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List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Authority: 33 U.S.C. 1251 *et seq.*

Peter Lopez,

Regional Administrator, Region 2.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 100

RIN 0906-AB24

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

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

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary proposes to amend the Vaccine Injury Table (Table) by regulation. The proposed regulation 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 on or before January 12, 2021.

ADDRESSES: Comments must be identified by HHS Docket No. HRSA-2020-0002. Because of staff and resource limitations, comments must be submitted electronically to www.regulations.gov. Follow the "Submit a comment" instructions.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including personally identifiable or confidential

business information that is included in a comment. You may wish to consider limiting the amount of personal information that you provide in any voluntary public comment submission you make. 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>.

Follow the search instructions on that website to view the public comments.

FOR FURTHER INFORMATION CONTACT:

Please visit the National Vaccine Injury Compensation Program's website, <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; or by telephone at (855) 266-2427.

SUPPLEMENTARY INFORMATION: This is a notice of proposed rulemaking by which HHS proposes to amend the provisions of 42 CFR 100.3 by removing Shoulder Injury Related to Vaccine Administration, vasovagal syncope, and Item XVII from the Vaccine Injury Table.

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.

A public hearing on this proposed rule will be held before the end of the public comment period. A separate document will be published in the **Federal Register** providing details of this hearing. Subject to consideration of the comments received, the Secretary intends to publish a final regulation.

Instructions: If you submit a comment, you must include the agency name and the HHS Docket No. HRSA-2020-0002 for this rulemaking. 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 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>.

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. Almost all individuals who are vaccinated have no serious reactions.¹ Nonetheless, in the 1980s, Congress became concerned that a 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.² Claimants alleging vaccine-related injuries in civil litigation encountered a time-consuming, expensive, and often inadequate system.³ Moreover, increased litigation against vaccine manufacturers resulted in difficulties in their ability to secure affordable product liability insurance, stabilize vaccine prices and supply, and enter the market.⁴

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 objectives of the VICP are to ensure an adequate supply of vaccines, stabilize vaccine costs, and establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines to be federally compensated. Petitions for compensation under the VICP are filed

¹ National Vaccine Injury Compensation Program, Health Resources & Servs. Admin., <https://www.hrsa.gov/vaccine-compensation/index.html> (last reviewed Jan. 2020).

² H.R. Rep. No. 99-908, pt. 1, 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. See Recommended Vaccines by Age, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/vaccines/vpd/vaccines-age.html> (last reviewed Nov. 22, 2016).

³ H.R. Rep. No. 99-908, at 6.

⁴ See *id.* at 4-6.

in the United States Court of Federal Claims (Court), rather than the civil tort system, with a copy served on the Secretary, who is the Respondent. The U.S. Department of Justice (DOJ) represents HHS in Court, and the Court, acting through judicial officers called Special Masters, makes the final decision as to eligibility for, and the type and amount of, compensation.

To gain entitlement to compensation under this Program, a petitioner must establish that 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 what is referred to as a “Table injury.” That is, a petitioner may show that the vaccine recipient (1) received a vaccine covered under the Act; (2) 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 (3) that the onset of such injury took place within the time period specified in the Table. If so, the injury is presumed to have been caused by the vaccine, 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 unrelated to 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 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.”⁵ 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, among other things, added SIRVA and vasovagal syncope to the Table. 85 FR 6294. 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. 82 FR 11321. The Final Rule followed a 2012 Institute of Medicine (IOM)⁶ 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.

The Department now proposes to remove SIRVA and vasovagal syncope from the Table found at 42 CFR 100.3(a) and to remove the corresponding descriptions of those injuries—“Qualifications and Aids to Interpretation” (QAI)—from 42 CFR 100.3(c). This proposal is based upon a review of the relevant statutory provisions and the scientific literature, as well as the Department’s experience since SIRVA and vasovagal syncope were added to the Table. The Department also proposes to remove Item XVII from the Table found at 42 CFR 100.3(a), because the Department has serious concerns that Item XVII is contrary to applicable law, for the reasons set forth below.

Scientific Literature Concerning SIRVA and Vasovagal Syncope

The scientific literature indicates that SIRVA likely results from poor vaccination technique, rather than the vaccine or its components alone. 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.”⁷ The IOM similarly concluded that “the injection, and not the contents of the vaccine,

contributed to the development of deltoid bursitis.”⁸ 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.⁹ There is nearly uniform agreement in the scientific community that SIRVA is caused by improper vaccine administration, rather than by the vaccine itself.¹⁰ 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 [a] patient’s characteristics, *i.e.*, sex, body weight, and physical constitution),” rather than “antigens or adjuvants contained in the vaccines that would trigger an immune or inflammatory response.”¹¹

⁸ IOM Report at 620. SIRVA is a medicolegal term, not a medical diagnosis, that is meant to capture a broad array of potential shoulder injuries. However the IOM only made findings concerning deltoid bursitis.

⁹ Atanasoff S, Ryan T, Lightfoot R, and Johann Liang R. 2010, Shoulder injury related to vaccine administration (SIRVA), *Vaccine* 28(51): 8049–52 (recommending that injections avoid the top third of the deltoid muscle to avoid shoulder injury).

¹⁰ 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.

