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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: Revisions and Additions to the Vaccine Injury Table

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary has made findings as to a condition that can reasonably be determined in some circumstances to be caused by vaccines containing live, oral, rhesus-based rotavirus. Based on these findings, the Secretary proposes to amend the Vaccine Injury Table (Table) by adding to the Table vaccines containing live, oral, rhesus-based rotavirus as a distinct category, with intussusception listed as a covered Table injury. This proposal is based upon the recommendation by the Centers for Disease Control and Prevention (CDC) that Rotashield, the only U.S.-licensed rotavirus vaccine, no longer be administered to infants in the United States based on review of data indicating a strong association between Rotashield and intussusception in the 1 to 2 weeks following vaccination. The Secretary also proposes several additional amendments to the Table described below under **SUPPLEMENTARY INFORMATION**.

DATES: Comments on this proposed rule must be submitted by January 9, 2002. A public hearing on this proposed rule will be held before the end of the public comment period. A separate notice will be published in the **Federal Register** to provide the details of this hearing.

ADDRESSES: Written comments should be addressed to Samuel Shekar, Associate Administrator for Health Professions, Bureau of Health Professions (BHPr), Health Resources and Services Administration (HRSA), Parklawn Building, Room 8–05, 5600 Fishers Lane, Rockville, Maryland 20857. All comments received will be available for public inspection and copying at the Office of Planning and Program Development, BHPr, Room 8–67, Parklawn Building, at the above address weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Geoffrey Evans, Medical Director, Division of Vaccine Injury Compensation, BHPr, HRSA, Parklawn Building, Room 8A–46, 5600 Fishers Lane, Rockville, Maryland 20857; telephone number (301) 443–4198.

SUPPLEMENTARY INFORMATION:

Rotavirus Vaccine

On August 31, 1998, the Food and Drug Administration (FDA) licensed a live, oral, rhesus-based rotavirus tetravelant vaccine for use in infants between the ages of 6 weeks and 1 year. Distribution of the vaccine began on October 1, 1998. Following a review by the Advisory Committee on Immunization Practices (ACIP), the CDC published its rotavirus recommendation in the March 19, 1999, issue of the *Morbidity and Mortality Weekly Report* (MMWR), calling for doses to be administered at 2, 4 and 6 months of age, the first dose to be administered between 6 weeks and 6 months. The series was not to be initiated in children who were 7 months of age or older due to an increased rate of febrile (fever) reactions after the first dose among older infants.

Over the next 8 months, the Secretary's Vaccine Adverse Event Reporting System (VAERS) began receiving reports of intussusception (a type of bowel obstruction that occurs when the bowel folds in on itself) in infants receiving rotavirus vaccine, mostly after the first dose. Based on an analysis of 15 reports, CDC, in the July 16, 1999, issue of the MMWR, recommended that health-care providers and parents postpone use of the rotavirus vaccine. Additional epidemiological studies were undertaken by CDC to determine if there was a true association between the vaccine and intussusception. Also at that time, the manufacturer, in consultation with FDA, voluntarily ceased further distribution of the vaccine. Upon further consideration, and following consultation with CDC officials in preparation for the upcoming ACIP meeting, the manufacturer announced withdrawal of the only U.S.-licensed rotavirus vaccine from the market on October 15, 1999, and requested the immediate return of all doses of the vaccine.

At its October 22, 1999, meeting, the ACIP reviewed scientific data from several sources, including a 19-State case-control study which showed a statistically significant rate of intussusception among recipients of the live, oral, rhesus-based rotavirus vaccine in the 1- to 2-week period following vaccine administration. Beyond 14 days, there did not appear to be more cases than might occur by chance alone. The ACIP concluded that intussusception occurs with significantly increased frequency in the first 14 days following rotavirus administration and withdrew its recommendation for use of the rhesus-based rotavirus vaccine in infants. CDC published the Committee's decision in the November 5, 1999, issue of the MMWR.

