

**Pursuant to Section 10(b) of the Federal Advisory Committee Act and 5 U.S.C. § 552(b)(5), this draft notice of proposed rulemaking is protected by the deliberative process privilege. HRSA has waived this privilege. The ACCV may publicly discuss this proposal.**

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

42 CFR Part 100

**RIN: 0906-XXXX**

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

**AGENCY:** Health Resources and Services Administration (HRSA).

**ACTION:** Notice of Proposed Rulemaking.

**SUMMARY:** The Department of Health and Human Services (HHS) proposes to amend the Vaccine Injury Table (Table) by regulation. These proposed regulations will have effect only for petitions for compensation under the National Vaccine Injury Compensation Program (VICP) filed after the final regulations become effective. HHS is seeking public comment on the proposed revisions to the Table.

**DATES:** Written comments and related material to this proposed rule must be received to the online docket via [www.regulations.gov](http://www.regulations.gov), or to the mail address listed in the ADDRESSES section below, on or before [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** You may submit comments on this proposed rule identified by the HHS Docket No. HRSA-2020-XXXX, by one of the following methods:

1. Federal eRulemaking Portal (preferred). You may submit comments electronically to <https://www.regulations.gov>. Follow the website instructions for submitting comments.
2. Mail: Alford Danzy, Regulations Officer, Executive Secretariat, Room 13N110, HRSA, 5600 Fishers Lane, Rockville, MD 29857. Mail must be postmarked by the comment

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submission deadline.

To ensure proper handling, please reference HHS Docket No. HRSA-2020-XXXX in your correspondence. Mail must be postmarked by the comment submission deadline. .

**FOR FURTHER INFORMATION CONTACT:** Please visit the National Vaccine Injury Compensation Program's Web site, <https://www.hrsa.gov/vaccinecompensation/>, or contact Tamara Overby, Acting Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, Room 08N146B, 5600 Fishers Lane, Rockville, MD 20857; by email at [vaccinecompensation@hrsa.gov](mailto:vaccinecompensation@hrsa.gov); or by telephone (855) 266-2427.

**SUPPLEMENTARY INFORMATION:**

I. Public Participation

All interested parties are invited to participate in this rulemaking by submitting written views, comments and arguments on all aspects of this proposed rule, as well as additional data that should be considered. HHS also invites comments that relate to the economic, legal, environmental, or federalism effects that might result from this proposed rule. Comments that will provide the most assistance to HRSA in implementing these changes will reference a specific portion of the proposed rule, explain the reason for any recommended change, and include data, information, or authority that supports such recommended change.

*Instructions:* If you submit a comment, you must include the agency name and the HHS Docket No. HRSA-2020-XXXX for this rulemaking. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at <http://www.regulations.gov>, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider

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limiting the amount of personal information that you provide in any voluntary public comment submission you make to HHS. HHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of <http://www.regulations.gov>.

*Docket:* For access to the docket and to read background documents or comments received, go to <http://regulations.gov>, referencing HHS Docket No. HRSA-2020-XXXX. You may also sign up for email alerts on the online docket to be notified when comments are posted or a final rule is published.

## **II. Background and Purpose**

Vaccination is one of the best ways to protect against potentially harmful diseases that can be very serious, may require hospitalization, or even be deadly. The vast majority of individuals who are vaccinated have no serious reactions. Nonetheless, in the 1980s, Congress became concerned that a very small number of children who received immunizations had serious reactions to them, and it was not always possible to predict which children would have reactions, or what reactions they would have.<sup>1</sup> Claimants alleging vaccine-related injuries in civil litigation encountered a time-consuming, expensive, and often inadequate system.<sup>2</sup> Moreover, increased litigation against vaccine manufacturers resulted in difficulties (1) securing affordable product

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<sup>1</sup> H.R. Rep. No. 99-908, at 6 (1986). Even though in rare instances individuals may have adverse reactions to vaccines, the Centers for Disease Control and Prevention (CDC) recommends that individuals be vaccinated against a wide range of illnesses and diseases. Vaccination is one of the best ways to protect against potentially harmful diseases that can be very serious, may require hospitalization, or even be deadly. See <https://www.cdc.gov/vaccines/vpd/vaccines-age.html>.

<sup>2</sup> *Id.*

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liability insurance, (2) stabilizing vaccine prices and supply, and (3) entering the market.<sup>3</sup>

Therefore, Congress enacted the National Childhood Vaccine Injury Act of 1986, title III of Public Law 99–660 (42 U.S.C. § 300aa-1 *et seq.*) (Vaccine Act), which established the National Vaccine Injury Compensation Program (VICP). The VICP is a Federal compensation program for individuals thought to be injured by certain vaccines. Petitions for compensation under the VICP 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 gain entitlement to compensation under this Program, a petitioner must establish a vaccine-related injury or death has occurred, 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 suffered an injury of the type enumerated in the regulations at 42 CFR § 100.3—the “Vaccine Injury Table” (Table)—corresponding to the vaccination in question and that the onset of such injury took place within the time period also specified in the Table. If so, 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)).

42 U.S.C. § 300aa–14(c) and (e) permit the Secretary to revise the Table. The Table

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<sup>3</sup> *See id.* at 4-6.

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currently includes 17 vaccine categories, with 16 categories for specific vaccines, as well as the corresponding illnesses, disabilities, injuries, or conditions 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. The final category of the Table, "Item XVII," includes "[a]ny 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."<sup>4</sup> 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 deemed covered under the VICP prior to being added to the Table as a separate vaccine category through Federal rulemaking.

On January 19, 2017, the Department issued a final rule amending the Table (Final Rule). That Final Rule was scheduled to take effect on February 21, 2017. A notice published in the Federal Register delayed the effective date until March 21, 2017. The Final Rule followed a 2012 Institute of Medicine (IOM)<sup>5</sup> report, "Adverse Effects of Vaccines: Evidence and Causality;" the work of nine HHS workgroups that reviewed the IOM findings; and consideration of the Advisory Commission on Childhood Vaccines' (ACCV) recommendations. Among other things, the Final Rule added SIRVA and vasovagal syncope to the Table.

Upon further review, including a review of the relevant statutory provisions, the scientific literature, and the Department's experience since SIRVA and vasovagal syncope were added to

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<sup>4</sup> 42 CFR 100.3(a).

<sup>5</sup> The IOM is now known as the National Academy of Medicine.

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the Table, the Department proposes to remove SIRVA and vasovagal syncope from the Table.

The Department also proposes to remove Item XVII from the Table, because it has serious concerns that Item XVII is contrary to applicable law.

*Scientific Literature Concerning SIRVA and Vasovagal Syncope*

The scientific literature indicates that SIRVA likely results from poor vaccination technique, rather than an antigen. The notice of proposed rulemaking that preceded the Final Rule characterized SIRVA as an “adverse event following vaccination thought to be related to the technique of intramuscular percutaneous injection (the procedure where access to a muscle is obtained by using a needle to puncture the skin) into an arm resulting in trauma from the needle and/or the unintentional injection of a vaccine into tissues and structures lying underneath the deltoid muscle of the shoulder.”<sup>6</sup> The IOM similarly concluded that “the injection, and not the contents of the vaccine, contributed to the development of deltoid bursitis.”<sup>7</sup> Indeed, the primary case series relied upon by the Department in promulgating the proposed rule and Final Rule found that the medical literature supports the possibility that SIRVA may result from inappropriate needle length and/or injection technique.<sup>8</sup> There is nearly uniform agreement in the scientific community that SIRVA is caused by improper vaccine administration, rather than

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<sup>6</sup> See National Vaccine Injury Compensation: Revision to the Vaccine Injury Table (“2015 Proposed Rule”), 80 Fed. Reg. 45132, 45136 (July 29, 2015) (emphasis supplied); Adverse Effects of Vaccines: Evidence and Causality (“IOM Report”), at 620, available at <https://www.nap.edu/catalog/13164/adverse-effects-of-vaccines-evidence-and-causality>.

