''Exclusive''. This document removes MR series 11000 and 12000 from being designated as ''Exclusive''. All other parameters of the Final Rule remain the same as published on June 5, 2015.

DATES: Effective June 23, 2015.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–2118.

SUPPLEMENTARY INFORMATION: This document corrects § 51–6.4 by removing MR series 11000 and 12000 from paragraphs (b), (c)(4), and (d) so the series are no longer designated as ''Exclusive''. All other parameters of the Final Rule remain the same as published on June 5, 2015.

List of Subjects in 41 CFR Part 51–6 Procurement procedures.

For the reasons set out in the preamble, the Committee amends 41 CFR part 51–6 as follows:

PART 51–6—PROCUREMENT PROCEDURES

■ 1. The authority citation for part 51–6 continues to read as follows:

Authority: 41 U.S.C. 8501–8506.

§ 51–6.4 [Amended]

■ 2. In § 51–6.4, in paragraphs (b), (c)(4), and (d), remove '', 11000 (11000–11999); 12000 (12000–12999)''.

Dated: June 17, 2015.

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2015–15284 Filed 6–22–15; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 100

RIN 0906–AB00

National Vaccine Injury Compensation Program: Addition of Intussusception as Injury for Rotavirus Vaccines to the Vaccine Injury Table

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

ACTION: Final rule.

SUMMARY: On July 24, 2013, 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). The basis for this change is consistent with the Secretary's findings that intussusceptions can reasonably be determined in some circumstances to be caused by rotavirus vaccines. The Secretary is now making this amendment to the Table and to the Qualifications and Aids to Interpretation (QAI), described below under Background Information, as proposed in the NPRM. These regulations will apply only to petitions for compensation under the VICP filed after this final rule becomes effective.

DATES: This final rule is effective July 23, 2015.

FOR FURTHER INFORMATION CONTACT: Dr. Avril M. Houston, Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, Parklawn Building, Room 11C–06, 5600 Fishers Lane, Rockville, MD 20857, or by telephone: (800) 338–2382. This is a toll-free number.

SUPPLEMENTARY INFORMATION:

I. Background Information

Under Title XXI of the Public Health Service Act, as amended (PHS Act), individuals who demonstrate a vaccine-related injury or death may receive compensation through the VICP. To be eligible for compensation from the VICP, a petitioner must demonstrate that the injured or deceased individual received a vaccine set forth in the Table (a ''covered vaccine'') and sustained a vaccine-related injury or death. A petitioner can prove a vaccine-related injury or death in three ways. First, the petitioner can show, by a preponderance of the evidence, that the vaccine recipient suffered an injury listed in the Table corresponding with the vaccine received, that the onset of such injury occurred within the timeframe specified in the Table, and that the injury meets the requirements set forth in the Table's QAI. A Table injury or death is given the legal presumption that it was caused by the vaccination. Sections 2111(c)(1)(C)(i), 2113(a)(1)(B), and 2114(a) of the PHS Act. Second, if the petitioner cannot demonstrate a Table injury, the petitioner can prevail by proving, by a preponderance of the evidence, that the vaccine caused the injury or death (off-Table injury). Third, a petitioner can prevail by proving, by a preponderance of the evidence, that the vaccine significantly aggravated a pre-existing condition. In all three cases, a petitioner must also show that the injury was sufficiently severe by demonstrating that such person suffered the residual effects of the injury for more than 6 months; died from the administration of the vaccine; or that the alleged injury resulted in inpatient hospitalization and surgical intervention. Section 2111(c)(1)(D) of the PHS Act. If the petitioner can prove a Table injury, off-Table injury, or significant aggravation of a pre-existing condition, the petitioner is entitled to compensation unless it is affirmatively shown that the injury was caused by some factor unrelated to the vaccination.

Under section 2114(e)(2) of the PHS Act, when the Centers for Disease Control and Prevention (CDC) recommends a vaccine for routine administration to children, the Secretary is required to amend the Table to include such vaccine. Coverage becomes effective when an excise tax is imposed on the vaccine. Additionally, the Secretary is authorized to include specific injuries on the Table with respect to each covered vaccine, including the timeframe when the first symptom or manifestation of the onset of such adverse event may occur. The Secretary may also define such injuries through the QAI. Under section 2114(c) of the PHS Act, the Secretary may make such modifications to the Table by promulgating regulations, with notice and opportunity for a public hearing, and at least 180 days of public comment.