As of December 2000, VAERS had received over 100 reports of confirmed and presumptive intussusception cases, 58 of which had onset within 7 days of vaccine receipt. No reports have been received thus far for vaccines administered after the July 1999 MMWR notice. Of the cases reported, approximately one-half required surgical intervention. Nearly all of the remaining cases of bowel obstruction were relieved through barium enema, a radiological procedure used to both diagnose and often rectify the telescoped bowel segment, or resolved without any intervention. At least one death associated with rotavirus vaccine was reported to VAERS.

The general category of rotavirus vaccines was added for coverage under the VICP effective October 22, 1998. Section 2114(e)(2) of the Public Health Service (PHS) Act provides for the inclusion of additional vaccines in the VICP when they are recommended by the CDC for routine administration to children. In compliance with the requirements of the Omnibus Budget Reconciliation Act of 1993, which added a new section 2114(e)(3) to the Act, a vaccine added to the Table through section 2114(e) will be included in the Table, effective when an excise tax to provide funds for they payment of compensation with respect to such vaccines takes effect. This section, codified at 42 U.S.C. 300aa–14(e)(3), read as follows:

> (3) **Effective Date**—A revision by the Secretary under section 2114(e) of the Public Health Service Act (42 U.S.C. 300aa–14(e)) (as amended by paragraph (2)) shall take effect upon the effective date of a tax enacted to provide funds for compensation paid with respect to the vaccine to be added to the vaccine injury table in section 2114(a) of the Public Health Service Act (42 U.S.C. 300aa–14(a)).

The two prerequisites for adding rotavirus vaccine to the VICP were satisfied by enactment of Public Law 105–77, the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999, which set

an excise tax of 75 cents per vaccine dose, and publication in the MMWR the following March of the CDC recommendation of the vaccine for ''routine use in children.'' The effective date of coverage, however, was the date of imposition of the excise tax, which was October 22, 1998.

In order to gain entitlement to compensation under title XXI of the PHS Act for a covered vaccine, a petitioner must establish a vaccine-related injury or death, either by showing an event listed on the Table (referred to as a ''Table injury'' case), and therefore presumed to be caused by a vaccine, or by proving causation in fact. In addition, section 2111(c) of the PHS Act requires that a petitioner must show (except in death cases) 6 months of residual effects of the injury or, as explained below, inpatient hospitalization and surgery resulting from the injury. With regard to a Table injury case, it must be shown that the vaccine recipient suffered an injury of the type enumerated in the ''Vaccine Injury Table'' corresponding to the vaccination in question, and that the *onset* of such injury took place within a time period from the vaccination also specified in the Table. If so, as set out in sections 2111(c)(1)(C)(i), 2113(a)(1)(B), and 2114(a) of the PHS Act, the Table injury is in effect given the legal presumption that it was caused by the vaccination, and the petitioner is entitled to compensation, *unless* it is affirmatively shown by the Secretary that the injury was caused by some factor unrelated to the vaccination.

Based on the requirements of section 2114(e) of the PHS Act, the Secretary added rotavirus vaccine to the Table with ''no condition specified.'' (42 CFR 100.3). In other words, at the time rotavirus was included for coverage under the Program, no adverse events had been identified to include in the Table. Until specified injuries are added to the Table through the Secretary's rulemaking authority, individuals who receive newly recommended vaccines do not receive a legal presumption of causation for any claimed injury, and are required to prove that the vaccine actually caused the claimed injury.

Consistent with the general process for revising the Table, once the Secretary determines that specific adverse events have been associated with newly recommended vaccines, the Secretary will propose further changes to the Vaccine Injury Table in order to confer the appropriate presumption of causation. Until the Table is amended, petitioners must prove causation in fact to prevail. However, once sufficient data is available to confirm a causal relationship between the newly added vaccine and the adverse event, the Secretary is able to concede causation in fact while the rulemaking process to revise the Table is underway.

