DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 100

RIN 0906–AA74

National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Final rule.

SUMMARY: On September 13, 2010, the Secretary of Health and Human Services (the Secretary) published in the **Federal Register** a Notice of Proposed Rulemaking (NPRM) proposing changes to the regulations governing the National Vaccine Injury Compensation Program (VICP). Specifically, the Secretary proposed revisions to the Vaccine Injury Table (Table) to create distinct listings for hepatitis A, trivalent influenza, meningococcal, and human papillomavirus vaccines. The Secretary is now making this amendment to the Table by final rule; it is technical in nature. The four categories of vaccines described in this final rule are already covered vaccines under the VICP (starting in 2004) and are currently listed in a placeholder category (box XIII) in the Table. This final rule will list these vaccines as separate categories on the Table, with no associated injuries noted at this time, in order to help the public identify clearly that these vaccines are covered by the VICP. The changes implemented here are authorized by section 2114(e) of the Public Health Service Act (the Act).

DATES: This regulation is effective July 22, 2011.

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

SUPPLEMENTARY INFORMATION: On September 13, 2010, the Secretary published in the **Federal Register** (75 FR 55503, September 13, 2010) an NPRM to revise and amend the Table by moving these vaccines to separate and distinct listings of the Table. The NPRM was issued pursuant to Section 2114(e) of the Act, which directs the Secretary to add to the Table, by rulemaking, coverage of additional vaccines which are recommended by the Centers for Disease Control and Prevention for routine administration to children.

The Department held a 6-month comment period, which ended on March 14, 2011, in connection with this NPRM. The Secretary received one non-substantive comment that was not responsive to the NPRM. A public hearing was held on March 4, 2011, as announced in the **Federal Register** (76 FR 8965, February 16, 2011), but no individual or organization appeared to testify.

Because the Secretary has not received any substantive comments, either written or oral, from any interested individual or organization on the proposals made in the NPRM, and because the Secretary continues to believe the advisability of effectuating such proposals, this final rule implements the proposals made in the NPRM. The rationale for all revisions were explained fully in the Preamble to the NPRM. For the reasons set forth in the NPRM, the Secretary amends the Table in this final rule.

Economic and Regulatory Impact

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 final rule. Therefore, in accordance with the Regulatory Flexibility Act of 1980 (RFA), and the Small Business Regulatory Enforcement Fairness Act of 1996, which amended the RFA, the Secretary certifies that this final rule will not have a significant impact on a substantial number of small entities.

The Secretary has also determined that this 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 this 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.

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.

The Secretary has reviewed this final rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have ''federalism implications.'' This 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.''

This final rule would not adversely affect 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.

Impact of the New Rule

This final rule is technical in nature. Because the vaccines being added to the Table as separate categories are already included on the Table under Category XIII, this Table will have no effect on current or potential petitioners other than to help clarify which vaccines are covered by the VICP. This final rule would not prevent otherwise eligible individuals with claims of injuries or deaths allegedly resulting from the hepatitis A, trivalent influenza, meningococcal and human papillomavirus vaccines from filing claims with the VICP and would not otherwise affect such petitioners.

Paperwork Reduction Act

This final rule does not have any information collection requirements.

Dated: May 2, 2011.

Mary Wakefield,

Administrator, Health Resources and Services Administration.

Approved: June 16, 2011.

Kathleen Sebelius,

Secretary.

List of Subjects in 42 CFR Part 100

Biologics, Health insurance, and Immunization.

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: Secs. 312 and 313 of Pub. L. 99–660, 100 Stat. 3779–3782 (42 U.S.C. 300aa–1 note); sec. 2114(c) and (e) of the PHS Act (42 U.S.C. 300aa–14(c) and (e)); sec. 2115(a)(3)(B) of the PHS Act (42 U.S.C. 300aa–15(a)(3)(B)); sec. 904(b) of Pub. L. 105–34, 111 Stat. 873; sec. 1503 of Pub. L. 105–277, 112 Stat. 2681–741; and sec. 523(a) of Pub. L. 106–170, 113 Stat. 1927–1928.