II. Discussion of the Final Rule

As discussed in the NPRM (78 FR 44512, July 24, 2013), the Secretary has reviewed the currently available data regarding the Rotarix and RotaTeq vaccines and the risk of intussusception. The background of the RotaShield experience in the U.S. and the published literature from Mexico, Brazil, Australia, and the U.S. supports a small attributable risk of intussusception after the first and second doses of Rotarix and RotaTeq (with a greater amount of data supporting an association with the first dose of both vaccines). Evidence shows the increased risk within the 1–7 days following immunization with peaks in the fourth and fifth days. As a consequence, the Secretary is amending the Table to add the injury of intussusception to the general Table category of ''rotavirus vaccines'' to allow a presumption of causation for claims that meet the requirements set forth in the Table for that injury. To allow for a generous timeframe that will capture any cases related to the vaccine after day 7, the Secretary has assigned an onset interval of 1–21 days under sections 2114(c) and (e) of the PHS Act.

The Secretary will stay informed of new information in the scientific and medical field about intussusception and

rotavirus vaccines and may propose changes in the future if such information warrants changes to the Table. In addition, the Secretary recognizes that one goal of the VICP is to provide compensation to petitioners harmed by vaccines through a less adversarial system. Therefore, the Secretary feels that adding the Table injury of intussusception after the first and second doses of rotavirus vaccines with a window of 1–21 days is appropriate.

The QAI section of the Table defines the injury of ''intussusception'' as the invagination of a segment of intestine into the next segment of intestine, resulting in bowel obstruction, diminished arterial blood supply, and blockage of the venous blood flow. This is characterized by a sudden onset of abdominal pain that may be manifested by anguished crying, irritability, vomiting, abdominal swelling, and/or passing of stools mixed with blood and mucus. The definition for presumption of vaccine causation only applies to the first and second dose of vaccine, and excludes intussusception occurring with or after the third dose. The third dose of rotavirus vaccines lacks sufficient evidence showing risk.

The definition also delineates the alternative causes of intussusception which, if present in a case, would prevent it from qualifying as a Table injury. The alternative causes were classified into four categories: infectious diseases; anatomic lead points; anatomic bowel abnormalities; and underlying gastrointestinal or systemic diseases. Cases of intussusception where the onset was within 14 days after an infectious disease secondary to non-enteric or enteric adenovirus, other enteric viruses (such as Enterovirus), enteric bacteria (such as Campylobacter jejuni), or enteric parasites (such as Ascaris lumbricoides) would not qualify as a Table injury. Proof of these alternate causes may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing.

Cases of intussusception in a person with a pre-existing condition identified as the lead point for intussusception, such as intestinal masses and cystic structures (*e.g.,* polyps; tumors; Meckel's diverticulum; lymphoma; or duplication cysts), would not qualify as a Table injury. Additionally, cases of intussusception in a person with abnormalities of the bowel, including congenital anatomic abnormalities, anatomic changes after abdominal surgery, and other anatomic bowel abnormalities caused by mucosal hemorrhage, trauma, or abnormal intestinal blood vessels (such as Henoch Scholein purpura, hematoma, or hemangioma); or in a person with underlying conditions or systemic diseases associated with intussusception (such as cystic fibrosis, celiac disease, or Kawasaki disease) would not qualify as a Table injury.

Petitioners may be eligible for compensation for vaccine-related cases of intussusception in which the onset is before 1 day or beyond 21 days, or where the condition does not satisfy the criteria under the QAI for intussusception (an ''off-Table'' claim); however, the petitioners will be required to prove causation-in-fact. Regardless of whether the claim satisfies the criteria in the Table, all petitioners must demonstrate sufficient severity of the injury by proving that the injured person: 1) suffered the residual effects or complications of the alleged vaccine-related injury for more than 6 months after vaccine's administration; 2) died from administration of the vaccine; or 3) sustained inpatient hospitalization and surgery as a result of the alleged vaccine-related injury. Section 2111(c)(1)(D), PHS Act (42 U.S.C. 300aa–11(c)(1)(D)). In the case of rotavirus vaccine administration and subsequent intussusception, the Secretary does not consider a reduction of intussusception with therapeutic enemas to be ''surgical intervention.''