The Secretary has reviewed the epidemiological data showing a strong statistical association between the rotavirus vaccine administration and subsequent onset of intussusception within a 14-day time interval. In addition, the studies conducted are not precise enough to demonstrate that an intussusception occurring in the 15- to 30-day interval is not caused by the rotavirus vaccine. For this reason, and because the evidence of a casual link between the Rotashield vaccine and the injury of intussusception is so strong, the Secretary is now proposing to add to the Table the category of ''vaccines containing live, oral, rhesus-based rotavirus'' with the injury of intussusception. The Secretary proposes that this injury of intussusception have an onset interval of 30 days under sections 2114(c) and (e) of the PHS Act. The Advisory Committee on Childhood Vaccines (ACCV) voted unanimously to approve this time interval at its December 1, 1999, meeting. Claims can be filed for alleged vaccine-related cases whose onset is beyond 30 days, but petitioners will be required to prove causation in fact.

Section XII of the Table in 42 U.S.C. 100.3(a) currently includes the broad category of ''rotavirus vaccine'' with no condition specified. At its December 1, 1999, meeting, the ACCV voted unanimously to retain this category of rotavirus vaccines on the Table, with no condition specified, and to add the category of ''vaccines containing live, oral, rhesus-based rotavirus'' with the injury of intussusception. In this Notice of Proposed Rulemaking, the Secretary proposes implementing this recommendation. Although the Secretary proposes retaining the current broad category of rotavirus vaccines on the Table in addition to adding the narrower category of ''vaccines containing live, oral, rhesus-based rotavirus,'' at this time the Secretary expects petitions for compensation relating only to this latter category, as the only rotavirus vaccine that has been licensed contains live, oral, rhesus-based rotavirus.

Under this approach, the Department proposes including two different categories of rotavirus vaccines on the Table, with different effective dates of coverage. Of course, petitions must also be filed within the applicable statute of limitations. The statutes of limitations applicable to petitions filed with the VICP, which are set out in section 2116(a) of the PHS Act (42 U.S.C. 300aa–16(a)) continue to apply. In addition, 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. Under this section, individuals who may be eligible to file petitions based on the revised Table may file a petition for compensation not later than 2 years after the effective date of the revision if the injury or death occurred not more than 8 years before the effective date of the revision of the Table (42 U.S.C. 300aa–16(b)).

The first category of rotavirus vaccines, the general category of ''rotavirus vaccines,'' will continue to have an effective date of coverage for petitions filed beginning on October 22, 1998, with no corresponding ending date of coverage. Therefore, this category of vaccines will continue to be effective for vaccines administered in the future. The second category of rotavirus vaccines, those ''vaccines containing live, oral, rhesus-based rotavirus,'' will have an effective date of coverage beginning on October 22, 1998, provided that they were administered on or before the effective date of the final rule resulting from this Notice of Proposed Rulemaking. Because the only live, oral, rhesus-based rotavirus vaccine licensed in the United States has been withdrawn from the market and is no longer recommended for routine administration to children, the Department believes that all petitions arising from administrations of the Rotashield vaccine will fall within this covered period.

Any rotovirus vaccines that are licensed in the future, including those containing live, oral, rhesus-based rotavirus, will automatically be covered under the Program under the Table's broad category of rotavirus vaccines. Because no injury is associated with this category of rotavirus vaccines, petitioners would retain the burden of showing causation in fact with respect to injuries unless and until the Department amended the Table through rulemaking. Thus, while both categories of vaccines will remain on the future Table resulting from the final rule, petitioners bringing claims concerning rotavirus vaccines administered after the effective date of that final rule will only be covered under the general category of rotavirus vaccines. The Department believes that this approach best maintains the scientific integrity of the Table because there is no evidence

that future rotavirus vaccines would be associated with the injury of intussusception. The Department presented this proposal, outlining the effective coverage dates for the two categories of rotavirus vaccines, to the ACCV at its December 2000 meeting. The ACCV reached consensus that this approach was appropriate.

Recent legislation also affects petitioners filing claims concerning rotavirus vaccines. Until recently, the PHS Act required all claimants to establish either that the residual effects of an injury persisted for more than 6 months after the administration of the vaccine or that a death resulted from the administration of a vaccine. Since most patients with intussusception recover after immediate treatment and do not suffer lasting complications for more than 6 months, some petitioners alleging intussusception from a rotavirus vaccine might have been denied compensation under that standard. However, a recent statutory amendment increases access to compensation for some petitions raising rotavirus-related intussusception claims. The Children's Health Act of 200 amends section 2111(c)(1)(D) of the PHS Act to permit payment of compensation for claims alleging injuries where the effects of the injury last less than 6 months if the petitioner demonstrates that the vaccine-related illness, disability, injury or condition ''resulted in inpatient hospitalization and surgical intervention.'' Pub. L. No. 106–310. This statutory change, which became effective on October 17, 2000, applies to new petitions for compensation as well as to petitions pending on that date. Thus, under current law, infants who experience intussusception following a rotavirus vaccine and do not suffer residual effects for more than 6 months may qualify for compensation if their injury resulted in inpatient hospitalization and surgery.

