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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### 42 CFR Part 100

RIN 0906-AA55

### National Vaccine Injury Compensation Program: Removal of Separate Category for Vaccines Containing Live, Oral, Rhesus-Based Rotavirus From the Vaccine Injury Table

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Interim final rule.

**SUMMARY:** Through this interim final rule, the Secretary removes the category of vaccines containing live, oral, rhesus-based rotavirus, Category XII, from the Vaccine Injury Table (Table). The Table includes a list of covered vaccines under the National Vaccine Injury Compensation Program (VICP). The VICP provides a system of no-fault compensation for certain individuals who have been injured by covered childhood vaccines. This interim final rule is technical in nature. Even prior to the publication of this final rule, Category XII, the category that is being removed from the Table, only applied to vaccines that were administered on or before August 26, 2002. Given the applicable statute of limitations and the fact that Category XII limited its application to vaccines administered on or before August 26, 2002, the Secretary believes that no persons have claims that could be pursued under that category. Petitioners may still be able to file petitions relating to rotavirus vaccines under Category XI of the Table, the category of "rotavirus vaccines," which does not include any associated injuries. Although the Secretary believes that the changes made in this interim final rule are noncontroversial as they do not affect the rights of any potential petitioners with the VICP, the Department is seeking public comment on this interim final rule. Written comments must be submitted on or before November 10, 2008. The Department will consider the comments received and will decide whether to amend the Table based on such comments.

**DATES:** This regulation is effective November 10, 2008.

**ADDRESSES:** You may submit written comments, identified by the Regulatory Information Number (RIN) 0906-AA55 by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *E-mail:* [gevans@hrsa.gov](mailto:gevans@hrsa.gov). Include RIN 0906-AA55 in the subject line of the message.

- *Mail:* Geoffrey Evans, M.D., Director, Division of Vaccine Injury Compensation, Healthcare Systems Bureau, Health Resources and Services Administration (HRSA), Room 11C-26, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

- *Instructions:* All submissions received must include the agency name and RIN for this rulemaking. All comments received will be available for public inspection and copying without charge, including any personal information provided, at Parklawn Building, 5600 Fishers Lane Room 11C-26, Rockville, Maryland 20857, weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5 p.m.

**FOR FURTHER INFORMATION CONTACT:**

Geoffrey Evans, M.D., Director, Division of Vaccine Injury Compensation, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C-26, 5600 Fishers Lane, Rockville, Maryland 20857; telephone number (301) 443-6593.

**SUPPLEMENTARY INFORMATION:**

The National Childhood Vaccine Injury Act of 1986, title III of Public Law 99-660 (42 U.S.C. 300aa-10 *et seq.*) established the National Vaccine Injury Compensation Program (VICP) for persons found to be injured by vaccines. Under this Federal program, petitions for compensation are filed with the United States Court of Federal Claims (Court). The Court, acting through special masters, makes findings as to eligibility for, and amount of, compensation. In order to gain entitlement to compensation under title XXI of the Public Health Service (PHS) Act for a covered vaccine, a petitioner must establish a vaccine-related injury or death, either by proving that the first symptom of an injury/condition, as defined by the Qualifications and Aids to Interpretation, occurred within the time period listed on the Vaccine Injury Table (Table), and therefore presumed to be caused by a vaccine (unless another cause is found), or by proof of vaccine causation, if the injury/condition is not on the Table or did not occur within the time period specified on the Table.

The statute authorizing the VICP provides for the inclusion of additional vaccines in the VICP when they are recommended by the Centers for Disease Control and Prevention (CDC) for routine administration to children. See section 2114(e)(2) of the PHS Act, 42 U.S.C. 300aa-14(e)(2). Consistent with section 13632(a)(3) of Public Law 103-66, the regulations governing the VICP provide that such vaccines will be included in the Table as of the effective date of an excise tax to provide funds for the payment of compensation with respect to such vaccines. (42 CFR 100.3(c)(5)). The statute authorizing the VICP also authorizes the Secretary to create and modify a list of injuries, disabilities, illnesses, conditions, and deaths (and their associated time frames) associated with each category of vaccines included on the Table. See sections 2114(c)(3) and 2114(e)(2) of the PHS Act, 42 U.S.C. 300aa-14(c)(3) and 300aa-14(e)(2).

Because the prerequisites for adding rotavirus vaccines to the VICP occurred, the Secretary published a final rule in the **Federal Register** (FR) on July 27, 1999, adding vaccines against rotavirus to the Table (64 FR 40517). Because the Secretary had not identified any illness, disease, injury or condition caused by vaccines against rotavirus, the category of vaccines was added to the Table with "[n]o condition specified." The Secretary made clear that if he learned of any such illness, disease, injury or condition, he would consider amending the Table.

In a notice of proposed rulemaking published on July 13, 2001, the Secretary announced his findings that the condition of intussusception could reasonably be determined in some circumstances to be caused by vaccines containing live, oral, rhesus-based rotavirus (66 FR 36735). Based on those findings, the Secretary proposed amending the Table by adding to the Table vaccines containing live, oral, rhesus-based rotavirus (trade name Rotashield) as a distinct category, with intussusception listed as a covered Table injury. This proposal was based upon the recommendation by the CDC that Rotashield, the only rotavirus vaccine licensed in the United States (U.S.) at the time, no longer be administered to infants in the U.S. based on review of data indicating a strong association between Rotashield and intussusception in the 1 to 2 weeks following vaccination.

In a final rule published July 25, 2002, the Secretary made the changes proposed in the earlier rule (67 FR 48558). After these amendments, the Table included two categories of

rotavirus vaccines. The first, the general category of rotavirus vaccines (current Category XI), did not include an associated injury. This category of vaccines was effective as of October 22, 1998, the effective date of the excise tax enacted for rotavirus vaccines. See 42 CFR 100.3(a), 100.3(c)(3). The second, the more specific category of vaccines containing live, oral, rhesus-based rotavirus (current Category XII), contained an associated injury of intussusception with an onset interval of 0–30 days. This category of vaccines was also effective on October 22, 1998, but only applied to vaccines administered on or before August 26, 2002 (the effective date of the final rule imposing this category). Because the manufacturer of the only U.S.-licensed rotavirus vaccine voluntarily ceased distribution of the vaccine in July 1999, and because the CDC recommended that this vaccine no longer be routinely administered to children in the United States in October 1999, the Secretary concluded that it was unlikely that potential claims under Category XII would arise after the rule's publication. Because that final rule limited the Table injury of intussusception to live, oral, rhesus-based rotavirus vaccines administered on or before the effective date of the final rule, individuals who sought compensation for injuries related to such a vaccine administered after the effective date of the final rule were not entitled to the presumption of a Table injury for intussusception. Such individuals were still able to file claims under the Table's general category for rotavirus vaccines. No claims had been filed under the general category of rotavirus vaccines from August 2004 to January 2008. Licensure of a new rotavirus vaccine in 2006 led to one claim filed under this general category since January 2008.

The Secretary views this rule as technical in nature because he does not believe that any potential petitioners would be able to file a claim relying on the Table condition set forth in Category XII if it were retained on the Table. As explained above, petitioners are already limited to filing claims relying on this Category if the underlying rotavirus vaccine was administered on or before August 26, 2002. Moreover, petitioners are only entitled to the presumption of causation conferred by the Table injury associated with Category XII if the injury of intussusception's first symptom or manifestation of onset occurred within 0–30 days after the vaccine's administration. Because the applicable statute of limitations requires petitioners to file claims within three

years of the injury's first symptom or manifestation of onset (or four years from such onset and two years from the date of death, in death cases), the Secretary believes that any person with a potential Table claim under Category XII would be time-barred. The statute of limitations available to certain petitioners for vaccines or injuries newly added to the Table under section 2116(b) of the PHS Act, 42 U.S.C. 300aa–16(b), would no longer be available for potential claims concerning the rotavirus vaccine because that section imposes a limitations period of two years from the effective date of the Table change.

Although the CDC in 1999 recommended that the only then-available rotavirus vaccine licensed in the U.S. (which was a live, oral, rhesus-based product), no longer be administered to infants in the U.S., FDA has subsequently licensed two additional rotavirus vaccines, and the excise tax passed for rotavirus vaccines remains in effect. Thus, the general category of rotavirus vaccines continues to be covered under the VICP under the Table's Category XI for all newly licensed rotavirus vaccines. No corresponding injury/condition is listed in this category since no injuries have been associated with these products.

Because the Table category of rotavirus vaccines with the associated injury of intussusception is no longer available to prospective petitioners, this interim final rule is an effort to minimize confusion relating to available Table categories.

All petitions filed concerning rotavirus vaccines are still subject to the applicable statute of limitations. The filing limitations applicable to petitions filed with the VICP are set out in section 2116(a) of the PHS Act (42 U.S.C. 300aa–16(a)). Although section 2116(b) of the PHS Act lays out specific exceptions to these statutes of limitations that apply when the effect of a revision to the Table makes a previously ineligible person eligible to receive compensation or when an eligible person's likelihood of obtaining compensation significantly increases, this change would not trigger that section.

#### **Justification for Omitting Notice of Proposed Rulemaking**

This amendment to 42 CFR 100.3 is technical in nature. As explained above, the Secretary believes that no persons have claims that could be pursued under the category that is being removed from the Table through this interim final rule. For this reason, the Secretary has determined under 5 U.S.C.

553 and Departmental policy that it is unnecessary and impractical to follow proposed rulemaking procedures.

#### **Economic and Regulatory Impact**

##### *Regulatory Flexibility Act and Executive Order 12866*

Executive Order 12866, as amended by Executive Orders 13258 and 13422, directs agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that provide the greatest net benefits (including potential economic, environmental, public health, safety, distributive and equity effects). In addition, under the Regulatory Flexibility Act, if a rule has a significant economic effect on a substantial number of small entities the Secretary must specifically consider the economic effect of a rule on small entities and analyze regulatory options that could lessen the impact of the rule. Executive Order 12866, as amended by Executive Orders 13258 and 13422, requires that all regulations reflect consideration of alternatives, of costs, of benefits, of incentives, of equity, and of available information. Regulations must meet certain standards, such as avoiding an unnecessary burden. Regulations which are "significant" because of cost, adverse effects on the economy, inconsistency with other agency actions, effects on the budget, or novel legal or policy issues, require special analysis.

The Secretary has determined that no resources are required to implement the requirements in this Interim Final Rule. Therefore, in accordance with the Regulatory Flexibility Act of 1980 (RFA), and the Small Business Regulatory Enforcement Act of 1996, which amended the RFA, the Secretary certifies that this rule will not have a significant impact on a substantial number of small entities.

The Secretary has also determined that this Interim Final Rule does not meet the criteria for a major rule as defined by Executive Order 12866, as amended by Executive Orders 13258 and 13422, and would have no major effect on the economy or Federal expenditures. The Secretary has determined that the Interim Final Rule is not a "major rule" within the meaning of the statute providing for Congressional Review of Agency Rulemaking, 5 U.S.C. 801.

##### *Unfunded Mandates Reform Act of 1995*

Similarly, it will not have effects on State, local, and tribal governments and on the private sector such as to require

consultation under the Unfunded Mandates Reform Act of 1995.

#### *Federalism Impact Statement*

The Secretary has also reviewed this Interim Final Rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have “federalism implications.” The Interim Final Rule would not have “substantial direct effects on the States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.”

#### *Impact on Family Well-Being*

This Interim Final Rule will not adversely affect the following family elements of family well-being: family safety, family stability, marital commitment; parental rights in the education, nurture and supervision of their children; family functioning, disposable income or poverty; or the behavior and personal responsibility of youth, as determined under section 654(c) of the Treasury and General Government Appropriations Act of 1999. As stated above, this Interim Final Rule will modify the Table included in the regulations governing the VICP based on legal authority.

#### **Impact of the New Rule**

This Interim Final Rule is technical in nature and will not prevent otherwise eligible individuals with claims of injuries or deaths allegedly resulting from rotavirus vaccines (including vaccines containing live, oral, rhesus-based rotavirus) from filing claims with the VICP.

#### *Paperwork Reduction Act*

This rule has no information collection requirements.

#### **List of Subjects in 42 CFR Part 100**

Biologics, Health insurance, and Immunization.

Dated: July 30, 2007.

**Elizabeth M. Duke,**  
Administrator, HRSA.

Approved: June 23, 2008.

**Michael O. Leavitt,**  
Secretary, HHS.

**Editorial Note:** This document was received in the Office of the Federal Register on Monday, October 6, 2008.

■ Accordingly, 42 CFR part 100 is amended as set forth below.

### **PART 100—VACCINE INJURY COMPENSATION**

■ 1. The authority citation for 42 CFR part 100 continues to read as follows:

**Authority:** Sec. 215 of the PHS Act (42 U.S.C. 216); secs. 312 and 313 of Public Law 99–660, 100 Stat. 3779–3782 (42 U.S.C. 300aa–1 note); sec. 2114(c) and (e) of the PHS Act, 100 Stat. 3766 and 107 Stat. 645–646 (42 U.S.C. 300aa–14(c) and (e)); sec. 904(b) of Public Law 105–34, 111 Stat. 873; sec. 1503 of Public Law 105–277, 112 Stat. 2681–741; and sec. 523(a) of Public Law 106–170, 113 Stat. 1927–1928.

#### **§ 100.3 [Amended]**

■ 2. Section 100.3 is amended as follows:

■ A. In paragraph (a) in the Vaccine Injury Table remove Item XII and redesignate Items XIII and XIV as XII and XIII respectively.

■ B. In paragraph (c)(3) remove the second sentence; in paragraph (c)(4) remove the words “(Item XIII of the Table)” and add in their place “(Item XII of the Table)”; in paragraph (c)(5) remove the words “(Item XIV of the Table)” and add in their place “(Item XIII of the Table)”.

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### **DEPARTMENT OF TRANSPORTATION**

#### **Maritime Administration**

#### **46 CFR Part 393**

[Docket No. MARAD–2008 0096]

RIN 2133–AB70

#### **America’s Marine Highway Program**

**AGENCY:** Maritime Administration, DOT.  
**ACTION:** Interim final rule with request for comments.

**SUMMARY:** The purpose of this interim final rule is to solicit recommendations for short sea transportation routes to be designated as Marine Highway Corridors and to solicit applications from interested parties to participate in a short sea transportation Project, as required by section 55605(c) of Public Law 110–140, the Energy Independence and Security Act of 2007. Section 55601(d) specifically states, that “[t]he Secretary may designate a project to be a short sea transportation project if the Secretary determines that the project may—offer a waterborne alternative to available landside transportation services using documented vessels; and provide transportation services for passengers or freight (or both) that may reduce congestion on landside

infrastructure using documented vessels.” Further, section 55605 defines short sea transportation as meaning “the carriage by vessel of cargo that is contained in intermodal cargo containers and loaded by crane on the vessel or loaded on the vessel by means of wheeled technology; and that is loaded at a port in the United States and unloaded either at another port in the United States or at a port in Canada located in the Great Lakes Saint Lawrence Seaway System; or loaded at a port in Canada located in the Great Lakes Saint Lawrence Seaway System and unloaded at a port in the United States.” Section 55605(c) directs the Secretary of Transportation to promulgate interim regulations not later than 90 days after the date of enactment of this Act. The Secretary of Transportation will delegate authority to the Maritime Administrator to administer this program. Final regulations are to be issued no later than October 1, 2008. The program established in Section 55605 will be titled “America’s Marine Highway Program.” A final regulation will be published following this public comment period. Solicitations from applicants desiring Marine Highway Project designation will be initiated through notification in the **Federal Register** at a future date.

#### **DATES:**

The effective date of this interim regulation is November 10, 2008. Any further comments are due by February 6, 2009.

**ADDRESSES:** You may submit comments [identified by DOT Docket Number MARAD–2008–0096] by any of the following methods:

- **Web Site:** <http://www.regulations.gov>. Follow the instructions for submitting comments on the electronic docket site.
- **Mail:** Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., Room PL–401, Washington, DC 20590–0001.
- **Hand Delivery:** Room PL–401 of the Department of Transportation, 1200 New Jersey Avenue, SE., Washington, DC, between 9 am and 5 pm, Monday through Friday, except Federal holidays.
- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.

**Instructions:** All submissions must include the agency name and docket number for this rulemaking. Note that all comments received will be posted without change to <http://www.regulations.gov> including any personal information provided. Please