<sup>7</sup> SIRVA is a medicolegal term, not a medical diagnosis, that is meant to capture a broad array of potential shoulder injuries, but the IOM only made findings concerning deltoid bursitis.

<sup>8</sup> Atanasoff S, Ryan T, Lightfoot R, and Johann- Liang R, 2010, Shoulder injury related to vaccine administration (SIRVA), *Vaccine* 28(51):8049–8052 (recommending that injections avoid the top third of the deltoid muscle to avoid shoulder injury).

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by the vaccine itself.<sup>9</sup> Since the Final Rule was promulgated, additional scientific research concluded that subdeltoid or subacromial bursitis and other shoulder lesions are “more likely to be the consequence of a poor injection technique (site, angle, needle size, and failure to take into account patient’s characteristics, i.e., sex, body weight, and physical constitution),” rather than the vaccine antigen.<sup>10</sup>

The scientific literature also indicates that vasovagal syncope results from the act of injection, rather than any antigen. Vasovagal syncope is the loss of consciousness (fainting) caused by a transient decrease in blood flow to the brain.<sup>11</sup> In proposing to add vasovagal syncope to the Table, the Department noted that the IOM found that syncope did not result from any particular antigen, but instead from the injection.<sup>12</sup> The scientific literature suggests that those administering vaccines can take steps to significantly reduce the likelihood of injury from vasovagal syncope, such as by ensuring that the patient sit or lie down for the vaccination, and observing him or her for 15 to 20 minutes after administering the vaccine.<sup>13</sup>

#### *Reasons for Removal of SIRVA and Vasovagal Syncope*

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<sup>9</sup> See Barnes MG, Ledford C, Hogan K. A "needling" problem: shoulder injury related to vaccine administration. *J Am Board Fam Med.* 2012 Nov-Dec;25(6):919-22; Cross GB, Moghaddas J, Buttery J, Ayoub S, Korman TM. Don't aim too high: Avoiding shoulder injury related to vaccine administration. *Aust Fam Physician.* 2016 May;45(5):303-6.

<sup>10</sup> Martín Arias, K.H., Fadrique, R., Sáinz Gil, M., and Salgueiro-Vazquez, M.E., Risk of bursitis and other injuries and dysfunctions of the shoulder following vaccinations, *Vaccine*, 2017; 35: 4870-4876. See also Bancsi A, Houle SKD, Grindrod KA. Shoulder injury related to vaccine administration and other injection site events. *Can. Fam. Physician.* 2019 Jan; 65(1): 40-42 (explaining that SIRVA “is a preventable occurrence caused by the injection of a vaccine into the shoulder capsule rather than the deltoid muscle”); Macomb CV, Evans MO, Dockstater JE, Montgomery JR, Beakes DE. Treating SIRVA Early With Corticosteroid Injections: A Case Series. *Mil Med.* 2019 Oct 17 (noting that SIRVA does not occur unless the vaccine is mistakenly given in the shoulder capsule).

<sup>11</sup> 82 Fed. Reg. 6294-01, 6304 (Jan. 19, 2017).

<sup>12</sup> 80 Fed. Reg. at 45137 (The IOM found that one case report suggested that “the injection, and not the contents of the vaccine, contributed to the development of syncope”). See also IOM Report at 18 (“injection of vaccine, independent of the antigen involved, can lead to” syncope).

<sup>13</sup> Miller, E. and Woo, E.J. 2006 Time to prevent injuries from postimmunization syncope, *Nursing*, 36 (12): 20; Braun, M., Patriarca, P., and Ellenberg, S. Syncope After Immunization, *Arch. Pediatr. Adolesc. Med.* 1997; 151: 255-259.

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The Department has concluded that several reasons merit removal of SIRVA and vasovagal syncope from the Table. First, the Vaccine Act's essentially strict liability compensation system works best for injuries and illnesses that cannot be predicted in advance and can occur without fault. SIRVA and vasovagal syncope are generally not those types of injuries or illnesses. With proper injection technique, most cases of SIRVA are likely preventable. The scientific literature also suggests that those administering vaccines can take steps to significantly reduce the likelihood of injury from vasovagal syncope. However, awarding no-fault compensation from the VICP to those with SIRVA and vasovagal syncope claims lessens the incentive to take appropriate precautions. After all, if SIRVA and vasovagal syncope are included in the Table, petitioners will seek to recover from the VICP, where they can recover more easily because they need not prove causation, rather than from those who failed to properly administer the vaccine.

The Department has also concluded that the better reading of the Vaccine Act is that the Table should only include injuries resulting from the antigen, not the manner in which the vaccine was administered. Only those with a "vaccine-related injury or death" can sue under the Vaccine Act, 42 U.S.C. § 300aa-11(a)(9), and the Vaccine Act defines "Vaccine-related injury or death" as one "associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine." 42 U.S.C. § 300aa-33(5) (emphasis supplied); *see also Dean v. HHS*, No. 16-1245V, 2018 WL 3104388 (Fed. Cl. Spec. Mstr. May 29, 2018) (defining "vaccine"). Thus, a petitioner must have an injury or death "associated" with the vaccine, not one resulting from poor injection technique or the



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administration of the vaccine. Moreover, by excluding from the definition those injuries associated with an adulterant or contaminant, Congress indicated its intent to permit suit only where the injury was caused by the antigen, not individual fault.

Furthermore, when Congress initially passed the Vaccine Act in 1986, the table included “the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines.” 42 U.S.C. § 300aa-14(a) (emphasis supplied). While concerns about injuries to children were considered by Congress when passing the Vaccine Act, the plain language of the original statute was not expressly limited to children. In 1993, Congress amended the statute to state that by August 1, 1995, the Secretary shall revise the Table to include the injuries, disabilities, illnesses, conditions, and deaths “associated with . . . vaccines” that the CDC recommends for routine administration to children. *See* 42 U.S.C. § 300aa-14(e) (emphasis supplied). Therefore, Congress intended to only add those injuries (1) “associated” with the vaccine and (2) recommended for routine administration to children.<sup>14</sup> Congress knew how to provide a cause of action for injuries resulting from the “administration” of a vaccine, but was now choosing only to provide for recovery where the injury was “associated” with the vaccine.

Furthermore, the Department has found that SIRVA petitions are unnecessarily risking reducing the funding available for children and others who are injured by vaccine antigens. In the VICP’s early years, the overwhelming majority of cases brought, and compensation awarded, involved injuries to children.<sup>15</sup> However, over 99.2% of SIRVA cases (3,034 out of 3,057) filed

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<sup>14</sup> In 2016, Congress further amended the statute to have the Secretary add injuries associated with vaccines that the CDC recommends be administered to pregnant women. *Id.* at § 300aa-14(e)(3).

<sup>15</sup> Peter H. Meyers, *Fixing the Flaws in the Federal Vaccine Injury Compensation Program*, 63 ADMIN. L. REV. 785, 795 (2011).

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since FY 2010 were filed by adults. From FY 2016 through FY 2019, approximately \$119,154,985 has been paid out of the Vaccine Injury Compensation Trust Fund (Trust Fund) to compensate SIRVA petitioners. The sheer prevalence of shoulder injuries and the low burden of proof placed on petitioners have made it attractive to file SIRVA petitions, even when such claims are dubious.<sup>16</sup> Petitioners in such cases often prevail because of the low burden of proof and because it is not necessary to prove causation. If SIRVA and vasovagal syncope were removed from the Table, plaintiffs could still successfully file SIRVA and vasovagal syncope claims in state court<sup>17</sup> if they prove causation. Requiring plaintiffs to prove causation would mitigate the filing of frivolous claims that are draining the Trust Fund.

Moreover, those opposed to vaccination often cite the total amount paid out of the VICP as evidence that vaccines are not safe.<sup>18</sup> SIRVA claims are not associated with the actual vaccine or vaccine antigen, but these claims are included when individuals cite the total amount paid out of the VICP, and thereby enable individuals to misleadingly suggest that vaccines are less safe than they truly are.

#### *Item XVII*

As discussed in further detail below, the Department also proposes to remove Item XVII from the Table because it has serious concerns that this category is contrary to law, including the

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<sup>16</sup> See also B. F. Hibbs, C. S. Ng, O. Museru *et al.*, Reports of atypical shoulder pain and dysfunction following inactivated influenza vaccine, Vaccine Adverse Event Reporting System (VAERS), 2010–2017, *Vaccine*, <https://doi.org/10.1016/j.vaccine.2019.11.023> (reports of atypical shoulder pain following injection of inactivated influenza vaccine (IIV) are uncommon and the level of reporting has remained fairly constant in recent years, “in contrast to the substantial increase in SIRVA claims filed with the VICP for IIV during the same time period”).

<sup>17</sup> Or Federal district court if they satisfy the requirements of 28 U.S.C. 1332 or 28 U.S.C. 1367.

<sup>18</sup> See, e.g., James Hamblin, Why the Government Pays Billions to People Who Claim Injury by Vaccines, *THE ATLANTIC* (May 14, 2019); Jeffrey Kluger, Here’s How the Anti-Vaxxers’ Strongest Argument Falls Apart, *TIME*, (Aug. 19, 2015).

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procedures described in the Vaccine Act for amending the Table. Specifically, to the extent that Item XVII provides a unilateral mechanism for adding injuries and vaccines to the Table, it may be inconsistent with the Vaccine Act. SIRVA and vasovagal syncope are the only illnesses, disabilities, injuries, or conditions listed for Item XVII.

#### *Guiding Principles for Recommending Changes to the Vaccine Injury Table*

In 2006, the ACCV established “Guiding Principles for Recommending Changes to the Vaccine Injury Table” (Guiding Principles) to assist the ACCV in evaluating proposed Table revisions and determining whether to recommend changes to the Table to the Secretary. The Guiding Principles 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 also state, among other factors, that “[t]o the extent that the [IOM] has studied the possible association between a vaccine and an adverse effect, the conclusions of the IOM should be considered by the ACCV and deemed credible but those conclusions should not limit the deliberations of the ACCV.” As part of its mandate under the Act, the ACCV considered the proposed changes set forth in this NPRM on [INSERT DATE(S)]. The ACCV deliberations included scientific and public policy considerations, and were also influenced by the 2006 Guiding Principles. For each proposed change by the Secretary, the ACCV voted for one of three options:

1. ACCV concurs with the proposed change(s) to the Table and would like the Secretary to move forward (with or without comments);

2. ACCV does not concur with the proposed change(s) to the Table and would not like

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the Secretary to move forward; or

3. ACCV would like to defer a recommendation on the proposed change(s) to the Table pending further review at a future ACCV meeting.

The Guiding Principles are not binding on the Secretary. [INSERT DISCUSSION OF GUIDING PRINCIPLES AFTER ACCV CONCLUDES ITS REVIEW]

### **Findings**

In prior Table revisions, the Secretary determined that the appropriate framework for making changes to the Table is to make specific findings as to the illnesses or conditions that can reasonably be determined in some circumstances to be caused or significantly aggravated by the vaccines under review and the circumstances under which such causation or aggravation can reasonably be determined to occur. The Secretary continues this approach, and finds that the scientific literature does not provide a sufficient association between either SIRVA or vasovagal syncope and any vaccine antigen so as to support including SIRVA or vasovagal syncope in the Table. Accordingly, the Secretary proposes to remove SIRVA and vasovagal syncope from the Table for the reasons discussed in this NPRM. The Secretary also has serious concerns that Item XVII does not comport with applicable law, and therefore also recommends removal of Item XVII from the Table for the reasons discussed in this NPRM. For any vaccine adverse event pairs for which future scientific evidence develops to support a finding of a causal relationship, the Secretary will consider future rulemaking to revise the Table accordingly.

In support of his proposals, and in view of the recommendations of the ACCV, the Secretary makes the following findings:

### **Findings That Result in Removals from the Table Because the Evidence Favors Rejection**

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### **of a Causal Relationship**

1. The scientific evidence does not support a causal relationship between injection of any specific vaccine antigen or other contents and SIRVA. For reasons detailed below, the Secretary proposes removing SIRVA from the Table.
2. The scientific evidence does not support a causal relationship between an injection of any specific vaccine antigen or other contents and vasovagal syncope. For reasons detailed below, the Secretary proposes removing vasovagal syncope from the Table.

### **Findings That Result in Removals from the Table for Procedural Reasons**

1. Item XVII in the Table may not comport with applicable law. For reasons detailed below, the Secretary proposes removing Item XVII from the Table.

### **III. Discussion of Proposed Rule**

The Secretary has examined the recommendations of the ACCV and proposes that the Table set forth at 42 CFR 100.3 be revised as described below. Following each proposed removal from the Table, as applicable, there is a discussion of the 2017 addition of each injury to the Table, the IOM's 2012 conclusions about that injury cited by HHS in its 2015 Proposed Rule, and other relevant research and conclusions, as well as the Department's proposal. It should be noted that the ACCV concurred with all of the proposals regarding the Table. Each of the changes proposed by the Department and the rationale for the proposal is described in detail.

As provided in 42 U.S.C. § 300aa-14(c)(4), the modified Table will apply only to petitions filed under the Program after the effective date of the final regulation. 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 42 U.S.C. § 300aa-16(a), continues to

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apply. In addition, the statute 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, an individual who may be eligible to file a petition based on the revised Table may file the 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)). This is true even if such individual previously filed a petition for compensation, and is thus an exception to the "one petition per injury" limitation of 42 U.S.C. § 300aa-11(b)(2).

Based on the requirements of the Administrative Procedure Act, the Department publishes a Notice of Proposed Rulemaking in the **Federal Register** before a regulation is promulgated. The public is invited to submit comments on the proposed rule. In addition, a public hearing will be held for this proposed rule. After the public comment period has expired, the comments received and the Department's responses to the comments will be addressed in the preamble to the final regulation. The Department will publish the final rule in the **Federal Register**.

In the following sections, background information on different categories of vaccines as well as the Secretary's rationale for any proposed Table change is provided.

### **1. Shoulder Injury Related to Vaccination**

Shoulder Injury Related to Vaccine Administration (SIRVA) is an adverse event following vaccination thought to be related to the technique of intramuscular percutaneous

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injection (the procedure where access to a muscle is obtained by using a needle to puncture the skin) into an arm resulting in trauma from the needle and/or the unintentional injection of a vaccine into tissues and structures lying underneath the deltoid muscle of the shoulder.

On March 21, 2017, HHS adopted the Final Rule adding SIRVA to the Table. As defined in the Final Rule, SIRVA is an injury related to the intramuscular injection of a vaccine. Since the addition of SIRVA to the Table, SIRVA has become the predominant claim under the National Vaccine Injury Compensation Program. In Fiscal Year 2018, of the 1,238 claims filed, 672 were SIRVA claims.

By definition, a Table injury of SIRVA results from the injection technique. For that reason, the Department did not include SIRVA as an injury on the 2017 revised Table for vaccines that are not administered by intramuscular injection, including oral polio and rotavirus; subcutaneous MMR, MMRV, varicella, and meningococcal-polysaccharide; intranasal influenza; and intradermal influenza. In addition, the Department did not add a SIRVA injury to the revised 2017 Table for vaccines administered via a needleless jet device. Similarly, the Department found that a SIRVA injury would not apply to formulations of influenza vaccine where the route of administration was intradermal, such as those delivered through a needle that was only 1.5 millimeters long, because the “needle is not long enough to enter the deltoid bursa or any other structure in the shoulder related to the development of SIRVA.”<sup>19</sup>

In addition, in the 2012 IOM review of medical and scientific literature related to SIRVA cited by the Department in the 2015 Proposed Rule, the IOM found a causal connection between

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<sup>19</sup> 80 Fed. Reg. at 45144.

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the injury of deltoid bursitis and vaccine injection *with a needle only*.<sup>20</sup> The IOM did *not* find a causal connection between the injury of deltoid bursitis and the contents of the vaccine itself.

Since the Final Rule was promulgated, additional scientific research has concluded that subdeltoid or subacromial bursitis and other shoulder lesions are “more likely to be the consequence of a poor injection technique (site, angle, needle size, and failure to take into account patient’s characteristics, i.e., sex, body weight, and physical constitution),” rather than from the vaccine antigen.<sup>21</sup> The evidence is thus insufficient to support an adequate causal connection between the contents of any vaccine and SIRVA.

As discussed above, SIRVA is not a “vaccine-related injury” and therefore should not be included on the Table or compensable under the VICP.<sup>22</sup> Because the 2017 addition of SIRVA to the Table was based on a causal connection between the “administration” of the vaccine and the injury, not an association of the injury with the contents of the vaccine itself, SIRVA’s addition to the Table was not appropriate under the Vaccine Act. Moreover, as discussed in the Background section, the Department has concluded that there are strong policy reasons for removing SIRVA from the Table. Accordingly, the Secretary recommends removing SIRVA from the Table for all vaccines.

## **2. Vasovagal Syncope**

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<sup>20</sup> 80 Fed. Reg. at 45136. *See also* IOM Report.

<sup>21</sup> Martín Arias, K.H., Fadrique, R., Sáinz Gil, M., and Salgueiro-Vazquez, M.E., Risk of bursitis and other injuries and dysfunctions of the shoulder following vaccinations, *Vaccine*, 2017 35: 4870-4876; Bancsi A, Houle SKD, Grindrod KA. Shoulder injury related to vaccine administration and other injection site events. *Can. Fam. Physician*. 2019 Jan; 65(1):40-42 (explaining that SIRVA “is a preventable occurrence caused by the injection of a vaccine into the shoulder capsule rather than the deltoid muscle”); Macomb CV, Evans MO, Dockstater JE, Montgomery JR, Beakes DE. Treating SIRVA Early With Corticosteroid Injections: A Case Series. *Mil Med*. 2019 Oct 17 (noting that SIRVA does not occur unless the vaccine is mistakenly given in the shoulder capsule).

<sup>22</sup> 42 U.S.C. §§ 300aa-11, 300aa-14(e).



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Vasovagal syncope is the loss of consciousness (fainting) caused by a transient decrease in blood flow to the brain. Vasovagal syncope is usually a benign condition but may result in falling and injury.

On March 21, 2017, the Department adopted the Final Rule adding vasovagal syncope to the Table. In making that revision, the Department relied on the IOM's 2012 review of medical and scientific literature concerning a possible link between the injection of a vaccine and syncope. The Committee found insufficient epidemiologic evidence of an association between the injection of a vaccine and syncope, but it found sufficient mechanistic evidence supporting the conclusion that syncope is "directly related to vaccine administration."<sup>23</sup> The IOM explained that evidence it examined as part of its review suggested "that the injection, and not the contents of the vaccine, contributed to the development of syncope."<sup>24</sup> In addition, because syncope is an injury related *solely* to the injection of a vaccine, the Department did not add syncope to the 2017 revisions to the Table as an injury for vaccines that are not administered by injection, including oral polio and rotavirus vaccine.

Other scientific and medical literature support the conclusion that syncope may be caused by the act of vaccination, but not its contents.<sup>25</sup> The evidence is thus insufficient to support a causal connection between the contents of any vaccine and vasovagal syncope.

As discussed above, vasovagal syncope is not a "vaccine-related injury" and therefore

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<sup>23</sup> 80 Fed. Reg. at 45137.

<sup>24</sup> 80 Fed.Reg. at 45137. *See also* IOM Report.

<sup>25</sup> 80 Fed. Reg. at 45137 (The IOM found that one case report suggested that "the injection, and not the contents of the vaccine, contributed to the development of syncope"). *See also* IOM Report at 18 ("injection of vaccine, independent of the antigen involved, can lead to" syncope); Miller, E. and Woo, E.J. Time to prevent injuries from postimmunization syncope, *Nursing*, 2006 36 (12): 20.

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should not be included on the Table or compensable under the VICP.<sup>26</sup> Because the 2017 addition of syncope to the Table was based on a causal connection between the “administration” of the vaccine and the injury, not an association of the injury with the contents of the vaccine itself, syncope’s addition to the Table was not appropriate under the Vaccine Act. Moreover, as discussed in the Background section, the Department has concluded that there are strong policy reasons for removing vasovagal syncope from the Table. Accordingly, the Secretary recommends removing vasovagal syncope from the Table for all vaccines.

[INSERT DISCUSSION OF GUIDING PRINCIPLES AFTER ACCV CONCLUDES ITS REVIEW]

**3. Category for 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**

Item XVII of the current Table includes “[a]ny new vaccine recommended by the CDC for routine administration to children, after publication by the Secretary of a notice of coverage.”<sup>27</sup> Through this general category, new vaccines recommended by the CDC for routine administration to children and subject to an excise tax are deemed covered under the VICP prior to being added to the Table as a separate vaccine category through Federal rulemaking. SIRVA and vasovagal syncope are the only illnesses, disabilities, injuries, or conditions listed in Item XVII of the Table.

The Department has serious concerns that Item XVII is contrary to law. The Vaccine

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<sup>26</sup> 42 U.S.C. §§ 300aa-11, 300aa-14(e).

<sup>27</sup> 42 CFR 100.3(a).

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Act provides a method for adding new vaccines to the Table, and it is far from clear that the approach in Item XVII complies with that method. The Vaccine Act provides that the Secretary may promulgate regulations to modify the Table, but in doing so, he “shall provide for notice and opportunity for a public hearing and at least 180 days of public comment.”<sup>28</sup> Moreover, the Table cannot be revised unless “the Secretary has first provided to the [ACCV] a copy of the proposed regulation or revision, requested recommendations and comments by the [ACCV], and afforded the [ACCV] at least 90 days to make such recommendations.”<sup>29</sup> Item XVII, by contrast, suggests that vaccines are added to the Table once the CDC recommends them for routine administration to children and an excise tax is imposed, even prior to notice and public comment or comments from the ACCV.<sup>30</sup> This would be inconsistent with the rulemaking requirements of the Administrative Procedure Act § 4, 5 U.S.C. § 553, the Regulatory Flexibility Act, 5 U.S.C. § 601 *et seq.*, various Executive Orders that cabin rulemaking (*see, e.g.*, Executive Order 12866), and the Vaccine Act.

Further, SIRVA and vasovagal syncope are the only illnesses, disabilities, injuries, or conditions listed for Item XVII.

#### **IV. Statutory and Regulatory Requirements**

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<sup>28</sup> 42 U.S.C. § 300aa-14(c)(1).

<sup>29</sup> 42 U.S.C. § 300aa-14(d).

<sup>30</sup> The language in Item XVII also raises Constitutional concerns. Item XVII in effect allows CDC to add vaccines to the Table so long as the Secretary publishes notice of coverage. The Office of Legal Counsel has previously opined that a statute that sought to authorize the CDC director to take certain action unilaterally was inconsistent with the Executive Powers Clause. (Statute Limiting The President's Authority To Supervise The Director Of The Centers For Disease Control In The Distribution Of An AIDS Pamphlet, 12 U.S. Op. Off. Legal Counsel 47, 48, 1988 WL 390999, at \*1). For the same reasons, it is not clear that the CDC director, as an inferior officer, has the authority to unilaterally add vaccines to the Table without the approval of the Secretary.

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A. Executive Orders 12866, 13563, and 13771: Regulatory Planning and Review

E.O. 12866 and E.O. 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). E.O. 13563 supplements and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866, which emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

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 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. The Department anticipates that the proposed rule will decrease total costs. The proposed rule will benefit the general public and save limited compensation funds under the National Vaccine Injury Compensation Program. Specifically, it will reduce the amount of program funds spent on program administration, reduce the amount of funds paid out to those with SIRVA or vasovagal syncope claims, and ensure that funds awarded from the VICP are awarded to individuals whose claims arise from vaccine-related injuries, which is consistent with the original intent of the VICP. Moreover, the Department anticipates that the proposed rule will result in fewer individuals suffering from SIRVA or vasovagal syncope, because it will better

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incentivize those administering vaccines to use proper injection technique. If those who administer vaccines can be held liable when a patient suffers from SIRVA or vasovagal syncope as a result of the administration of the vaccine, those who administer vaccines will have greater incentive to use proper injection technique. In addition, the proposed rule will also limit the ability of those opposed to vaccinations to misleadingly suggest that vaccines are less safe than they truly are.

**B. Initial Regulatory Flexibility Analysis**

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. Between FY 2017 and FY 2019, the VICP on average paid out \$30,893,481.90 per year to petitioners alleging SIRVA claims. The VICP on average paid out \$124,489.56 per year to petitioners alleging vasovagal syncope claims. The Department anticipates that small entities would not actually pay these amounts, because fewer SIRVA and vasovagal syncope claims would be filed if petitioners had to prove causation. In addition, vaccines are often administered by non-small entities, so even if total amounts paid approximated the amounts paid on average between FY 2017 and FY 2019, claims against small entities would be less. Besides, even if after publication of a final rule, the amounts paid equaled the amounts annually paid out of the VICP between FY 2017 and FY 2019, and such claims were paid in full by small entities, these amounts would not constitute a significant impact on a substantial number of small entities for purposes of the RFA.

The Secretary has also determined that this proposed rule does not meet the criteria for a

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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.

The provisions of this rule will also not negatively affect family well-being or 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.

On January 30, 2017, the White House issued Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment or otherwise promulgates a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. This proposed rule would partially repeal prior regulations and is not expected to impose more

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than de minimis costs, so it is not anticipated to be a regulatory or deregulatory action under Executive Order 13771.

As stated above, this proposed rule would modify the Vaccine Injury Table to ensure that the Table complies with applicable law, the Table is consistent with medical and scientific literature, those administering vaccines have additional incentive to use proper injection technique, and the VICP has sufficient funds to adequately compensate those injured by vaccines listed in the Table.

### **Summary of Impacts**

This proposed rule will have the effect of removing injuries from the Table that are not encompassed by the provisions of the Vaccine Act and that are depleting the pool of funds available to those injured by vaccine antigens. It will therefore align the Table with Congressional intent and public policy in favor of compensating those harmed by injuries associated with the contents of a vaccine, and particularly children who have suffered such harm. The rule will also have the effect of ensuring that limited compensation resources available under the National Vaccine Injury Compensation Program are provided to those injured due to the contents of a vaccine. In addition, because of the large volume of SIRVA claims, removing SIRVA from the Table will reduce the amount of program funds spent on program administration and ensure that funds awarded from the VICP are awarded to individuals whose claims arise from vaccine-related injuries, which is consistent with the original intent of the VICP.. The rule will also better incentivize those who administer vaccines to use proper injection technique. It will also limit the ability of those opposed to vaccinations to misleadingly

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suggest that vaccines are less safe than they truly are. SIRVA claims are a large proportion (and in many years a majority) of claims filed in the VICP, so removing SIRVA from the Table will dramatically reduce the number of cases that those opposed to vaccination can point to.

#### A. Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year.” HHS does not expect this proposed rule to exceed the threshold.

#### B. Executive Order 13132—Federalism

HHS has reviewed this proposed rule in accordance with E.O. 13132 regarding federalism and has determined that it does not have “federalism implications.” This proposed 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.”

#### C. Collection of Information

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) (PRA) requires that OMB approve all collections of information by a federal agency from the public before they can be implemented. This proposed rule is projected to have no impact on current reporting and recordkeeping burden, as the amendments proposed in this rule will not impose any data collection requirements under the PRA.



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### List of Subjects in 42 CFR Part 100

Biologics, Health insurance, Immunization.

Dated: \_\_\_\_\_

\_\_\_\_\_  
Thomas J. Engels,  
Administrator,  
Health Resources and Services Administration.

Approved: \_\_\_\_\_

\_\_\_\_\_  
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. Revise § 100.3 to read as follows:

#### **§ 100.3 Vaccine injury table.**

(a) In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Public Law 99–660, 100 Stat. 3779 (42 U.S.C. 300aa–1 note) and section 2114(c) of the Public Health Service Act, as amended (PHS Act) (42 U.S.C. 300aa–14(c)), the following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first

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symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program. Paragraph (b) of this section sets forth additional provisions that are not separately listed in this Table but that constitute part of it. Paragraph (c) of this section sets forth the Qualifications and Aids to Interpretation for the terms used in the Table. Conditions and injuries that do not meet the terms of the Qualifications and Aids to Interpretation are not within the Table. Paragraph (d) of this section sets forth a glossary of terms used in paragraph (c).

**VACCINE INJURY TABLE**

<b>Vaccine</b>	<b>Illness, disability, injury or condition covered</b>	<b>Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration</b>
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT)	A. Anaphylaxis B. Brachial Neuritis	≤4 hours. 2-28 days (not less than 2 days and not more than 28 days).
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 B. Encephalopathy or encephalitis	≤4 hours. ≤72 hours.
III. Vaccines containing measles, mumps, and rubella virus or any of its	A. Anaphylaxis	≤4 hours.

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components (e.g., MMR, MM, MMRV)	B. Encephalopathy or encephalitis	5-15 days (not less than 5 days and not more than 15 days).
IV. Vaccines containing rubella virus (e.g., MMR, MMRV)	A. Chronic arthritis	7-42 days (not less than 7 days and not more than 42 days).
V. Vaccines containing measles virus (e.g., MMR, MM, MMRV)	A. Thrombocytopenic purpura	7-30 days (not less than 7 days and not more than 30 days).
	B. Vaccine-Strain Measles Viral Disease in an immunodeficient recipient	
	—Vaccine-strain virus identified	Not applicable.
	—If strain determination is not done or if laboratory testing is inconclusive	≤12 months.
VI. Vaccines containing polio live virus (OPV)	A. Paralytic Polio	≤30 days.
	-in a non-immunodeficient recipient	≤6 months.
	—in an immunodeficient recipient	Not applicable.
	—in a vaccine associated community case	
	B. Vaccine-Strain Polio Viral Infection	≤30 days.
	—in a non-immunodeficient recipient	≤6 months.
	—in an immunodeficient recipient	Not applicable.

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	—in a vaccine associated community case	
VII. Vaccines containing polio inactivated virus (e.g., IPV)	A. Anaphylaxis	≤4 hours.
VIII. Hepatitis B vaccines	A. Anaphylaxis	≤4 hours.
IX. Haemophilus influenzae type b (Hib) vaccines	No Condition Specified.	Not applicable.
X. Varicella vaccines	A. Anaphylaxis  B. Disseminated varicella vaccine-strain viral disease  —Vaccine-strain virus identified  —If strain determination is not done or if laboratory testing is inconclusive  C. Varicella vaccine-strain viral reactivation	≤4 hours.  Not applicable.  7-42 days (not less than 7 days and not more than 42 days).  Not applicable.
XI. Rotavirus vaccines	A. Intussusception	1-21 days (not less than 1 day and not more than 21 days).
XII. Pneumococcal conjugate vaccines	No Condition Specified.	Not applicable.
XIII. Hepatitis A vaccines	No Condition Specified.	Not applicable.
XIV. Seasonal influenza vaccines	A. Anaphylaxis  B. Guillain-Barré Syndrome	≤4 hours.  3-42 days (not less than 3 days and not more than 42 days).
XV. Meningococcal vaccines	A. Anaphylaxis	≤4 hours.
XVI. Human papillomavirus (HPV) vaccines	A. Anaphylaxis	≤4 hours.

(b) Provisions that apply to all conditions listed.

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(1) Any acute complication or sequela, including death, of the illness, disability, injury, or condition listed in paragraph (a) of this section (and defined in paragraphs (c) and (d) of this section) qualifies as a Table injury under paragraph (a) except when the definition in paragraph (c) requires exclusion.

(2) In determining whether or not an injury is a condition set forth in paragraph (a) of this section, the Court shall consider the entire medical record.

(3) An idiopathic condition that meets the definition of an illness, disability, injury, or condition set forth in paragraph (c) of this section shall be considered to be a condition set forth in paragraph (a) of this section.

(c) Qualifications and aids to interpretation. The following qualifications and aids to interpretation shall apply to, define and describe the scope of, and be read in conjunction with paragraphs (a), (b), and (d) of this section:

(1) Anaphylaxis. Anaphylaxis is an acute, severe, and potentially lethal systemic reaction that occurs as a single discrete event with simultaneous involvement of two or more organ systems. Most cases resolve without sequela. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. There are no specific pathological findings to confirm a diagnosis of anaphylaxis.

(2) Encephalopathy. A vaccine recipient shall be considered to have suffered an encephalopathy if an injury meeting the description below of an acute encephalopathy occurs

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within the applicable time period and results in a chronic encephalopathy, as described in paragraph (d) of this section.

(i) Acute encephalopathy.

(A) For children less than 18 months of age who present:

(1) Without a seizure, an acute encephalopathy is indicated by a significantly decreased level of consciousness that lasts at least 24 hours.

(2) Following a seizure, an acute encephalopathy is demonstrated by a significantly decreased level of consciousness that lasts at least 24 hours and cannot be attributed to a postictal state—from a seizure or a medication.

(B) For adults and children 18 months of age or older, an acute encephalopathy is one that persists at least 24 hours and is characterized by at least two of the following:

(1) A significant change in mental status that is not medication related (such as a confusional state, delirium, or psychosis);

(2) A significantly decreased level of consciousness which is independent of a seizure and cannot be attributed to the effects of medication; and

(3) A seizure associated with loss of consciousness.

(C) The following clinical features in themselves do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness: sleepiness, irritability (fussiness), high-pitched and unusual screaming, poor feeding, persistent inconsolable crying, bulging fontanelle, or symptoms of dementia.

(D) Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy and in the absence of other evidence of an acute encephalopathy seizures shall not be viewed as

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the first symptom or manifestation of an acute encephalopathy.

(ii) Exclusionary criteria for encephalopathy. Regardless of whether or not the specific cause of the underlying condition, systemic disease, or acute event (including an infectious organism) is known, an encephalopathy shall not be considered to be a condition set forth in the Table if it is shown that the encephalopathy was caused by:

(A) An underlying condition or systemic disease shown to be unrelated to the vaccine (such as malignancy, structural lesion, psychiatric illness, dementia, genetic disorder, prenatal or perinatal central nervous system (CNS) injury); or

(B) An acute event shown to be unrelated to the vaccine such as a head trauma, stroke, transient ischemic attack, complicated migraine, drug use (illicit or prescribed) or an infectious disease.

(3) Encephalitis. A vaccine recipient shall be considered to have suffered encephalitis if an injury meeting the description below of an acute encephalitis occurs within the applicable time period and results in a chronic encephalopathy, as described in paragraph (d) of this section.

(i) Acute encephalitis. Encephalitis is indicated by evidence of neurologic dysfunction, as described in paragraph (c)(3)(i)(A) of this section, plus evidence of an inflammatory process in the brain, as described in paragraph (c)(3)(i)(B) of this section.

(A) Evidence of neurologic dysfunction consists of either:

(1) One of the following neurologic findings referable to the CNS: Focal cortical signs (such as aphasia, alexia, agraphia, cortical blindness); cranial nerve abnormalities; visual field defects; abnormal presence of primitive reflexes (such as Babinski's sign or sucking reflex); or cerebellar dysfunction (such as ataxia, dysmetria, or nystagmus); or

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(2) An acute encephalopathy as set forth in paragraph (c)(2)(i) of this section.

(B) Evidence of an inflammatory process in the brain (central nervous system or CNS inflammation) must include cerebrospinal fluid (CSF) pleocytosis (>5 white blood cells (WBC)/mm<sup>3</sup> in children >2 months of age and adults; >15 WBC/mm<sup>3</sup> in children <2 months of age); or at least two of the following:

(1) Fever (temperature  $\geq$ 100.4 degrees Fahrenheit);

(2) Electroencephalogram findings consistent with encephalitis, such as diffuse or multifocal nonspecific background slowing and periodic discharges; or

(3) Neuroimaging findings consistent with encephalitis, which include, but are not limited to brain/spine magnetic resonance imaging (MRI) displaying diffuse or multifocal areas of hyperintense signal on T2-weighted, diffusion-weighted image, or fluid-attenuation inversion recovery sequences.

(ii) Exclusionary criteria for encephalitis. Regardless of whether or not the specific cause of the underlying condition, systemic disease, or acute event (including an infectious organism) is known, encephalitis shall not be considered to be a condition set forth in the Table if it is shown that the encephalitis was caused by:

(A) An underlying malignancy that led to a paraneoplastic encephalitis;

(B) An infectious disease associated with encephalitis, including a bacterial, parasitic, fungal or viral illness (such as herpes viruses, adenovirus, enterovirus, West Nile Virus, or human immunodeficiency virus), which may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing; or

(C) *Acute disseminated encephalomyelitis (ADEM)*. Although early ADEM may have



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laboratory and clinical characteristics similar to acute encephalitis, findings on MRI are distinct with ADEM displaying evidence of acute demyelination (scattered, focal, or multifocal areas of inflammation and demyelination within cerebral subcortical and deep cortical white matter; gray matter involvement may also be seen but is a minor component); or

(D) Other conditions or abnormalities that would explain the vaccine recipient's symptoms.

(4) *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 preexisting condition identified as the lead point for intussusception such as intestinal masses and cystic structures (such as polyps, tumors, Meckel's

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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 Schölein 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).

(5) *Chronic arthritis*. Chronic arthritis is defined as persistent joint swelling with at least two additional manifestations of warmth, tenderness, pain with movement, or limited range of motion, lasting for at least 6 months.

(i) Chronic arthritis may be found in a person with no history in the 3 years prior to vaccination of arthropathy (joint disease) on the basis of:

(A) Medical documentation recorded within 30 days after the onset of objective signs of acute arthritis (joint swelling) that occurred between 7 and 42 days after a rubella vaccination; and

(B) Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination; and

(C) Medical documentation of an antibody response to the rubella virus.

(ii) The following shall not be considered as chronic arthritis: Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile idiopathic arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective

**Pursuant to Section 10(b) of the Federal Advisory Committee Act and 5 U.S.C. § 552(b)(5), this draft notice of proposed rulemaking is protected by the deliberative process privilege. HRSA has waived this privilege. The ACCV may publicly discuss this proposal.**

tissue disease, polymyositis/ dermatomyositis, fibromyalgia, necrotizing vasculitis and vasculopathies and Sjogren's Syndrome), degenerative joint disease, infectious agents other than rubella (whether by direct invasion or as an immune reaction), metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders, and arthritis associated with ankylosing spondylitis, psoriasis, inflammatory bowel disease, Reiter's Syndrome, blood disorders, or arthralgia (joint pain), or joint stiffness without swelling.

(6) *Brachial neuritis*. This term is defined as dysfunction limited to the upper extremity nerve plexus (i.e., its trunks, divisions, or cords). A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is typically followed in days or weeks by weakness in the affected upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. Atrophy of the affected muscles may occur. The neuritis, or plexopathy, may be present on the same side or on the side opposite the injection. It is sometimes bilateral, affecting both upper extremities. A vaccine recipient shall be considered to have suffered brachial neuritis as a Table injury if such recipient manifests all of the following:

(i) Pain in the affected arm and shoulder is a presenting symptom and occurs within the specified time-frame;

(ii) Weakness:

(A) Clinical diagnosis in the absence of nerve conduction and electromyographic studies requires weakness in muscles supplied by more than one peripheral nerve.

(B) Nerve conduction studies (NCS) and electromyographic (EMG) studies localizing the injury to the brachial plexus are required before the diagnosis can be made if weakness is limited

to muscles supplied by a single peripheral nerve.

(iii) Motor, sensory, and reflex findings on physical examination and the results of NCS and EMG studies, if performed, must be consistent in confirming that dysfunction is attributable to the brachial plexus; and

(iv) No other condition or abnormality is present that would explain the vaccine recipient's symptoms.

(7) *Thrombocytopenic purpura*. This term is defined by the presence of clinical manifestations, such as petechiae, significant bruising, or spontaneous bleeding, and by a serum platelet count less than  $50,000/\text{mm}^3$  with normal red and white blood cell indices.

Thrombocytopenic purpura does not include cases of thrombocytopenia associated with other causes such as hypersplenism, autoimmune disorders (including alloantibodies from previous transfusions) myelodysplasias, lymphoproliferative disorders, congenital thrombocytopenia or hemolytic uremic syndrome. Thrombocytopenic purpura does not include cases of immune (formerly called idiopathic) thrombocytopenic purpura that are mediated, for example, by viral or fungal infections, toxins or drugs. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with disseminated intravascular coagulation, as observed with bacterial and viral infections. Viral infections include, for example, those infections secondary to Epstein Barr virus, cytomegalovirus, hepatitis A and B, human immunodeficiency virus, adenovirus, and dengue virus. An antecedent viral infection may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing. However, if culture or serologic testing is performed, and the viral illness is attributed to the vaccine-strain measles virus, the presumption of causation will remain in effect. Bone marrow examination, if performed, must reveal a normal or an increased number of megakaryocytes in an otherwise

normal marrow.

(8) *Vaccine-strain measles viral disease*. This term is defined as a measles illness that involves the skin and/or another organ (such as the brain or lungs). Measles virus must be isolated from the affected organ or histopathologic findings characteristic for the disease must be present. Measles viral strain determination may be performed by methods such as polymerase chain reaction test and vaccine-specific monoclonal antibody. If strain determination reveals wild-type measles virus or another, non-vaccine- strain virus, the disease shall not be considered to be a condition set forth in the Table. If strain determination is not done or if the strain cannot be identified, onset of illness in any organ must occur within 12 months after vaccination.

(9) *Vaccine-strain polio viral infection*. This term is defined as a disease caused by poliovirus that is isolated from the affected tissue and should be determined to be the vaccine-strain by oligonucleotide or polymerase chain reaction. Isolation of poliovirus from the stool is not sufficient to establish a tissue specific infection or disease caused by vaccine-strain poliovirus.

(10) *Disseminated varicella vaccine- strain viral disease*. Disseminated varicella vaccine-strain viral disease is defined as a varicella illness that involves the skin beyond the dermatome in which the vaccination was given and/or disease caused by vaccine-strain varicella in another organ. For organs other than the skin, the disease must be demonstrated in the involved organ and not just through mildly abnormal laboratory values. If there is involvement of an organ beyond the skin, and no virus was identified in that organ, the involvement of all organs must occur as part of the same, discrete illness. If strain determination reveals wild-type varicella virus or another, non-vaccine- strain virus, the viral disease shall not be considered to be a condition set forth in the Table. If strain determination is not done or if the strain cannot be identified,

onset of illness in any organ must occur 7– 42 days after vaccination.

(11) *Varicella vaccine-strain viral reactivation disease*. Varicella vaccine-strain viral reactivation disease is defined as the presence of the rash of herpes zoster with or without concurrent disease in an organ other than the skin. Zoster, or shingles, is a painful, unilateral, pruritic rash appearing in one or more sensory dermatomes. For organs other than the skin, the disease must be demonstrated in the involved organ and not just through mildly abnormal laboratory values. There must be laboratory confirmation that the vaccine-strain of the varicella virus is present in the skin or in any other involved organ, for example by oligonucleotide or polymerase chain reaction. If strain determination reveals wild-type varicella virus or another, non-vaccine-strain virus, the viral disease shall not be considered to be a condition set forth in the Table.

(12) *Immunodeficient recipient*. Immunodeficient recipient is defined as an individual with an identified defect in the immunological system which impairs the body's ability to fight infections. The identified defect may be due to an inherited disorder (such as severe combined immunodeficiency resulting in absent T lymphocytes), or an acquired disorder (such as acquired immunodeficiency syndrome resulting from decreased CD4 cell counts). The identified defect must be demonstrated in the medical records, either preceding or postdating vaccination.

(13) *Guillain-Barre' Syndrome (GBS)*.

(i) GBS is an acute monophasic peripheral neuropathy that encompasses a spectrum of four clinicopathological subtypes described below. For each subtype of GBS, the interval between the first appearance of symptoms and the nadir of weakness is between 12 hours and 28 days. This is followed in all subtypes by a clinical plateau with stabilization at the nadir of

symptoms, or subsequent improvement without significant relapse. Death may occur without a clinical plateau. Treatment related fluctuations in all subtypes of GBS can occur within nine weeks of GBS symptom onset and recurrence of symptoms after this time-frame would not be consistent with GBS.

(ii) The most common subtype in North America and Europe, comprising more than 90 percent of cases, is acute inflammatory demyelinating polyneuropathy (AIDP), which has the pathologic and electrodiagnostic features of focal demyelination of motor and sensory peripheral nerves and nerve roots. Another subtype called acute motor axonal neuropathy (AMAN) is generally seen in other parts of the world and is predominated by axonal damage that primarily affects motor nerves. AMAN lacks features of demyelination. Another less common subtype of GBS includes acute motor and sensory neuropathy (AMSAN), which is an axonal form of GBS that is similar to AMAN, but also affects the sensory nerves and roots. AIDP, AMAN, and AMSAN are typically characterized by symmetric motor flaccid weakness, sensory abnormalities, and/or autonomic dysfunction caused by autoimmune damage to peripheral nerves and nerve roots. The diagnosis of AIDP, AMAN, and AMSAN requires:

- (A) Bilateral flaccid limb weakness and decreased or absent deep tendon reflexes in weak limbs;
- (B) A monophasic illness pattern;
- (C) An interval between onset and nadir of weakness between 12 hours and 28 days;
- (D) Subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse; however, death may occur without a clinical plateau); and,
- (E) The absence of an identified more likely alternative diagnosis.

(iii) Fisher Syndrome (FS), also known as Miller Fisher Syndrome, is a subtype of GBS characterized by ataxia, areflexia, and ophthalmoplegia, and overlap between FS and AIDP may be seen with limb weakness. The diagnosis of FS requires:

- (A) Bilateral ophthalmoparesis;
- (B) Bilateral reduced or absent tendon reflexes;
- (C) Ataxia;
- (D) The absence of limb weakness (the presence of limb weakness suggests a diagnosis of AIDP, AMAN, or AMSAN);
- (E) A monophasic illness pattern;
- (F) An interval between onset and nadir of weakness between 12 hours and 28 days;
- (G) Subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse; however, death may occur without a clinical plateau);
- (H) No alteration in consciousness;
- (I) No corticospinal track signs; and
- (J) The absence of an identified more likely alternative diagnosis.

(iv) Evidence that is supportive, but not required, of a diagnosis of all subtypes of GBS includes electrophysiologic findings consistent with GBS or an elevation of cerebral spinal fluid (CSF) protein with a total CSF white blood cell count below 50 cells per microliter. Both CSF and electrophysiologic studies are frequently normal in the first week of illness in otherwise typical cases of GBS.

(v) To qualify as any subtype of GBS, there must not be a more likely alternative diagnosis for the weakness.



(vi) Exclusionary criteria for the diagnosis of all subtypes of GBS include the ultimate diagnosis of any of the following conditions: chronic immune demyelinating polyradiculopathy (CIDP), carcinomatous meningitis, brain stem encephalitis (other than Bickerstaff brainstem encephalitis), myelitis, spinal cord infarct, spinal cord compression, anterior horn cell diseases such as polio or West Nile virus infection, subacute inflammatory demyelinating polyradiculoneuropathy, multiple sclerosis, cauda equina compression, metabolic conditions such as hypermagnesemia or hypophosphatemia, tick paralysis, heavy metal toxicity (such as arsenic, gold, or thallium), drug-induced neuropathy (such as vincristine, platinum compounds, or nitrofurantoin), porphyria, critical illness neuropathy, vasculitis, diphtheria, myasthenia gravis, organophosphate poisoning, botulism, critical illness myopathy, polymyositis, dermatomyositis, hypokalemia, or hyperkalemia. The above list is not exhaustive.

(d) *Glossary for purposes of paragraph (c) of this section—(1) Chronic encephalopathy—(i)* A chronic encephalopathy occurs when a change in mental or neurologic status, first manifested during the applicable Table time period as an acute encephalopathy or encephalitis, persists for at least 6 months from the first symptom or manifestation of onset or of significant aggravation of an acute encephalopathy or encephalitis.

(ii) Individuals who return to their baseline neurologic state, as confirmed by clinical findings, within less than 6 months from the first symptom or manifestation of onset or of significant aggravation of an acute encephalopathy or encephalitis shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy or encephalitis.

(2) *Injected* refers to the intramuscular, intradermal, or subcutaneous needle administration of a vaccine.

(3) *Sequela* means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table.

(4) *Significantly decreased level of consciousness* is indicated by the presence of one or more of the following clinical signs:

(i) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(ii) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(iii) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

(5) *Seizure* includes myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures, but not absence (petit mal), or pseudo seizures. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.

(e) *Coverage provisions.* (1) Except as provided in paragraph (e)(2), (3), (4), (5), (6), or (7) of this section, this section applies to petitions for compensation under the Program filed with the United States Court of Federal Claims on or after [EFFECTIVE DATE OF THE FINAL REGULATION.]

(1) Hepatitis B, Hib, and varicella vaccines (Items VIII, IX, and X of the Table) are included in the Table as of August 6, 1997.

(2) Rotavirus vaccines (Item XI of the Table) are included in the Table as of October 22, 1998.

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

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

(5) Trivalent influenza vaccines (Included in item XIV of the Table) are included on the Table as of July 1, 2005. All other seasonal influenza vaccines (Item XIV of the Table) are included on the Table as of November 12, 2013.

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

For Review During ACCV Meeting