Residual Seizure Disorder: Qualifications and Aids to Interpretation

In a final rule published in the **Federal Register** on February 20, 1997, which became effective on March 24, 1997, residual seizure disorder was removed from the Table as an adverse event for vaccines containing the components of measles, mumps, or rubella. Because residual seizure disorder is no longer listed on the Table in 42 CFR 100.3 as an illness, disability, injury or condition for any covered vaccine, the Secretary proposes removing residual seizure disorder from the Table's Qualifications and Aids to Interpretation. The Secretary believes that his approach will minimize confusion about the Table. At its December 2000 meeting, the ACCV reached consensus that this technical change was appropriate.

Hemophilus Influenzae Type b (Hib) Polysaccharide (Unconjugated) Vaccines

The Secretary proposes removing hemophilus influenzae type b (Hib) polysaccharide (unconjugated) vaccines from the Table. The first licensed Hib vaccine was an unconjugated polysaccharide vaccine, which was licensed in April 1985. Two other unconjugated Hib vaccines were licensed in December 1985. In December 1987, the first conjugate Hib vaccine was licensed. Several conjugate Hib vaccines have subsequently been licensed. Because studies demonstrated the superior immunogenicity of conjugate Hib vaccines as compared to unconjugated Hib vaccines, the Secretary, believes that unconjugated Hib vaccines had little, if any, use since 1989.

In a February 20, 1997, final rule, the Secretary added both Hib conjugate and Hib unconjugated vaccines to the Table. Based on the Secretary's findings, early-onset Hib disease was listed as a table injury for unconjugated Hib vaccines. No condition was specified for Hib conjugate vaccines.

Section 904(b) of the Taxpayer Relief Act of 1997, which was signed into law on August 5, 1997, provided an excise tax for Hib vaccines. Thus, petitioners alleging an injury or death as a result of a Hib vaccine, either conjugate or unconjugated, were able to seek compensation beginning on August 6, 1997, the effective date of the addition of the vaccine to the Table.

The Secretary now proposes removing the unconjugated Hib vaccine from the Table for several reasons. First, under section 2116(b) of the PHS Act, petitions relating to unconjugated Hib vaccines administered before August 6, 1989, are not eligible for compensation. Under the terms of section 2116(b), petitions related to a vaccine added to the Table are compensable only if the vaccine-related injury or death occurred within the 8-year period before the date of the addition of the vaccine to the Table. Because Hib vaccines were added to the Table as of August 6, 1997, petitions relating to Hib vaccines administered before August 6, 1989, are ineligible for compensation. Second, because section 2116(b) imposes a 2-year statute of limitations for vaccines added to the Table, all petitions relating to a Hib vaccine administered between August 6, 1989, and August 5, 1997, had to be filed by August 6, 1999. Because this date has passed, such claims are no longer eligible for compensation. Third, the Department believes that unconjugated Hib vaccines have had little, if any, use since 1989 and expects no petitions relating to unconjugated Hib vaccines administered after August 5, 1997. This belief is supported by the fact that the Department has never received any petitions for compensation relating to unconjugated Hib vaccines. In sum, the Secretary proposes removing unconjugated Hib vaccines from the Table because the Secretary believes that no potential claims relating to this category of vaccines exist.

Because the Secretary proposes removing the unconjugated Hib vaccines from the Table, the Secretary further proposes removing early onset Hib disease from the Table's Qualifications and Aids to Interpretation. This proposal arises from the fact that early-onset Hib disease is associated with only the unconjugated polysaccaride Hib vaccine. Because the unconjugated Hib vaccine will no longer be listed on the Table, it is unnecessary to list any illness, disability, injury or condition for the unconjugated Hib vaccine. The Secretary believes this approach will minimize confusion about the Table. At its December 2000 meeting, the ACCV reached consensus that these technical changes were appropriate.