Petitions must also be filed within the applicable statute of limitations. The general statute of limitations applicable to petitions filed with the VICP, set forth in section 2116(a) of the PHS Act (42 U.S.C. 300aa–16(a)), continues to apply. In addition, section 2116(b) of the PHS Act identifies a specific exception to this statute of limitations that applies 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 two years after the effective date of the revision if the injury or death occurred not more than eight years before the effective date of the revision of the Table (42 U.S.C. 300aa–16(b)).

III. Comments and Responses

The comment period for this regulation ran for 6 months (July 24, 2013–January 21, 2014) and included two public hearings that were held on January 13, 2014, and April 28, 2014. The Secretary received ten comments as a result of this process. None of the commenters objected to the Secretary's proposal to add intussusception as an injury for rotavirus vaccines to the Table, and the overwhelming majority of commenters expressed their support for the proposal. In addition, commenters raised four additional points. Below is a summary of those points and the Secretary's responses to them.

1. Notice to Potential Petitioners

COMMENT: A commenter suggested that the Secretary make additional efforts to increase public awareness about expanding the Table and to increase the general public awareness about the VICP.

RESPONSE: The Secretary will continue efforts to increase the general public's awareness about the VICP, including revisions to the Table.

2. Demonstrating Severity of Injury

COMMENT: One commenter suggested that the definition of surgical intervention be broadened to include therapeutic enema treatment.

RESPONSE: Defining the term ''surgical intervention'' is beyond the scope of the Table amendments. While the preamble to both the NPRM and final rule includes the Secretary's view that a reduction of intussusception with an enema is not a ''surgical intervention,'' such language is not included in the regulatory text. Further, the definition of ''surgical intervention'' is decided by the court.

3. Onset Time Frame

COMMENT: A commenter stated that none of the data for either vaccine supports an association with intussusception for days 8–21 after dose 2 and suggested that the Secretary consider revising the time frame for qualification as a Table injury after dose 2 to 1–7 days.

RESPONSE: The Secretary has considered the approach suggested by the commenter and also the recommendation of the Advisory Commission on Childhood Vaccines (ACCV). The ACCV unanimously recommended the proposed change of 1–21 days for all rotavirus vaccines.

The ACCV's ''Guiding Principles for Recommending Changes to the Vaccine Injury Table,'' consist of two overarching principles: (1) the Table should be scientifically and medically credible; and (2) where there is credible scientific and medical evidence both to support and to reject a proposed change (addition or deletion) to the Table, the change should, whenever possible, be made to the benefit of petitioners. The Guiding Principles were established in 2006 to assist the ACCV in evaluating

proposed Table revisions and determining whether to recommend Table changes to the Secretary. The ACCV followed these Guiding Principles in making its recommendations to the Secretary for revising this Table. Therefore, the Secretary has decided that the 1–21 day timeframe for both vaccines is the best approach to capture any cases related to the vaccine after day 7.

4. Published Studies since the Publication of the NPRM

COMMENT: A commenter identified studies that have been published since the initial NPRM was published.

RESPONSE: The Secretary has reviewed these studies and found that the most recent data have shown a small but statistically significant increased risk of intussusception within 7 days after the first and second doses of the licensed rotavirus vaccines. However, as discussed above, following the Guiding Principles, the ACCV unanimously recommended the proposed change of 1–21 days for all rotavirus vaccines. Therefore, the Secretary has decided that the 1–21 day timeframe for both vaccines is the best approach to capture any cases related to the vaccine after day 7.

IV. Regulatory Impact Analysis

HHS has examined the impact of this rulemaking as required by Executive Order 12866 on Regulatory Planning and Review, Executive Order 13563 on Improving Regulation and Regulatory Review, the Congressional Review Act (5 U.S.C. 804(2)), the Regulatory Flexibility Act (RFA), section 202 of the Unfunded Mandates Reform Act of 1995, section 654(c) of the Treasury and General Government Appropriations Act of 1999, and Executive Order 13132 on Federalism.