■ 2. Amend § 100.3 by revising the Vaccine Injury Table following paragraph (a), revising paragraph (c)(1), redesignating paragraph (c)(5) as paragraph (c)(8) and revising newly designated paragraph (c)(8), and adding new paragraphs (c)(5), (c)(6), and (c)(7), to read as follows:

§ 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
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT).	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Brachial Neuritis	2–28 days.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, DTaP, P, DTP–Hib).	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Encephalopathy (or encephalitis)	72 hours.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
III. Measles, mumps, and rubella vaccine or any of its components (e.g., MMR, MR, M, R).	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Encephalopathy (or encephalitis)	5–15 days (not less than 5 days and not more than 15 days).
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
IV. Vaccines containing rubella virus (e.g., MMR, MR, R).	A. Chronic arthritis	7–42 days.
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
V. Vaccines containing measles virus (e.g., MMR, MR, M).	A. Thrombocytopenic purpura	7–30 days.
	B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient.	6 months.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
VI. Vaccines containing polio live virus (OPV).	A. Paralytic Polio	
	—in a non-immunodeficient recipient	30 days.
	—in an immunodeficient recipient	6 months.
	—in a vaccine associated community case	Not applicable.
	B. Vaccine-Strain Polio Viral Infection.	
	—in a non-immunodeficient recipient	30 days.
	—in an immunodeficient recipient	6 months.
	—in a vaccine associated community case	Not applicable.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.

VACCINE INJURY TABLE—Continued

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
VII. Vaccines containing polio inactivated virus (e.g., IPV).	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Any acute complication or sequela (including death of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed..	Not applicable.
VIII. Hepatitis B. vaccines	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
IX. Hemophilus influenzae type b polysaccharide conjugate vaccines.	No Condition Specified	Not applicable.
X. Varicella vaccine	No Condition Specified	Not applicable.
XI. Rotavirus vaccine	No Condition Specified	Not applicable.
XII. Pneumococcal conjugate vaccines	No Condition Specified	Not applicable.
XIII. Hepatitis A vaccines	No Condition Specified	Not applicable.
XIV. Trivalent influenza vaccines	No Condition Specified	Not applicable.
XV. Meningococcal vaccines	No Condition Specified	Not applicable.
XVI. Human papillomavirus (HPV) vaccines.	No Condition Specified	Not applicable.
XVII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage.	No Condition Specified	Not applicable.

* * * * *

(c) * * * (1) Except as provided in paragraph (c)(2), (3), (4), (5), (6), or (7) of this section, the revised Table of Injuries set forth in paragraph (a) of this section and the Qualifications and Aids to Interpretation set forth in paragraph (b) of this section apply to petitions for compensation under the Program filed with the United States Court of Federal Claims on or after March 24, 1997. Petitions for compensation filed before such date shall be governed by section 2114(a) and (b) of the Public Health Service Act as in effect on January 1, 1995, or by § 100.3 as in effect on March 10, 1995 (see 60 FR 7678, *et seq.,* February 8, 1995), as applicable.

* * * * *

(5) Hepatitis A vaccines (Item XIII of the Table) are included on the Table as of December 1, 2004.

(6) Trivalent influenza vaccines (Item XIV of the Table) are included on the Table as of July 1, 2005.

(7) Meningococcal vaccines and human papillomavirus vaccines (Items XV and XVI of the Table) are included on the Table as of February 1, 2007.

(8) Other new vaccines (Item XVII of the Table) will be included in the Table as of the effective date of a tax enacted to provide funds for compensation paid with respect to such vaccines. An amendment to this section will be published in the **Federal Register** to announce the effective date of such a tax.

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2011–0002; Internal Agency Docket No. FEMA–8185]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date.

DATES: *Effective Dates:* The effective date of each community's scheduled suspension is the third date (''Susp.'') listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact David Stearrett, Mitigation Directorate, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2953.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the NFIP, 42 U.S.C. 4001 *et seq.;* unless an appropriate public body adopts adequate floodplain management