

TABLE 2.—WASTES EXCLUDED FROM SPECIFIC SOURCES—Continued

Facility	Address	Waste description
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 BILLING CODE 6560–50–P

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: Final rule.

SUMMARY: On July 13, 2001, 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 (the Table). The primary proposal made in the NPRM was that vaccines containing live, oral, rhesus-based rotavirus be added to the Table as a distinct category, with intussusception listed as a covered Table injury. This proposal was based upon the Secretary’s determination that the condition of intussusception can reasonably be determined in some circumstances to be caused by vaccines containing live, oral, rhesus-based rotavirus. The Secretary is now making this amendment to the Table by final rule. The Secretary is also making additional amendments to the Table and to the Table’s Qualifications and Aids to Interpretation (Qualifications and Aids), described below under **SUPPLEMENTARY INFORMATION**, as proposed in the NPRM. The changes implemented here are authorized by section 2114(c) and (e) of the Public Health Service Act (the Act).

DATES: This regulation is effective on August 26, 2002. *Applicability dates:* As provided by section 13632(a)(3) of Public Law 103–66, the Omnibus Budget Reconciliation Act of 1993, the addition of vaccines containing live, oral, rhesus-based rotavirus took effect

on October 22, 1998, the effective date of the excise tax for rotavirus vaccines, provided that they were administered on or before August 26, 2002. Under the same authority, the addition of pneumococcal conjugate vaccines took effect on December 18, 1999, the effective date of the excise tax for this categories of vaccines. See discussion under **SUPPLEMENTARY INFORMATION** in the NPRM underlying this final rule (66 FR 36735, July 13, 2001) for an explanation of these applicability dates.

FOR FURTHER INFORMATION CONTACT: Geoffrey Evans, M.D., Medical Director, Division of Vaccine Injury Compensation, Office of Special Programs, Health Resources and Services Administration (HRSA), Parklawn Building, Room 8A–46, 5600 Fishers Lane, Rockville, Maryland 20857; telephone number (301) 443–4198.

SUPPLEMENTARY INFORMATION:

Introductory and Procedural History

On July 13, 2001, the Secretary published in the **Federal Register** (66 FR 36735, July 13, 2001) an NPRM to revise and amend the Table and the Qualifications and Aids. The NPRM was issued pursuant to Section 2114(c) of the Act, which authorizes the Secretary to promulgate regulations to modify the Table, and Section 2114(e), which directed the Secretary to add to the Table, by rulemaking, coverage of additional vaccines which are recommended by the Centers for Disease Control and Prevention (CDC) for routine administration to children.

The Department held a 6-month comment period, which ended on January 9, 2002, in connection with this NPRM. The Secretary did not receive any comments in response to the NPRM. A public hearing was held on December 6, 2001, as announced in the **Federal Register** (66 FR 58154, Nov. 20, 2001), but no individual or organization appeared to testify.

Because the Secretary has not received any 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 in the advisability of effectuating such proposals, this final rule implements the proposals made in the NPRM. One technical amendment to

42 CFR 100.3(c)(4), which was inadvertently omitted from the NPRM, is being implemented in this final rule. In addition, we are modifying the authority citation for 42 CFR part 100. The rationales for all other revisions and additions made in this final rule were explained fully in the Preamble to the NPRM. For the reasons set forth in the NPRM, the Secretary makes several amendments affecting the operation of the VICP in this rule.

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.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget. 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. The final rule only lessens the burden of proof for certain 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 rule does not meet the criteria for a major rule as defined by Executive Order 12866 and will have no major effect on the economy or Federal expenditures. We have determined that this 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 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.

The Department has also reviewed this rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have "federalism implications." The rule does 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."

As stated above, this rule will modify the Vaccine Injury Table and the Qualifications and Aids based on legal authority.

Impact of the New Rule

The final rule will have the effect of decreasing the burden of proof on expected future petitioners filing petitions alleging a vaccine-related injury caused or aggravated by a rotavirus vaccine. Under this 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 United States, will be afforded a presumption of causation. This 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 final 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 in October 1999, the Secretary has concluded that no potential claims arising after this rule is published will be likely to exist.

This final rule will have a similar effect for petitioners seeking compensation for injuries related to hemophilus influenzae type b polysaccharide (unconjugated) vaccines. As explained in the NPRM, the Secretary believes 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 upon future petitioners.

Finally, this rule will have the effect of making petitioners seeking compensation for injuries related to pneumococcal conjugate vaccines eligible for compensation under a separate category on the Table.

Paperwork Reduction Act of 1980

This final rule has no information collection requirements.