Pneumococcal Conjugate Vaccine

On December 17, 1999, the excise tax for pneumococcal conjugate vaccines was enacted by Public Law 106–170, the Ticket to Work and Work Incentives Improvement Act of 1999, with an effective date of December 18, 1999. Section 523 of this Act provides that all conjugate vaccines against streptococcus pneumoniae (pneumococcus) are added to section 4132(a)(1) of the Internal Revenue Code of 1986, which defines all taxable vaccines. On February 17, 2000, a pneumococcal conjugate vaccine, Prevnar, was licensed by the FDA. Following a review by the ACIP, the CDC recommended the pneumococcal conjugate vaccine for routine administration to children up to 23 months of age. This recommendation was published in the October 6, 2000, issue of the MMWR.

Because the excise tax for the pneumococcal conjugate vaccines has been enacted, and because the CDC has recommended a licensed pneumococcal conjugate vaccine for routine administration to children, the Secretary proposes adding this vaccine to the Table listed at 42 CFR 100.3(a). We have not identified any illness, disease,

injury, or condition which is caused by pneumococcal conjugate vaccines. Thus, the Secretary proposes adding this vaccine to the Table of Injuries with ''No Condition Specified.'' If we learn of any such illness, disease, injury, or condition which is caused by pneumococcal conjugate vaccines, we will consider amending the Table of Injuries to provide for its coverage, and a time period in which the first symptom or manifestation of its onset will be presumed to be vaccine-related. Pneumococcal conjugate vaccines are presently included in the Table under the Table's broad category XIII (notice published in the **Federal Register** on May 22, 2001, 66 FR 28166).

Under section 2114(e)(3) of the PHS Act, as amended by section 13632(a) of the Omnibus Budget Reconciliation Act of 1993, a revision to the Table adding a vaccine recommended by the CDC for routine administration to children shall take effect upon the effective date of the tax enacted to provide funds for compensation with respect to the vaccine added to the Table. Thus, the Secretary proposes covering pneumococcal conjugate vaccines under the Program effective for petitions filed beginning on December 18, 1999, the date the excise tax for these vaccines became effective. Because the addition of pneumococcal conjugate vaccines to the Table is mandated by the PHS Act, this Table change has not been submitted to the ACCV for review.

Economic and Regulatory Impact

Executive Order 12866 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 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 rule. Compensation will be made in the same manner. This proposed rule only lessens the burden of proof for potential petitioners. 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 proposed rule does not meet the criteria for a major rule as defined by Executive Order 12866 and would have no major effect on the economy or Federal expenditures. We have determined that the proposed rule is not a ''major rule'' within the meaning of the statute providing for Congressional Review of Agency Rulemaking, 5 U.S.C. 801. 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.

Nor on the basis of family well-being will the provisions of this rule effect the following family elements: 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 proposed rule would modify the Vaccine Injury Table based on legal authority.

Impact of the New Rule

To date, three petitions have been filed alleging a vaccine-related injury caused or aggravated by a rotavirus vaccine. This proposed rule will have the effect of decreasing the burden of proof on expected future petitioners. Under this proposed rule, future petitioners alleging the injury of intussusception as the result of a live, oral rhesus-based rotavirus vaccine, the only type of rotavirus vaccine licensed to date in the U.S., will be afforded a presumption of causation. This proposed rule will not change the burden of proof applicable to petitioners alleging other injuries related to a rotavirus vaccine, who must rely on a causation in fact analysis.

Because the proposed rule limits the Table injury of intussusception to live, oral, rhesus-based rotavirus vaccines, administered on or before the effective date of the final rule, individuals seeking compensation for injuries related to such a vaccine administered after the final rule becomes effective will no longer receive the presumption of a Table injury for intussusception. 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 recommended for infants in the United States on October 22, 1999, the Secretary has concluded that no potential claims arising after the final rule is published will be likely to exist. This proposed rule adds a Table injury only for rotavirus vaccines that contain live, oral, rhesus-based rotavirus. Because the only U.S.-licensed rotavirus vaccine falls within this category, the Secretary has concluded that this will not negatively disadvantaged potential petitioners.