¹¹ 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). Another recent study reviewed the Vaccine Adverse Event Reporting System (VAERS) database from July 2010 to June 2017 for reports of atypical shoulder pain and dysfunction following injection of inactivated influenza vaccine (IIV). See 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*. The review found that, of the 266 reports where contributing factors for the injury were reported, 216 (81.2%) described the vaccination as being given “too high” on the arm. Other reports described improper or poor administration technique (*e.g.*, bone strikes, “administered in tendon”), uneven position between vaccinator and

⁶ The IOM is now known as the National Academy of Medicine.

⁷ National Vaccine Injury Compensation: Revision to the Vaccine Injury Table (“2015 Proposed Rule”), 80 FR 45132, 45136 (July 29, 2015) (emphasis supplied); see also *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>.

⁵ 42 CFR 100.3(a).

The scientific literature also indicates that vasovagal syncope results from the act of injection, rather than the vaccine or its components. Vasovagal syncope is the loss of consciousness (fainting) caused by a transient decrease in blood flow to the brain.¹² In proposing the addition of 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 act of the injection.¹³ The scientific literature suggests that those administering vaccines can take steps to significantly reduce the likelihood of injury from vasovagal syncope, such as having the patient sit or lie down for the vaccination, and observing the patient for 15 to 20 minutes after administering the vaccine.¹⁴

Reasons for Removal of SIRVA and Vasovagal Syncope

The Department has concluded that several reasons merit removal of SIRVA and vasovagal syncope from the Table found at 42 CFR 100.3(a), and to correspondingly remove the descriptions of those injuries from the QAI found at 42 CFR 100.3(c).

First, the Department has concluded that the Vaccine Act should be read as not applying to cover injuries, like SIRVA and vasovagal syncope, which involve negligence by the vaccine administrator. At best, the Vaccine Act is ambiguous in how it handles such injuries, and in the Department's view there are strong reasons to exclude them from coverage under the Act's compensation scheme.

The Act creates a compensation program "for a vaccine-related injury or

the patient (e.g., vaccinator standing while patient sitting), vaccination needle too long, and others (e.g., difficulty injecting vaccine). A small minority of reports also indicated the patient had a history of thyroid dysfunction or diabetes.

It is possible that certain injuries characterized as SIRVA occur when an immunologically active substance designed to trigger an inflammatory response (i.e., the vaccine antigen) is injected into an area where the inflammatory response can cause joint damage (i.e., the bursa or tendons) as opposed to an area where the inflammatory response will not cause joint damage or permanent harm (i.e., the deltoid muscle). Such injuries are fairly characterized as resulting from the vaccination technique, since they would not have occurred if the injection occurred in the proper part of the body.

¹² 82 FR 6294–01, 6304 (Jan. 19, 2017).

¹³ 80 FR 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).

¹⁴ 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.

death." 42 U.S.C. 300aa–11(a)(1). Under the Act, "only . . . a person who has sustained a vaccine-related injury or death" can recover. 42 U.S.C. 300aa–11(a)(9). The Act defines "[v]accine-related injury or death" as "an illness, injury, condition, or death 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 added); see also *Dean v. HHS*, No. 16–1245V, 2018 WL 3104388, at *9 (Fed. Cl. Spec. Mstr. May 29, 2018) (defining "vaccine" as "any substance designed to be administered to a human being for the prevention of 1 or more diseases") (quoting 26 U.S.C. 4132(a)(2)). Thus, the compensation program covers injuries "associated with" the vaccine itself.

SIRVA is, of course, not a vaccine, and it is not an injury caused by a vaccine antigen, but by administration of the vaccine by the health care provider. The Department does not think the term "associated with" was meant to sweep in injuries caused by negligent administration of the vaccine. Although the Act permits petitioners to recover for Vaccine Table injuries without demonstrating causation in individual cases, the term "associated with" nevertheless requires that the injury, in general, be causally related to the vaccine itself. This is clear both from dictionary definitions of "associated," which means "related, connected, or combined together" (Merriam-Webster.com Dictionary, Merriam-Webster, <https://www.merriam-webster.com/dictionary/associated>. Accessed 10 Jul. 2020), and from the text of the Act itself, see, e.g., 42 U.S.C. 300aa–22(b)(1) (focusing on injuries that "resulted" from vaccine side effects); 42 U.S.C. 300aa–13(a)(1)(B) & (2)(B) (excluding "trauma" that has "no known relation to the vaccine involved"). Importantly, in the key operative provisions discussed above, the phrase "associated with" is linked to the vaccine itself, not to the technique in administering the vaccine. See *Decker v. Nw. Env'tl. Def. Ctr.*, 568 U.S. 597, 611 (2013) (in interpreting phrase "associated with industrial activity," the key consideration is the scope of "industrial activity"; the "statute does not foreclose a more specific definition by the agency" and "a reasonable interpretation . . . could . . . require the discharges to be related in a direct way to operations at 'an industrial plant'"); *Chevron, U.S.A.,*

Inc. v. Nat. Resources Def. Council, Inc., 467 U.S. 837, 861 (1984) ("[T]he meaning of a word must be ascertained in the context of achieving particular objectives, and the words associated with it may indicate that the true meaning of the series is to convey a common idea.").

That basic requirement is not met with SIRVA and vasovagal syncope. While the act of being vaccinated may be a but-for cause of those injuries, the injury is not associated with the vaccine itself because, with proper administration technique, those injuries will not result from the vaccine. Rather, SIRVA and vasovagal syncope result from the use of improper—that is, negligent—administration technique. Furthermore, to the extent there is ambiguity about the scope of injuries encompassed by the phrase "associated with," this reading, grounded in tort law principles, better achieves the Act's objectives for the reasons below.

There are several indicators in the language and structure of the Vaccine Act that show it was not meant to cover negligent administration of the vaccine. First, as the Federal Circuit has explained, troubling issues arise if the Act were to apply to "negligence facially unrelated to the vaccine's effects." *Amendola v. Sec., Dept. of Health & Human Servs.*, 989 F.2d 1180, 1187 (Fed. Cir. 1993). It could include, for example, "the doctor's negligent dropping of an infant patient" or use of contaminated equipment. *Id.* at 1186–87. The better reading of the statute is that it does not reach this far.

Second, the definition of vaccine-related injury carves out "an adulterant or contaminant intentionally added to such a vaccine." 42 U.S.C. 300aa–33(5) (emphasis added). By excluding from the definition those injuries associated with an adulterant or contaminant intentionally added to the vaccine, Congress indicated its intent to permit suit only where the injury was caused by the components of the vaccine itself, not individual fault. Relatedly, in the provisions setting forth the standard for awarding compensation, Congress specified that an award is not appropriate when injury was "due to factors unrelated to the administration of the vaccine," and further defined that phrase to include "trauma . . . which have no known relation to the vaccine involved." 42 U.S.C. 300aa–13(a)(1)(B) & (2)(B). In other words, Congress excluded compensation for injuries that were not related "to the vaccine involved."

Third, the statutory scheme requires that the patient "received a vaccine set forth in the Vaccine Injury Table," 42

U.S.C. 300aa–11(c)(1)(A), tying compensation to the receipt of a specific listed vaccine. See 42 U.S.C. 300aa–11(c)(1)(C)(i) (speaking to an injury aggravated “in association with the vaccine referred to” on the Vaccine Injury Table); 42 U.S.C. 300aa–11(c)(1)(C)(ii)(I) (for conditions not on the Vaccine Injury Table, allowing proof that the condition “was caused by a vaccine” on the Table); 42 U.S.C. 300aa–11(c)(1)(C)(ii)(II) (same). But negligent administration can occur without regard to the specific vaccine and, as noted above, can encompass anything from negligent needle placement to “the doctor’s negligent dropping of an infant patient.” *Amendola*, 989 F.2d at 1186–87. Congress strongly signaled that it was focused on compensation for harm caused by the vaccine by requiring that the Table list the vaccines themselves and the types of injuries the vaccines themselves would cause.

Fourth, in the provision preempting state tort liability, Congress protected manufacturers from liability when the injury “resulted from side effects that were unavoidable even though the vaccine was properly prepared. . . .” 42 U.S.C. 300aa–22(b)(1). This language shows Congress wanted to preserve a state tort remedy for certain avoidable injuries, such as those caused by negligent vaccine administration. Given that the Vaccine Act seeks to replace state tort remedies for the injuries it covers, this reinforces the conclusion that the Act does not reach SIRVA and vasovagal syncope.

Fifth, Congress provided for health care providers who administer vaccines to record detailed information about the vaccination, including the date of administration; the manufacturer; the name of the provider; and other identifying information. 42 U.S.C. 300aa–25. This information is well suited to a program designed to compensate for injuries associated with the vaccine itself, since it provides the key details about the vaccine provided and when. But this reporting requirement is woefully inadequate if the Program was designed to compensate for negligence by the provider, which would require maintaining careful records regarding the actual administration of the vaccine.

To be sure, the Vaccine Act does in certain places refer to “administration of” or the “administrator” of the vaccine. But we think that those usages were not meant to suggest the Program covers negligence in the administration of the vaccine, but served other purposes. At most, these usages render the statute ambiguous with respect to

needle injuries. In Section 300aa–11(a)(2)(A), the statute precludes suits against “a vaccine administrator,” but this reference does not define the scope of the compensation program—instead, it protects administrators from suits “arising from a vaccine-related injury or death associated with the administration of a vaccine.” This language is not entirely clear, as it appears to impose two distinct qualifications that both must be met but are worded slightly differently. It may be a belt and suspenders approach to ensure that vaccine administrators are protected from tort claims like in *Amendola*, where the vaccine itself was properly administered and caused the injury, but the petitioner alleged the administrator was negligent in deciding to give the vaccine. See 989 F.2d at 1186 (holding Vaccine Program does not exclude cases of “negligence in deciding, for example, whether to administer an otherwise satisfactory vaccine”). The important point is that the first qualification—“arising from a vaccine-related injury”—is also included here and, as discussed above, Congress defined this requirement to include only injuries associated with the vaccine itself. See also 42 U.S.C. 300aa–11(b)(1)(A) (referencing individuals who “died as the result of the administration of a vaccine” but only if the individual sustained a “vaccine-related injury”). In setting up the original Vaccine Injury Table, Congress referenced conditions “resulting from the administration of such vaccines.” 42 U.S.C. 300a–14(a). But this phrase was not designed to define the scope of the program or the Table; instead, Congress directed the Secretary to add conditions to the Table if they were “associated with such vaccines.” 42 U.S.C. 300aa–14(e)(1)(B) & (2)(B). And it is telling that Congress included nothing similar to SIRVA or other injuries caused by negligent vaccine administration in the original Table, rather than injuries associated with the vaccine components themselves. Finally, that Congress asked the Secretary to “make or assure improvements” in the “administration” of vaccines, 42 U.S.C. 300aa–27(a)(2), among many areas of improvement in the vaccination process, does not imply that the compensation program covers negligent administration.

Perhaps for some or all of these reasons, state courts have found that injuries arising from negligent administration of a vaccine are not “vaccine-related injuries” under 42 U.S.C. 300aa–33(5), and therefore are not preempted by the Vaccine Act. See,

e.g., *Neddeau v. Rite Aid of Conn.*, 2015 WL 5133151, at *3 (Super. Ct. Conn. July 28, 2015) (state court action did not allege a “vaccine-related” injury and therefore was not barred by the Vaccine Act, because plaintiff’s allegation that the administrator struck the needle too high was an allegation that her injuries “were caused by negligence in the physical process of injecting the vaccine, not by the effects of the vaccine”); *Nwosu ex rel. Ibrahim v. Adler*, 969 So. 2d 516, 519 (Ct. App. Fla. 2007) (claim arising from a physician’s negligent injection of a vaccine was not a “vaccine-related injury,” and adding that “[i]t is true that had the child not been vaccinated, she would not have been injured. However, her injury as alleged, does not flow from the inoculant injected into her body [so] it is not the type of injury covered under the Act”).

The Table should only include injuries caused by a vaccine or its components, not the manner in which the vaccine was administered. Thus, a petitioner must have an injury or death “associated” with the vaccine, not one resulting from poor injection technique or other improper administration of the vaccine.

Moreover, strong policy considerations support this reading of the Vaccine Act. It is the Department’s belief that Congress intended for the Vaccine Act’s compensation system to be used for unavoidable 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, SIRVA is likely preventable. The scientific literature also suggests that those administering vaccines can take steps to significantly reduce the likelihood of vasovagal syncope. However, while the Department is grateful for the many health care professionals and pharmacists who improve public health by vaccinating the American public, and does not believe they would intentionally administer a vaccine in an improper manner, awarding no-fault compensation from the VICP to those with SIRVA and vasovagal syncope claims lessens the incentive to take appropriate precautions. Since Vaccine Act proceedings are generally sealed and not made available to the public, vaccine administrators may be left unaware that they used an improper technique.¹⁵ If SIRVA and vasovagal

¹⁵ See Jodie Fleischer et al., *Half of All New Federal Vaccine Cases Allege Injury from Shots*

syncope are included in the Table, petitioners will continue to 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.

Furthermore, the Department has found that SIRVA petitions are likely to unnecessarily risk reductions in the funding available for children and others who sustained an unavoidable vaccine-related injury or death that did not result from improper technique or negligent administration. In the VICP’s early years, the overwhelming majority of cases brought, and compensation awarded, involved injuries to children.¹⁶ However, over 99.2% of SIRVA cases (3,034 out of 3,057) filed 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, who are overwhelmingly adults. The sheer prevalence of shoulder injuries in the country’s adult population and the low burden of proof placed on petitioners have made it attractive to file SIRVA petitions, even when such claims are dubious.¹⁷ 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, individuals could still file SIRVA and vasovagal syncope claims in state court¹⁸ where they would be required to prove causation between the manner of administration and the claimed injury. Requiring plaintiffs to prove causation in state court would mitigate the filing of frivolous claims in the VICP that are diminishing the Trust Fund.

Given Incorrectly, NBC Washington, <https://www.nbcwashington.com/investigations/Half-of-All-New-Federal-Vaccine-Injury-Cases-Allege-Shots-Given-Incorrectly-481441201.html> (explaining that “the program has no mechanism [due to privacy laws] to notify the shot-giver of the injury he or she likely caused,” and “[t]hus, they would have no reason to seek additional training”).

¹⁶ Peter H. Meyers, *Fixing the Flaws in the Federal Vaccine Injury Compensation Program*, 63 Admin. L. Rev. 785, 795 (2011).

¹⁷ 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 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”).

¹⁸ Or Federal district court if they satisfy the requirements of 28 U.S.C. 1332 or 28 U.S.C. 1367.

The removal of SIRVA and vasovagal syncope from the Table is intended to also preclude VICP claims for SIRVA or vasovagal syncope based on causation in fact, given that they are not injuries associated with vaccines or their components, nor are they unavoidable injuries or illnesses that cannot be predicted in advance, or that can occur without fault. While only eight and nine vasovagal syncope claims were filed in FY 18 and FY 19 respectively, the number of SIRVA claims has increased since the agency began suggesting that SIRVA could be a Table injury, and increased dramatically after SIRVA was in fact added to the Table in FY 17:

Fiscal year	Total number of SIRVA claims filed
FY 2010	5
FY 2011	10
FY 2012	20
FY 2013	34
FY 2014	116
FY 2015	225
FY 2016	433
FY 2017	605
FY 2018	671
FY 2019	711
FY 2020	227
Totals	3,057

Prior to SIRVA’s addition to the Table, SIRVA claims were sometimes awarded due to a combination of the government resolving the claims without litigating them to conclusion, and public statements by the Department suggesting SIRVA was a cognizable injury. The proposal to add SIRVA to the Table was in the works for several years before the 2015 notice of proposed rulemaking was published, and there was a great deal of public discussion about it at the ACCV and at the Court of Federal Claims’ annual judicial conference. The Department has in the past not always contested cases alleging injuries that have been proposed for addition to the Table if the case as pleaded fulfilled the criteria for entitlement to compensation. However, for the reasons discussed in this notice of proposed rulemaking, including the Department’s review of the statute and more recent scientific literature, the Department no longer believes such claims should be included on the Table or can be based on causation in fact, because they are not injuries associated with vaccines or their components, nor are they unavoidable injuries or illnesses that cannot be predicted in advance, or that can occur without fault.

In addition, DOJ informs the Department that, out of 2,214 SIRVA claims filed since 2017, DOJ has

identified 27 cases in which altered medical records have been filed, some of which involved changes to the site of vaccination. 2,214 SIRVA claims have been filed in this time period. Additionally, the median award for SIRVA claims is far higher than the damages awarded for comparable injuries in the civil tort system. See Memo re: Damages for Shoulder Injuries Outside of the Vaccine Program, Dep’t of Justice (Sept. 21, 2018) (indicating the median award for SIRVA claims resolved by stipulation, which ostensibly include a litigative risk discount, is \$71,355.26, but is \$22,530 for comparable claims awarded either by settlement or judgment in the civil tort system in 2015–2018); see also *Bossenbroek v. HHS*, 2020 WL 2510454, Appendix 2 (Fed. Cl. Spec. Mstr. Apr. 3, 2020) (citing the DOJ memo). The Department is concerned that the alteration of records and excessive awards to petitioners seen in SIRVA cases threaten the integrity of the VICP.

In FY 10, SIRVA claims made up 5 (1.1%) of the 448 claims filed in the VICP. However, for FY17–FY19, SIRVA claims made up 52.6% of all claims filed in the VICP. Thus, indications that SIRVA claims were cognizable and then adding SIRVA to the Table dramatically increased the number of claims filed in the VICP. Such claims, which are not associated with vaccines or their components, therefore erroneously suggest that vaccines are less safe than they in fact are. For example, if no SIRVA claims were filed, the number of claims filed in FY 19 would have fallen from 1,282 to 575. Thus, reductions in VICP petitions, particularly those claiming SIRVA, will support the overwhelming scientific understanding that vaccines are both safe and effective.

Item XVII

As discussed in further detail below, the Department also proposes to remove Item XVII from the Table found at 42 CFR 100.3(a), and to remove 42 CFR 100.3(e)(8), which describes the mechanism for adding new vaccines to Item XVII. The Department proposes these changes because it has serious concerns that Item XVII is contrary to law, including the 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, as discussed in more detail below. 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 March 6, 2020 and May 18, 2020.¹⁹ Four members of the ACCV also held a workgroup meeting on April 3, 2020 to discuss the proposed changes. 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 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. The ACCV’s findings and recommendations are discussed at page 26–31.

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 component alone 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 and from the QAI found at 42 CFR 100.3(c) 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 and the removal of 42 CFR 100.3(e)(8) 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 notwithstanding the recommendations of the ACCV, the Secretary makes the following findings:

Findings That Result in Removals From the Table Because the Evidence Favors Rejection of a Causal Relationship

1. The scientific evidence does not adequately support a causal relationship between any specific vaccine’s antigen or other component and SIRVA. For reasons detailed below, the Secretary proposes removing SIRVA from the Table.

2. The scientific evidence does not adequately support a causal relationship between any specific vaccine’s antigen or other components 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 relevant statutory provisions, the scientific literature, the Department’s experience since SIRVA and vasovagal syncope were added to the Table, and the recommendations of the ACCV and proposes that the Table set forth at 42 CFR 100.3(a) be revised to remove SIRVA, vasovagal syncope, and Item XVII, as described below. Due to these amendments, the Secretary also

proposes making the corresponding changes of removing 42 CFR 100.3(c)(10), 42 CFR 100.3(c)(13), and 42 CFR 100.3(e)(8), which describe the injuries or items that the Secretary proposes to remove from the Table. 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. 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 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 42 U.S.C. 300aa–16(b), 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. 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 injuries and Item XVII, as well as the Secretary’s rationale for the proposed Table changes, is provided.

¹⁹ The Department first provided the proposed revisions to the Table and requested recommendations and comments by the ACCV on or about February 15, 2020.

1. Shoulder Injury Related to Vaccination

SIRVA is 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.

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, 671 were SIRVA claims (54.2%). In Fiscal Year 2019, of the 1,282 claims filed, 711 were SIRVA claims (55.4%). Thus, the number of SIRVA claims have increased dramatically, having comprised only 5 (1.1%) of the 448 claims filed in Fiscal Year 2010 and 10 (2.6%) of the 386 claims filed in Fiscal Year 2011.

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; and intranasal 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.”²⁰

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 the injury of deltoid bursitis and vaccine injection *with a needle only*.²¹ The IOM did *not* find a causal connection between the injury of

deltoid bursitis and the components 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 “antigens or adjuvants contained in the vaccines that would trigger an immune or inflammatory response.”²² The evidence is thus insufficient to support an adequate causal connection between the contents of any vaccine by themselves and SIRVA.

As discussed above, it is the Department’s belief that SIRVA is not a “vaccine-related injury” and therefore should not be included on the Table or compensable under the VICP.²³ 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 altogether from the Table.

2. Vasovagal Syncope

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 January 19, 2017, the Department adopted the Final Rule adding vasovagal syncope to the Table. 82 FR 6294; 82 FR 11321. 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 IOM 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

²⁰ 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).

²¹ 42 U.S.C. 300aa–11, 300aa–14(e).

administration.”²⁴ 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.”²⁵ 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, such as 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.²⁶ The evidence is thus insufficient to support a causal connection between the contents of any vaccine and vasovagal syncope.

As discussed above, it is the Department’s belief that vasovagal syncope is not a “vaccine-related injury” and therefore should not be included on the Table or compensable under the VICP.²⁷ 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.

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.”²⁸ 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.

²⁴ 80 FR 45137.

²⁵ 80 FR 45137. *See also* IOM Report.

²⁶ 80 FR 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.

²⁷ 42 U.S.C. 300aa–11, 300aa–14(e).

²⁸ 42 CFR 100.3(a).

²⁰ 80 FR 45144.

²¹ 80 FR 45136. *See also* IOM Report.

The Department has serious concerns that Item XVII is contrary to law. The Vaccine 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.”²⁹ 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.”³⁰ 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.³¹ This may be inconsistent with the rulemaking requirements of the Administrative Procedure Act 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.

4. The ACCV's Recommendations and Comments

More than 90 days after it received the Department's proposed changes to the Table, on May 20, 2020 the ACCV sent a letter to the Secretary (May 20 Letter) explaining why it opposed the proposed changes.³² The Department is grateful to the ACCV for its time spent considering the proposed changes and for providing its comments.

However, the Department found the ACCV's comments not adequately

persuasive, and for the reasons stated above has decided to issue this notice of proposed rulemaking and provide for public comment and notice and opportunity for a public hearing. The May 20 Letter stated that, although rare, SIRVA and vasovagal syncope are injuries that can be caused by vaccination, so they should be eligible for compensation from the VICP. However, for the reasons stated herein, only “vaccine-related injuries or deaths,” as defined in the statute, are eligible for compensation. The May 20 Letter also stated that one intent of the VICP is to provide liability protection to vaccine manufacturers and administrators, and that removing SIRVA or vasovagal syncope could (1) result in higher malpractice premiums for those who administer vaccines and (2) disincentivize administering vaccines, thereby resulting in lower vaccination rates. However, the May 20 Letter failed to cite any evidence that these issues were problematic in the United States before SIRVA and vasovagal syncope were added to the Table in 2017, and the Department has been unable to locate any evidence that premiums have materially declined due to the addition of SIRVA and vasovagal syncope to the Table. Moreover, the vaccination rate has gone down slightly since SIRVA and vasovagal syncope were added to the Table.³³ The Department is grateful for the many health care professionals and pharmacists who improve public health by vaccinating the American public, and does not believe they would intentionally administer a vaccine in an improper manner, but the Department also wants to incentivize those who administer vaccines to do so properly. Doing so will improve public confidence in vaccinations.

The May 20 Letter also stated that the Vaccine Act has a subrogation clause which permits the Federal government to seek recompense if the VICP compensates a claim, but determines later that a health care professional was negligent in administering a vaccine. Thus, injury claims resulting from the administration of vaccines should still be eligible for VICP compensation. However, this subrogation provision does not properly incentivize the vaccine administrator, since it is unlikely that the Federal government would assert many claims against administrators, given the burden and expense compared to the relatively small potential recovery for the Federal

government. Individuals would have a greater incentive to assert such claims if the administrator were negligent.

The May 2020 Letter further stated that the explanations in the proposal that the Department submitted to the ACCV do not meet the tenets of the ACCV's Guiding Principles. As noted above, the Guiding Principles state: “When recommending changes to the Vaccine Injury Table (“the Table”), members of the Advisory Commission on Childhood Vaccines (ACCV) shall utilize the following overarching guiding principles:

- The Table should be scientifically and medically credible; and
- 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 are not binding on the Secretary.³⁴ Nonetheless, the Department believes that credible scientific and medical evidence supports removing SIRVA and vasovagal syncope from the Table. In addition, the Secretary must consider what will benefit the public, not only petitioners. Furthermore, in determining whether a proposed change benefits petitioners, it is important to consider all petitioners. The inclusion of SIRVA has harmed the petitioners with injuries that the VICP was primarily designed to compensate, including children, because the high number of SIRVA claims has significantly slowed down the adjudication process. The Vaccine Act established a compensation program that was “designed to work faster and with greater ease than the civil tort system.” *Bruesewitz v. Wyeth*, 562 U.S. 223, 228 (2011) (quoting *Shalala v. Whitecotton*, 514 U.S. 268, 269, (1995)). However, since 2017, the average amount of time for a case to finally resolve has increased significantly (from 575 days to 751 days). As of March 2020, 926 petitions awaited initial review, including 530 that had been filed in FY 2019.³⁵ Prior to FY 2014, there generally were not even 530 total petitions filed per year. Non-SIRVA cases, including those filed on behalf of children, are adversely affected as resources are stretched or diverted to litigate SIRVA cases. Because SIRVA claims are lucrative to pursue and simpler to prosecute than childhood vaccine injuries, there is little reason to

²⁹ 42 U.S.C. 300aa-14(c)(1).

³⁰ 42 U.S.C. 300aa-14(d).

³¹ 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.

³² <https://www.hrsa.gov/advisory-committees/vaccines/reports-recommendations.html>.

³³ *See, e.g.*, <https://www.cdc.gov/flu/fluview/coverage-1718estimates.htm>; <https://www.cdc.gov/nchs/data/hus/2018/031.pdf>.

³⁴ 80 FR 45134.

³⁵ <https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/meetings/2020/03062020-dicp-update.pdf>.

believe this is a temporary phenomenon.

The May 20 Letter also stated that since enactment of the Vaccine Act and the inception of the program, claims resulting from the administration of a vaccine have been filed and some have been compensated. The May 20 Letter added that the ACCV was not presented with any new peer-reviewed medical or scientific literature on SIRVA or syncope. Thus, since no new medical and scientific literature has been published about the proposed changes, HHS should not be proposing any changes to the Table. However, the proposal that the Department provided to the ACCV, as well as this notice of proposed rulemaking, includes the findings of additional studies concluded since SIRVA and vasovagal syncope were added to the Table. The Department has also learned from its experience since SIRVA and vasovagal syncope were added to the Table, and believes this experience supports the proposed changes. Additionally, the Department believes the changes are supported by the IOM, which found that (1) “the injection, and not the contents of the vaccine, contributed to the development of deltoid bursitis”³⁶ and (2) “the injection, and not the contents of the vaccine, contributed to the development of syncope.”³⁷ Thus, there was insufficient scientific evidence to support adding SIRVA and vasovagal syncope in the first place, as there was insufficient evidence that either are vaccine-related injuries.

The May 20 Letter added that the Trust Fund has a balance of over \$4 billion, so funds are available to pay valid claims resulting from the administration of vaccines. However, it is the Department’s belief that the availability of funds at this moment does not justify their dispersal for claims that are not associated with vaccines or vaccine components. Lastly, the May 20 Letter also recommended that the Secretary support an increase in the number of Special Masters and staffing and funding resources for the VICP in order to reduce the backlog caused by SIRVA claims. It is Congress’s decision whether to increase funding and the number of Special Masters. Moreover, any increase in staffing or funding by Congress would only address one of the several issues identified above.

The May 20 Letter did not provide any reasons why it opposed the

Department’s proposal to remove Item XVII from the Table.³⁸

One member of the ACCV sent a letter to the Secretary on May 26, 2020. The letter stated that the member was concerned that the large number of SIRVA claims has clogged the VICP, resulting in delayed resolution of claims; the large amount paid annually from the Trust Fund has reinforced vaccine hesitancy among some who incorrectly believe this figure reflects lack of vaccine safety; and the number of awards for SIRVA are in excess of the true number of cases. This member recommended revising the definition of SIRVA so that those with true shoulder injuries are able to recover while reducing the number of “inappropriate claims.” The Department believes the concerns expressed in this letter can best be accomplished by removing SIRVA from the Table. If SIRVA is removed from the Table, those with SIRVA injuries would still be able to recover in state court. Removal is preferable to redefining SIRVA, because it better addresses the vaccine hesitancy concern, is more in line with the Vaccine Act and Congressional intent, and incentivizes learning proper administration technique. Indeed, because Vaccine Act proceedings are generally sealed and not made available to the public, vaccine administrators often are left unaware that they used an improper technique.

IV. Statutory Authority

The primary statutory authority for this rulemaking is 42 U.S.C. 300aa–14. 42 U.S.C. 300aa–14(c)(1) provides that the “Secretary may promulgate regulations to modify in accordance with paragraph (3) the Vaccine Injury Table. In promulgating such regulations, he shall provide for notice and opportunity for a public hearing and at least 180 days of public comment.” 42 U.S.C. 300aa–14(c)(3), in turn, provides: “A modification of the Vaccine Injury Table under paragraph (1) may add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or may change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such

³⁸ The May 20 Letter also stated that the ACCV wished it could have heard from an HHS official who could provide the evidence and reasoning to support the proposal and to explain and discuss the original basis for the inclusion of SIRVA and vasovagal syncope on the Table. While perhaps an understandable concern, the proposal, which synthesized the views of many within the Department, was the Department’s best explanation for why it was proposing the changes to the Table.

injury, disability, illness, condition, or death.”

V. Request for Comment

HHS and HRSA request comment on all aspects of this proposed rule, including its likely costs and benefits and the impacts that it is likely to have on the public health, as compared to the current requirements under 42 CFR 100.3.

VI. Statutory and Regulatory Requirements

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 Department anticipates that the proposed rule would 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 may result in fewer individuals suffering from SIRVA or vasovagal syncope, because it will better 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

³⁶ IOM Report at 620.

³⁷ 80 FR 45137. See also IOM Report.

of the vaccine, those who administer vaccines will have greater incentive to use proper injection technique. In addition, the proposed rule may also limit the ability of those opposed to vaccinations to cite to the high number of SIRVA awards to misleadingly suggest that vaccines are less safe than they truly are.

The Department considered, as an alternative to this NPRM, issuing a NPRM that would revise the definition of SIRVA so that those with true shoulder injuries were able to recover while reducing the number of less appropriate claims. However, the Department concluded that removing SIRVA from the Table is preferable. If SIRVA is removed from the Table, those with actual SIRVA injuries would still be able to recover in state court. Removal is preferable to redefining SIRVA, because it better addresses the vaccine hesitancy concern, is more in line with the Vaccine Act and Congressional intent, and incentivizes learning and utilizing proper administration technique. Indeed, because Vaccine Act proceedings are generally sealed and not made available to the public, vaccine administrators often are left unaware that they used an improper technique.

The Department also considered, as alternatives to this NPRM, not removing one or more of (1) SIRVA, (2) vasovagal syncope, or (3) Item XVII from the Table. For the reasons discussed herein, the Department rejected these alternatives.

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 one year, or adversely or 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 must be prepared for major rules with economically significant effects (\$100 million or more in any one year), and a “significant” regulatory action is subject to Office of Management and

Budget (OMB) review. As discussed below regarding the anticipated effects, these proposals are not likely to have economic impacts of \$100 million or more in any one year, and therefore do not meet the definition of “economically significant” under Executive Order 12866. OMB has determined, however, that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Accordingly, this rule has been reviewed by OMB.

B. Economic and Regulatory Impact

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. If this proposed rule went into effect, 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. Should this rule be finalized as proposed, it is the Department’s belief that should the amounts paid equal 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.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act) (2 U.S.C. 1532) requires that covered agencies prepare a budgetary impact statement before promulgating a 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 in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately \$154 million. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires covered agencies to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. The Department

has determined that this proposed rule will not result in expenditures by State, local, and tribal governments, or by the private sector, of \$154 million or more in any one year. Accordingly, the Department has not prepared a budgetary impact statement or specifically addressed the regulatory alternatives considered.

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.

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 increase incremental costs, so it is not anticipated to be a regulatory or deregulatory action under Executive Order 13771. Public comments will inform the ultimate designation of this rule.

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 reducing the pool of funds available to those injured by vaccines or vaccine components. It will therefore align the Table with the Department’s understanding of Congress’ intent and

public policy in favor of compensating those harmed by injuries associated with the vaccine or vaccine components, and particularly children who have suffered such harm. The rule will also have the effect of ensuring that the limited compensation resources available under the National Vaccine Injury Compensation Program are provided to those with vaccine-related injuries or deaths. 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 Department's interpretation of the original intent of the VICP.

The rule will also better incentivize those who administer vaccines to use proper injection technique. It may also help correct misleading and erroneous suggestions that vaccines are not safe. Because COVID-19 and a potential COVID-19 vaccine are not currently on the Table, the Department does not believe this rule would have an impact on patients with COVID-19 or a COVID-19 vaccine. However, HHS requests public comment on this determination.

Moreover, the rule is unlikely to unduly burden the civil tort system. The Department conducted a search in the WestLaw legal database for cases in state court that contained both the terms "SIRVA" and "vaccine," and found only 20 hits, at least two of which were cases involving an entity named SIRVA and not the injury.³⁹ It is possible that some additional cases were filed in federal district court. Nonetheless, the Department believes based on this data that any additional burden on the civil tort system, which would be dispersed

across States and not concentrated in any one or few States, from removing SIRVA and vasovagal syncope from the Table and reverting to the status quo as of January 2017 will be minimal.

A. 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."

B. 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.

List of Subjects in 42 CFR Part 100

Biologics, Health insurance, Immunization.

Dated: June 22, 2020.

Thomas J. Engels,

Administrator, Health Resources and Services Administration.

Approved: July 9, 2020.

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, revise paragraph (a) and remove paragraphs (c)(10) and (13) and (e)(8).

The revision reads 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 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).

TABLE 1 TO § 100.3(a)—VACCINE INJURY TABLE

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT).	A. Anaphylaxis	≤4 hours.
	B. Brachial Neuritis	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	≤4 hours.
	B. Encephalopathy or encephalitis	≤72 hours.
III. Vaccines containing measles, mumps, and rubella virus or any of its components (e.g., MMR, MM, MMRV).	A. Anaphylaxis	≤4 hours.
	B. Encephalopathy or encephalitis	5–15 days (not less than 5 days and not more than 15 days).

³⁹ <https://1.next.westlaw.com/Search/Results.html?query=%22sirva%22%20%26%20%22vaccine%22&jurisdiction=ALLSTATES&savejuris=False&contentType=CASE&querySubmissionGuid=i0ad6ad3f00000>

1733a44933a7bf4372d&startIndex=1&searchId=i0ad6ad3f000001733a44933a7bf4372d&kmSearchIdRequested=False&simpleSearch=False&isAdvancedSearchTemplatePage=False&skipSpellCheck=False&isTrDiscoverSearch=False&thesaurus

Search=False&thesaurusTermsApplied=False&ancillaryChargesAccepted=False&proviewEligible=False&eventingTypeOfSearch=FRM&transitionType=Search&contextData=%28sc.Search%29.

TABLE 1 TO § 100.3(a)—VACCINE INJURY TABLE—Continued

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
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. —in a non-immunodeficient recipient	≤30 days.
	—in an immunodeficient recipient	≤6 months.
	—in a vaccine associated community case	Not applicable.
	B. Vaccine-Strain Polio Viral Infection	
	—in a non-immunodeficient recipient	≤30 days.
	—in an immunodeficient recipient	≤6 months.
	—in a vaccine associated community case	Not applicable.
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	≤4 hours.
	B. Disseminated varicella vaccine-strain viral disease. —Vaccine-strain virus identified	Not applicable.
	—If strain determination is not done or if laboratory testing is inconclusive.	7–42 days (not less than 7 days and not more than 42 days).
	C. Varicella vaccine-strain viral reactivation	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	≤4 hours.
	B. Guillain-Barré Syndrome	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.

* * * * *

[FR Doc. 2020–15673 Filed 7–16–20; 4:15 pm]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 414, 424, and 484

[CMS–1730–P]

RIN 0938–AU–06

Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Home Infusion Therapy Services Requirements

Correction

In proposed rule document 2020–13792 beginning on page 39408 in the

issue of Tuesday, June 30, 2020, make the following correction:

On page 39408, in the first column, in the DATES section, “August 31, 2020” should read “August 24, 2020”.

[FR Doc. C1–2020–13792 Filed 7–17–20; 8:45 am]

BILLING CODE 1301–00–D