List of Subjects in 42 CFR Part 100

Biologics, Health insurance, and Immunization.

Dated: March 14, 2002.

Elizabeth M. Duke,

Administrator, Health Resources and Services Administration.

Approved: May 17, 2002.

Tommy G. Thompson,

Secretary.

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 is revised to read as follows:

Authority: Sec. 215 of the Public Health Service Act (42 U.S.C. 216); 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, 100 Stat. 3766 and 107 Stat. 645-646 (42 U.S.C. 300aa-14(c) and (e)); 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. 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 phrase 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) and is amended by revising the phrase "Item XIII" in the parenthetical phrase to read "Item XIV".

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 August 26, 2002.
 (4) Pneumococcal conjugate vaccines (Item XIII of the Table) are included in the Table as of December 18, 1999.

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1 and 80

[PR Docket No. 92–257; RM–9664; FCC 02–74]

Maritime Communications

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission adopts rules that will streamline our licensing process for Automated Maritime Telecommunications System (AMTS) stations by utilizing a geographic area licensing system. With respect to high seas spectrum, the Commission will now process applications on a first-come, first-served basis, thereby precluding the filing of mutually exclusive applications and thus, the need to use competitive bidding procedures. The Commission believes that these decisions will increase competition in the provision of telecommunications services, promote more efficient use of maritime spectrum, increase the types of telecommunications services available to vessel operators, allow maritime commercial mobile radio service (CMRS) providers to respond more

quickly to market demand, and reduce regulatory burdens on AMTS and high seas public coast station licensees.

EFFECTIVE DATE: Effective August 26, 2002.

FOR FURTHER INFORMATION CONTACT: Keith Fickner, Policy and Rules Branch, Public Safety and Private Wireless Division, Wireless Telecommunications Bureau at (202) 418–7308.

SUPPLEMENTARY INFORMATION: The Commission’s *Second Memorandum Opinion and Order and Fifth Report and Order*, PR Docket No. 92–257, FCC 02–74, was adopted March 13, 2002, and released on April 8, 2002. The full text of this Commission’s *Second Memorandum Opinion and Order and Fifth Report and Order* is available for inspection and copying during normal business hours in the FCC Reference Center, Room CY–A257, 445 12th Street, SW., Washington, DC. The complete text may be purchased from the Commission’s copy contractor, International Transcription Service, Inc., 1231 20th Street NW., Washington, DC 20037. The full text may also be downloaded at: <http://www.fcc.gov/Wireless/Orders/2002/fcc0274.txt>. Alternative formats are available to persons with disabilities by contacting Martha Contee at (202) 418–0260 or TTY (202) 418–2555.

Summary of the Second Memorandum Opinion and Order

1. The Commission resolves a petition for reconsideration of the suspension of acceptance of applications for new AMTS and HF radiotelephone high seas public coast stations that went into effect on November 16, 2000. The Commission states that it believes that suspension of acceptance and processing of AMTS applications is warranted in order to facilitate the orderly and effective resolution of the matters pending in this proceeding. By maintaining the processing suspension, it states that it will be able to weigh the costs and benefits of the existing

regulatory framework against its proposals.

2. The Commission also resolves a petition for declaratory ruling regarding section 309 of the Communications Act. The Commission states that sections 309(d)(2) and (e) do not restrict its authority to dismiss an AMTS application that, as of November 16, 2000, was mutually exclusive with other applications or for which the relevant period to file mutually exclusive applications had not expired. The Commission also rejects the petitioner’s argument that in instances where a petition to deny was filed against one or more mutually exclusive applications that were subject to the processing suspension, section 309(j)(6)(E) requires the Commission to first address the petition to deny because a grant of the petition could resolve the mutual exclusivity, thus enabling the surviving application(s) to be processed. The Commission states that section 309(j)(6)(E) merely requires that it take certain measures, when it is in the public interest, to avoid mutual exclusivity within the framework of existing, not outmoded, licensing policies.

Summary of the Fifth Report and Order

3. The Commission concludes that the public interest will be best served by a transition to geographic area licensing for AMTS spectrum. Such an approach will speed assignment of subsequent AMTS licenses, reduce processing burdens on the Commission, facilitate the expansion of existing AMTS systems and the development of new AMTS systems, eliminate inefficiencies arising from the intricate web of relationships created by site-specific authorization, and enhance regulatory symmetry.

4. The Commission adopts a 10 dB co-channel interference protection standard because it will afford AMTS incumbents with sufficient protection. The Commission believes that 10 dB protection to an incumbent’s 38 dBu service contour (the standard used in