This proposed rule will have a similar effect for petitioners seeking compensation for injuries related to hemophilus influenzae type b polysaccharide (unconjugated) vaccines. No claims relating to the administration of an unconjugated Hib vaccine before or on August 5, 1997, are eligible for compensation under the Act. In addition, the Secretary believes that these vaccines were not administered after 1997, and hence that no potential claims relating to this category of vaccines exist. Thus, it is very unlikely that the removal of unconjugated Hib vaccines from the Table will have an adverse impact upon potential petitioners. Removing early-onset Hib disease from the Table's Qualifications and Aids to Interpretation will not have an adverse effect on petitioners because it will no longer be listed as an adverse event for any vaccine on the Table.

Similarly, because residual seizure disorder is not listed on the Table as an adverse event for any vaccine on the Table, removing residual seizure disorder will not have an adverse impact for future petitioners.

Finally, this proposed rule will have the effect of making petitioners seeking compensation for injuries related to pneumococcal conjugate vaccines eligible for compensation under the PHS Act.

Paperwork Reduction Act of 1980

This proposed rule has no information collection requirements.

List of Subjects in 42 CFR Part 100

Biologics, Health insurance, and Immunization.

Dated: March 2, 2001.

Claude Earl Fox,

Administrator, Health Resources and Services Administration.

Approved: March 23, 2001.

Tommy G. Thompson,

Secretary.

Accordingly, 42 CFR part 100 is proposed to be amended as set forth below:

PART 100—VACCINE INJURY COMPENSATION

1. The authority citation for 42 CFR part 100 is revised to read as follows:

Authority: Sec. 215 of the Public Health Service Act (42 U.S.C. 216); sec. 2115 of the PHS Act; 100 Stat. 3767, as revised (42 U.S.C. 300aa–15); § 100.3 Vaccine Injury Table, issued under secs. 312 and 313 of Pub. L. 99–660, 100 Stat. 3779–3782 (42 U.S.C. 300aa–1 note); and sec. 2114(c) and (3) of the PHS Act, 100 Stat. 3766 and 107 Stat. 645 (42 U.S.C. 300aa–14(c) and (e)); sec. 904(b) of Pub. L. 105–34, 111 Stat. 873; and sec. 523(a) of Pub. L. 106–170, 113 Stat. 1860.

2. Section 100.3 is amended as follows:

a. In paragraph (a), the Table is amended by removing Item IX; redesignating Items X, XI, XII, and XIII as Items IX, X, XI, and XIV; and adding new Items XII and XIII to read as set forth below.

b. Paragraph (b)(3) is removed and reserved.

c. Paragraph (b)(4) is amended by revising the phrase ''paragraphs (b)(2) and (3)'' in the first sentence to read ''paragraph (b)(2)''.

d. Paragraph (b)(11) is removed.

e. Paragraph (c)(2) is amended by removing the words '', and XI'' in the parenthetical and adding the word ''and'' before the number ''X''.

f. Paragraph (c)(3) is revised as set forth below.

g. Paragraph (c)(4) is redesignated as (c)(5).

h. A new paragraph (c)(4) is added to read as set forth below.

§ 100.3 Vaccine Injury Table.

(a) * * *

VACCINE INJURY TABLE

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
* * * * * * *		
XII. Vaccines containing live, oral, rhesus-based rotavirus	Intussusception	0–30 days.
XIII. Pneumococcal conjugate vaccines	No condition specified	Not applicable
* * * * * * *		

(c) * * *

(3) Rotavirus vaccines (Item XI of the Table) are included in the Table as of October 22, 1998. Vaccines containing live, oral, rhesus-based rotavirus (Item XII of the Table) are included in the Table as of October 22, 1998, provided that they were administered on or before [Effective date of the final rule].

(4) Pneumococcal conjugate vaccines (Item XIII of the Table) are included in the Table as of December 18, 1999.

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