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, costs, benefits, incentives, equity, and available information. Regulations must meet certain standards, such as avoiding an unnecessary burden. Regulations that 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 used prior to the revisions of this final rule. The only purpose of this rule is to lessen 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 rule does not meet the criteria for a major rule as defined by Executive Order 12866, and it would not have a major effect on the economy or federal expenditures. The Secretary has 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, or on the private sector such as to require consultation under the Unfunded Mandates Reform Act of 1995.

The Secretary finds that the provisions of this rule will not have an adverse effect on family well-being, because this rule does not 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.

This rule is not being treated as a ''significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget. As stated above, this rule would modify the Table based on legal authority.

Impact of the New Rule

This rule will have the effect of making it easier for future VICP petitioners alleging the injury of intussusception as the result of a rotavirus vaccine that meets the criteria in the Table to receive the Table's presumption of causation (which relieves them of having to prove that the vaccine actually caused or significantly aggravated the injury).

Paperwork Reduction Act of 1995

This final rule has no information collection requirements.

List of Subjects in 42 CFR Part 100

Biologics, Health insurance, and Immunization.

Dated: May 27, 2015.

James Macrae,

Acting Administrator, Health Resources and Services Administration.

Approved: June 5, 2015.

Sylvia M. Burwell,

Secretary.

Therefore, for the reasons stated in the preamble, the Department of Health and Human Services amends 42 CFR part 100 as follows:

PART 100—VACCINE INJURY COMPENSATION

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

Authority: Secs. 312 and 313 of Public Law 99–660 (42 U.S.C. 300aa–1 note); 42 U.S.C. 300aa–10 to 300aa–34; 26 U.S.C. 4132(a); and sec. 13632(a)(3) of Public Law 103–66.

■ 2. Amend § 100.3 as follows:

■ a. Amend paragraph (a) by revising Item XI in the table.

■ b. Add paragraph (b)(3).

The revision and addition read as follows:

§ 100.3 Vaccine injury table.

(a) * * *

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
* *	* * *	* *
XI. Rotavirus vaccines	A. Intussusception	1–21 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
* *	* * *	* *

(b) * * *

(3) *Intussusception.* (i) For purposes of paragraph (a) of this section, intussusception means the invagination of a segment of intestine into the next segment of intestine, resulting in bowel obstruction, diminished arterial blood supply, and blockage of the venous blood flow. This is characterized by a sudden onset of abdominal pain that may be manifested by anguished crying, irritability, vomiting, abdominal swelling, and/or passing of stools mixed with blood and mucus.

(ii) For purposes of paragraph (a) of this section, the following shall not be considered to be a Table intussusception:

(A) Onset that occurs with or after the third dose of a vaccine containing rotavirus;

(B) Onset within 14 days after an infectious disease associated with intussusception, including viral disease (such as those secondary to non-enteric or enteric adenovirus, or other enteric viruses such as Enterovirus), enteric bacteria (such as *Campylobacter jejuni*), or enteric parasites (such as *Ascaris lumbricoides*), which may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing;

(C) Onset in a person with a pre-existing condition identified as the lead point for intussusception such as intestinal masses and cystic structures (such as polyps, tumors, Meckel's diverticulum, lymphoma, or duplication cysts);

(D) Onset in a person with abnormalities of the bowel, including congenital anatomic abnormalities, anatomic changes after abdominal surgery, and other anatomic bowel abnormalities caused by mucosal hemorrhage, trauma, or abnormal intestinal blood vessels (such as Henoch Scholein purpura, hematoma, or hemangioma); or

(E) Onset in a person with underlying conditions or systemic diseases associated with intussusception (such as cystic fibrosis, celiac disease, or Kawasaki disease).

* * * * *

[FR Doc. 2015–14771 Filed 6–22–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2015–0001; Internal Agency Docket No. FEMA–8385]

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. Also, information identifying the current participation status of a community can be obtained from FEMA's Community Status Book (CSB). The CSB is available at *http://www.fema.gov/fema/csb.shtm.*

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 Bret Gates, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–4133.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures 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 the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the **Federal Register**.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency