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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 100

RIN 0906-AB14

National Vaccine Injury Compensation Program: Adding the Category of Vaccines Recommended for Pregnant Women to the Vaccine Injury Table

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

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: As required by a recent amendment to the VICP's authorizing statute, the Secretary of the Department of Health and Human Services (Secretary) proposes to amend the National Vaccine Injury Compensation Program (VICP) Vaccine Injury Table (Table) to include vaccines recommended by the Centers for Disease Control and Prevention (CDC) for routine administration in pregnant women. Thus, the Secretary is only seeking public comment on how the addition of this new category is proposed to be formatted on the Table.

DATES: Written comments must be submitted on or before [**INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: You may submit comments, identified by the Regulatory Information Number (RIN) 0906-AB14 in one of three ways, as listed below. The first is the preferred method. Please submit your comments in only *one* of these ways to minimize the receipt of duplicate submissions.

1. Federal eRulemaking Portal. You may submit comments electronically to *http://www.regulations.gov*. Click on the link "Submit electronic comments" on HRSA

regulations with an open comment period. You may submit attachments to your comments in any file format accepted by Regulations.gov.

2. Regular, express, or overnight mail. You may mail written comments to the following address only: Health Resources and Services Administration, Department of Health and Human Services, Attention: HRSA Regulations Officer, 5600 Fishers Lane, Room 13N82, Rockville, MD 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. Delivery by hand (in person or by courier). If you prefer, you may deliver your written comments before the close of the comment period to the same address, 5600 Fishers Lane, Room 13N82, Rockville, MD 20857. Please call one of our HRSA Regulations Office staff members at telephone number (301) 443-1785 in advance to schedule your arrival. This is not a toll-free number.

Because of staffing and resource limitations, and to ensure that no comments are misplaced, the program cannot accept comments by facsimile (FAX) transmission. When commenting, by any of the above methods, please refer to file code (#HRSA-0906-AB14). Comments received on a timely basis will be available for public inspection online at www.regulations.gov or in person at the Health Resources and Services Administration's offices, 5600 Fishers Lane, Room 13N82, Rockville, MD, Monday through Friday of each week from 8:30 a.m. to 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Please visit the National Vaccine Injury Compensation Program's Web site, *http://www.hrsa.gov/vaccine-compensation/*, or contact Dr. Narayan Nair, Director, Division of Injury Compensation Programs, Healthcare Systems Bureau,

Health Resources and Services Administration, 5600 Fishers Lane, Room 08N146B, Rockville, MD 20857. Phone calls can be directed to (855) 266-2427. This is a toll-free number.

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) urges all interested parties to examine this regulatory proposal carefully and to share your views with us, including any supporting data. We must consider all relevant written comments received during the comment period before issuing a final rule. Subject to consideration of the comments received, the Secretary intends to publish a final regulation.

If you are a person with a disability and/or a user of assistive technology who has difficulty accessing this document, please see the "For Further Information" box above for the names and contact information to obtain this information in an accessible format. Please visit http://www.HHS.gov/regulations for more information on HHS rulemaking and opportunities to comment on proposed and existing rules.

Background

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 VICP as a no-fault alternative to the traditional legal system for resolving vaccine injury petitions and to provide compensation for individuals thought to be injured by certain vaccines. Congress has amended the statute governing the VICP several times since 1986. Petitions for compensation under this Program are filed in the United States Court of Federal Claims (Court), with a copy served on the Secretary, who is the "Respondent." The Court, acting through judicial officers called Special Masters, makes findings as to eligibility for, and the amount of, compensation.

To be entitled to an award under the VICP, a petitioner must establish a vaccine-related injury or death, either by proving that a vaccine actually caused or significantly aggravated an

injury (causation-in-fact) or by demonstrating the occurrence of what is referred to as a Table injury. That is, a petitioner may show that the vaccine recipient received a covered vaccine and suffered an injury of the type listed for that vaccine in the regulations at 42 CFR 100.3—the Table— and that the onset of such injury took place within the time period specified in the Table. If these criteria are met, the injury is presumed to have been caused by the vaccination, and the petitioner is entitled to compensation (assuming that other requirements are satisfied), unless the respondent affirmatively shows that the injury was caused by some factor other than the vaccination (see 42 U.S.C. 300aa-11(c)(1)(C)(i), 300aa-13(a)(1)(B)), and 300aa-14(a)). Currently, cases are often resolved by negotiated settlements between the parties and approved by the Court. In negotiated settlements, HHS and the Court have not concluded, based upon review of the evidence, that the vaccine caused the alleged injury.

Revisions to the Table are authorized under subsections 2114(c) and (e) of the Public Health Service (PHS) Act (42 U.S.C. 300aa-14(c) and (e)). Prior to the 21st Century Cures Act (Public Law 114-255), the only vaccines covered under the VICP were those recommended for routine administration to children by the CDC (for example, vaccines that protect against seasonal influenza), subject to an excise tax by Federal law, and added to the Program by the Secretary. The Table currently includes 17 vaccine categories, with 16 categories for specific vaccines, as well as the corresponding illness, disability, injury, or condition covered; and the requisite time period when the first symptom or manifestation of onset or of significant aggravation after the vaccine administration must begin to receive the Table's legal presumption of causation. One category of the Table, "Item XVII," includes "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." Two injuries - Shoulder

Injury Related to Vaccine Administration (SIRVA) and vasovagal syncope - are listed as associated injuries for this category. Through this general category, new vaccines recommended by the CDC for routine administration to children and subject to an excise tax are covered under the VICP prior to being added to the Table as a separate vaccine category through Federal rulemaking.

The 21st Century Cures Act amended section 2114(e) of the PHS Act (42 U.S.C. 300aa–14(e)) to expand the types of vaccines covered under the VICP. *See* section 3093(c)(1) of the 21st Century Cures Act. The revised statute requires that the Secretary revise the Table to include vaccines recommended by the CDC for routine administration in pregnant women (and subject to an excise tax by Federal law). *See* section 2114(e)(3) of the PHS Act (42 U.S.C. 300aa–14(e)(3)). Currently, the CDC recommends only two vaccines for routine administration in pregnant women: 1) the tetanus, diphtheria, and acellular pertussis vaccine,[1] and 2) the seasonal influenza vaccine.[2] These categories of vaccines are already covered under the VICP, as the CDC recommends them for routine administration to children and they are subject to an excise tax.

Discussion of Proposed Table Changes

Congress enacted a mechanism for modification of the statutory Table, through the promulgation of regulatory changes by the Secretary, after consultation with the Advisory Commission on Childhood Vaccines (ACCV). As required by statute, the Secretary is proposing to revise the Table to include new vaccines recommended by the CDC for routine administration in pregnant women, and seeks comment on the means of effectuating this revision. The

[1] Centers for Disease Control and Prevention. MMWR Morbid Mortal Wkly Rep. 2011 Oct 21:60(41); 1424-26. Available from: https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6041a4.htm

[2] Centers for Disease Control and Prevention. Pregnancy and vaccination: Guidelines for vaccinating pregnant women. Last updated Aug 2016. Website: https://www.cdc.gov/vaccines/pregnancy/hcp/guidelines.html#flu1

Secretary also proposes retaining the two injuries currently associated with Item XVII of the Table, SIRVA and vasovagal syncope, as Table injuries for vaccines recommended by the CDC for routine administration in pregnant women. In its 2012 Report, "Adverse Effects of Vaccines: Evidence and Causality," the Institute of Medicine considered SIRVA and vasovagal syncope as mechanistic injuries resulting from the injection of a vaccine and not from the contents of a particular formulation of a vaccine. Thus, these conditions are listed as Table injuries for any new vaccine recommended by the CDC for routine administration to children (after the imposition of an excise tax and publication by the Secretary of a notice of coverage) to account for any newly developed injected vaccines that potentially may lead to SIRVA or syncope. Therefore, the Secretary proposes including these injuries on the Table for new vaccines recommended by the CDC for routine administration in pregnant women.

On September 8, 2017, the Program consulted the ACCV regarding options for adding this new category of vaccines to the Table. The ACCV voted unanimously to amend the existing language in Item XVII of the Table to include "and/or pregnant women" after "children" permitting coverage under the VICP of any new vaccine recommended by CDC for routine administration in pregnant women and subject to an excise tax after publication by the Secretary of a notice of coverage. They viewed this option as a simple approach to revising the Table, rather than adding a new general Item XVII to the Table for vaccines recommended for routine administration in pregnant women. Therefore, the Secretary is proposing to amend the existing language in Item XVII of the Table to include "and/or pregnant women" after "children" in accordance with the ACCV's recommendation which would add to that general category of the Table, any new vaccine recommended by the CDC for routine administration in pregnant women, after imposition of an excise tax and publication of a notice of coverage.

HHS seeks comments regarding the proposed method of revising the Table, that is, to amend the existing language in Item XVII to include "and/or pregnant women" after "children" which would add to that general category of the Table any new vaccine recommended by the CDC for routine administration in pregnant women after imposition of an excise tax and publication of a notice of coverage. HHS notes that an important consideration in proposing changes to the Table is the clarity of such changes.

Petitions must be filed within the applicable statute of limitations. With the proposed change, the general statute of limitations applicable to petitions filed with the VICP, set forth in 42 U.S.C. 300aa-16(a) continue to apply. Specifically, in the case of an injury, the claim must be filed within 36 months after the first symptoms appeared. In the case of a death, the claim must be filed within 24 months of the death and within 48 months after the onset of the vaccine-related injury from which the death occurred.

In addition, 42 U.S.C. 300aa-16(b) allows petitioners an alternative statute of limitations of 2 years from the date of the Table change for injuries or deaths that occurred up to 8 years before the Table change if the revision makes a petitioner eligible to seek compensation or significantly increases the likelihood of a petitioner obtaining compensation. However, the alternate statute of limitations afforded by 42 U.S.C. 300aa-16(b) is not applicable at this time for this proposed Table change. At present, there are no vaccines to add to the Table under the revised general category because the only vaccines the CDC recommends for routine administration in pregnant women are already covered on the Table − 1) the diphtheria, tetanus, and pertussis vaccine and 2) the seasonal influenza vaccine − because they are also recommended by the CDC for routine administration to children, are subject to an excise tax. However, in the future, when any new vaccine not already covered under the VICP is

recommended by the CDC for routine administration in pregnant women, subject to an excise tax, and added to the Table (and/or any additional associated injury), the alternate statute of limitations afforded by 42 U.S.C. 300aa-16(b) would apply, if the effect of the revision would be to make an individual, who was not eligible before the revision, eligible to seek compensation under the Program or to significantly increase the individual's likelihood of obtaining compensation.

Based on the requirements of the Administrative Procedure Act, HHS publishes an NPRM in the Federal Register before a regulation is promulgated. The public is invited to submit comments on this proposed rule. HHS specifically requests the public's views on the proposed option for adding new vaccines recommended by the CDC for routine administration in pregnant women to the Table. In addition, a public hearing will be held for this proposed rule. After the 180-day public comment period has ended, the comments received and HHS's responses to the comments will be addressed in the preamble of the final rule. HHS will publish the final rule in the Federal Register.

Additional VICP Provisions in the 21st Century Cures Act

While not seeking comment on these changes in response to this NPRM, the Secretary notes that the 21st Century Cures Act included additional amendments to the Vaccine Act. The 21st Century Cures Act also amended section 2111 of the PHS Act (42 U.S.C. 300aa–11) to permit both a woman who received a covered vaccine while pregnant and any live-born child who was in utero at the time such woman received the vaccine to be considered persons to whom the covered vaccine was administered. *See* section 3093(c)(2) of the 21st Century Cures Act, adding 42 U.S.C. 300aa-11(f). The amendments to this section also provide that a covered vaccine administered to a pregnant woman constitutes more than one vaccine administration −

one to the mother and one to each live-born child who was in utero at the time such woman was administered the vaccine. *See* section 3093(c)(3) of the 21st Century Cures Act, amending 42 U.S.C. 300aa-11(b)(2). These provisions do not require regulatory actions to implement.

Economic and Regulatory Impact

HHS has examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (September 19, 1980), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act, and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866, 13563, and 13771

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel

legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). As discussed below, HHS estimates that this proposed rulemaking is not "economically significant" as measured by the $100 million threshold, and hence not a major rule under the Congressional Review Act.

The Secretary has determined that no substantial additional administrative and compensation resources are required to implement the requirements in this proposed rule. Compensation will be made in the same manner. As in all other VICP cases, to be found entitled to compensation, petitioners will need to prove by a preponderance of the evidence either that they meet the requirements of the Table or that their injury was actually caused by the vaccine, unless the respondent affirmatively shows that the injury was caused by some factor other than the vaccination. 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 National Vaccine Injury Compensation Program: Adding the Category of Vaccines Recommended for Pregnant Women to the Vaccine Injury Table Notice of Proposed Rulemaking is "not significant" because no substantial resources are required to implement the requirements in this rule. This rule adds "and/or pregnant women" to the new vaccines category (Item XVII) on the Table. Currently, the only vaccines recommended for routine administration in pregnant women are: 1) the tetanus, diphtheria, and acellular pertussis vaccine; and 2) the seasonal influenza vaccine. These vaccines are already on the Table because they are recommended for

routine administration to children and have an excise tax imposed on them. Therefore, this rule does not have a significant impact on a substantial number of small entities. Additionally, this 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 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 provisions of this proposed rule do not, on the basis of family well-being, 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 proposed rule is not being treated as a “significant regulatory action” as defined under section 3(f) of Executive Order 12866. As stated above, this proposed rule will modify the Table based on legal authority.

Executive Order 13771, titled “Reducing Regulation and Controlling Regulatory Costs,” was issued on January 30, 2017. It has been determined that this proposed rule is a not significant and thus is exempt from regulatory or deregulatory action for the purposes of Executive Order 13771.

Impact of the New Rule

This proposed rule will allow any new vaccines that in the future are recommended by the CDC for routine administration in pregnant women and subject to a Federal excise tax to be

covered under the VICP after the Secretary issues a notice of coverage, without requiring further rulemaking. In addition, this proposed rule will have the effect of making it easier for future petitioners alleging injuries that meet the criteria in the Vaccine Injury Table to receive the Table's presumption of causation (which relieves them of having to prove that the vaccine actually caused or significantly aggravated their injury).

Paperwork Reduction Act of 1995

This proposed rule has no information collection requirements.

Dated: March 16, 2018.

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George Sigounas

Administrator,

Health Resources and Services Administration.

Approved: March 28, 2018.

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Alex M. Azar II

Secretary,

Department of Health and Human Services.

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 continues 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. In § 100.3 amend the Table in paragraph (a) by adding "and/or pregnant women" after "children" to the existing language in Item XVII of the Table 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
XVII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children and/or pregnant women, after publication by the Secretary of a notice of coverage	A. Shoulder Injury Related to Vaccine Administration B. Vasovagal syncope	≤ 48 hours. ≤1hour.

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