D. - Chairman, Department of Family & Community Health, Marshall University School of Medicine: Dr. Walker supported promulgation of the rule as filed on October 29, 1986 and indicated he felt the rule was reasonable. Dr. Walker pointed out that pertussis is a very contagious disease with devastating effects and was a major killer prior to the vaccine. Although pertussis vaccine is not entirely without risk, it is better than nothing. Dr. Walker indicated that he feels the proposed rule provides a balance between individual rights and the public good.

Robert Lewine, M.D. - President, West Virginia Chapter of the American Academy of Pediatrics: Dr. Lewine supported adoption of the rule and stated he felt it was to the benefit of the children of West Virginia. Dr. Lewine cited statistics about the number of pertussis cases occurring pre-vaccine compared with the present. Dr. Lewine also suggested that Section 3.5 of the rule should be rewritten to delete the phrase "reasonable scientific or medical evidence" since it is too variable.

Linda Thornton - West Virginia Dissatisfied Parents Together (WVDPT): Mrs. Thornton stated that parents want the best possible guidelines to protect the health of their children. Mrs. Thornton stressed that WVDPT is not "anti-vaccine" but wants to ensure that the safest possible vaccines are available for children. Data was then presented regarding the vaccine's safety. Mrs. Thornton stated that although her group is pleased to have guidelines for pertussis administration, they had several suggestions to improve the guidelines:

Section 4.1 - The guidelines state that the vaccine should not be administered to an individual less than six weeks of age; the Lederle Labs Product insert says "two months." Is it really important to give the vaccine two weeks earlier? Is the benefit/risk ratio worth saying six weeks instead of the recommended two months as the manufacturer states?

Section 4.8 - Is there a way to determine hypersensitivity to the vaccine components before the vaccine is injected into a child?

Section 5.1 It was suggested that some important reasons for delaying the vaccine have been left out.

Section 5.1(a) - The wording should be changed from "an individual exhibits a severe febrile illness" to "an individual exhibits any illness" because viruses aren't always accompanied by fever and the vaccine may enhance a viral infection.

Section 5.1(c) - WVDPT said that Section 5.1(c) is considered a contraindication by manufacturers and should not be a reason for delay, but should be listed as a reason not to give pertussis vaccine.

WVDPT felt the following two reasons should be added to this section:

- 1) If an individual has severe allergies
- 2) If an individual's sibling or other family member has had a severe reaction.

Section 6 - WVDPT indicated that there are additional groups which should be listed as significantly more vulnerable to major adverse reactions, these are:

- 1) Individuals with hypoglycemia
- 2) Individuals with severe allergies
- 3) Individuals whose sibling or parent has had a severe reaction
- 4) Individuals who are sick at the time of vaccination are more vulnerable to reaction which is why the vaccine should be delayed during any illness.

Section 8.1(c) - WVDPT expressed concern that the manufacturer's dose number is not required to be recorded. The dose number could be helpful if part of a lot is mishandled during distribution, shipment, storage, etc.

Mrs. Thornton - Mrs. Thornton presented a letter on behalf of the West Virginia Advocates for the Developmentally Disabled (WVADD). WVADD supports the full disclosure of all contraindications identified by vaccine manufacturers to parents prior to administering the vaccine.

Robert Rodecker - Attorney representing WVDPT. Mr. Rodecker stated the rule filed October 29, 1986 was an improvement of the draft filed for public hearing in May, 1986. Mr. Rodecker offered the following comments:

Section 4.5(a) - Mr. Rodecker pointed out that the word seizure had been deleted after the word convulsion. He recommended the word seizure be put back in.

Section 4.6 - Mr. Rodecker indicated that it is not helpful to list a non-contraindication. It was suggested that this statement be removed.

Section 4.9 - Mr. Rodecker suggested that this section placed an unfair burden on health care providers by asking the provider to determine whether the "risk to the potential recipient outweighs the benefits both to the potential recipient and to the public ---." Mr. Rodecker indicated that in his opinion this should be the role of the Department of Health rather than the providers.

At this point, all individuals who had signed up to provide comments regarding the proposed rule had spoken. The hearing was then opened for general discussion. A record of this discussion is on file at the Department of Health.

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1987 FEB 20 10 12 AM
SECRETARY OF STATE

Response to Public Hearing of December 11, 1986
Modifications to Proposed Pertussis Guidelines

4.2. If pertussis vaccine is to be administered to an individual who is ~~between the ages of six weeks and six years (through and including the sixth year)~~ between six weeks of age and the seventh birthday, 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.

4.5. Pertussis Vaccine Contraindications - Major adverse reactions following pertussis immunization that constitute absolute contraindications to further administration of pertussis vaccine are as follows:

- (a) collapse or shock occurring within forty-eight hours;
- (b) crying persisting for three or more hours or an unusual high-pitched cry occurring within forty-eight hours;
- (c) temperature of 104.9° F or greater occurring within forty-eight hours;
- (d) a convulsion or seizure with or without accompanying fever occurring up to three days after receipt of pertussis vaccine;
- (e) severe alteration of consciousness within seven days;
- (f) generalized and/or focal neurologic signs within seven days;
- (g) systemic (severe) allergic reactions within seven days;
- (h) excessive somnolence within seven days;
- (i) an evolving neurologic disorder within seven days; or
- (j) an episode of limpness and paleness within seven days.

~~4.6. A family history of convulsion or other neurologic disorders is not considered to be a contraindication to giving pertussis vaccine.~~

~~4.7.~~ 4.6. Pertussis vaccine should not be administered if the individual has had confirmed Bordetella pertussis infection.

~~4.8.~~ 4.7. Pertussis vaccine should not be administered if the individual is hypersensitive to the vaccine components.

~~4.9-~~ 4.8 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, actual and potential, of adverse reactions to pertussis vaccine.~~