1999); availability of voluntary consensus standards pursuant to Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113; tribal implications pursuant to Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000); environmental health or safety effects on children pursuant to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997); energy effects pursuant to Executive Order 13211, entitled *Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001); Paperwork burdens pursuant to the Paperwork Reduction Act (PRA) (44 U.S.C. 3501); or human health or environmental effects on minority or low-income populations pursuant to Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994). The Agency will consider such comments during the development of any subsequent rulemaking.

List of Subjects in 40 CFR Part 414

Environmental protection, Chemicals, Plastics materials and synthetics, Waste treatment and disposal, Water pollution control.

Jane Nishida,

Acting Administrator.

[FR Doc. 2021–05402 Filed 3–16–21; 8:45 am]

BILLING CODE 6560–50–P

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 withdrawal; request for comments.

SUMMARY: HHS proposes rescinding the final rule entitled ''National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table,'' published in the **Federal Register** on January 21, 2021. That final rule, if it were to go into effect, would amend our regulations by removing Shoulder Injury Related to Vaccine Administration (SIRVA), vasovagal syncope, and the new vaccines category (Item XVII) from the Vaccine Injury Table (Table). HHS seeks comments on this proposed rescission.

DATES: The final rule published January 21, 2021, at 86 FR 6249, delayed February 23, 2021, at 86 FR 10835, is proposed to be withdrawn. Written comments and related material to this proposed withdrawal must be received on or before April 16, 2021.

ADDRESSES: You may submit written comments electronically by the following method: *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions on the website for submitting comments.

Instructions. Include the HHS Docket No. HRSA–2021–0001 in your comments. All comments received will be posted without change to *http://www.regulations.gov.* Please do not include any personally identifiable or confidential business information you do not want publicly disclosed.

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 rescind the final rule titled ''National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table,'' (final rule), January 21, 2021, 86 FR 6249, delayed February 23, 2021, 86 FR 10835, which, if it were to go into effect, would amend the provisions of 42 CFR 100.3 by removing Shoulder Injury Related to Vaccine Administration (SIRVA), vasovagal syncope, and the new vaccines category (Item XVII) from the Table.

I. Background and Purpose

The National Childhood Vaccine Injury Act of 1986, title III of Public Law 99–660 (42 U.S.C. 300aa–10 *et seq.*) (Vaccine Act), established the National Vaccine Injury Compensation Program (VICP) 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 compensated. The Vaccine Act has been amended several times since 1986.

Petitions for compensation under this Program are filed in the United States Court of Federal Claims (Court), with a copy served on the Secretary, who is the ''Respondent.'' The Court, acting through judicial officers called Special Masters, makes findings as to eligibility for, and the amount of, compensation. To be found entitled to an award under the VICP, a petitioner must establish a vaccine-related injury or death, either by proving that a vaccine actually caused or significantly aggravated an injury (causation-in-fact) or by demonstrating the occurrence of what has been 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—corresponding to the vaccination in question, and that the onset of such injury took place within a time period also specified in the Table. The Table is accompanied by, among other provisions, the Qualifications and Aids to Interpretation (QAI), which defines the injuries and conditions listed on the Table. If these criteria are met, the injury is presumed to have been caused by the vaccination, and the petitioner is entitled to compensation (assuming that other requirements are satisfied), unless the respondent affirmatively shows that the injury was caused by some factor other than the vaccination (*see* 42 U.S.C. 300aa–11(c)(1)(C)(i), 300aa–13(a)(1)(B)), and 300aa–14(a)). Currently, cases are often resolved by negotiated settlements between the parties and approved by the Court. In such situations, HHS and the Court have not concluded, based upon review of the evidence, that the vaccine caused the alleged injury.

Revisions to the Table are authorized under the Vaccine Act (42 U.S.C. 300aa–14(c)–(e)). The Vaccine Act prohibits the Secretary of HHS from proposing a revision to the Table ''unless the Secretary has first provided to the [Advisory] Commission [on Childhood Vaccines] a copy of the proposed regulation or revision, requested recommendations and comments by the Commission, and afforded the Commission at least 90 days to make such recommendations'' (42 U.S.C. 300aa–14(d)). Further, once the proposed revision is published, the Secretary must afford the public at least 180 days of public comment (42 U.S.C. 300aa–14(c)(1)).

HHS added SIRVA and vasovagal syncope to the Table in March 2017, following an extensive, multi-year process that involved nine HHS workgroups, including HRSA and the

Centers for Disease Control and Prevention, and the 2012 Institute of Medicine report, ''Adverse Effects of Vaccines: Evidence and Causality,'' 82 FR 6294–95. The notice of proposed rulemaking (NPRM) provided a 180-day comment period that resulted in the receipt of 14 written comments; 13 from individuals and one from a national organization (*Id.* at 6296). In addition, a public hearing on the proposed rule was held on January 14, 2016 (*Id.*). Almost a year after considering the 14 written comments and the remarks at the public hearing, HHS issued the final rule that added SIRVA and vasovagal syncope to the Table (*Id.* at 6294).

On July 20, 2020, HHS published an NPRM proposing to amend the Table by removing SIRVA, vasovagal syncope, and new vaccines category (Item XVII), 85 FR 43794. 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.'' SIRVA and vasovagal syncope are also listed as associated injuries for this category. That NPRM stated that HHS provided its proposed revisions to the Advisory Commission on Childhood Vaccines (ACCV) for its comments ''on or about February 15, 2020,'' and that ''[a]s part of its mandate under the [Vaccine] Act, the ACCV considered the proposed changes set forth in this NPRM on March 6, 2020, and May 18, 2020'' (*Id.* at 43799 & n. 19). However, the NPRM was not officially provided to the ACCV as a group in mid-February 2020, and, while the statute requires the Secretary to request ''recommendations and comments by the Commission,'' instead the draft NPRM was mailed in hard copy to each of the ACCV members, marked ''privileged and confidential,'' with a request for comments from the individual members. Although the then-Chair started the first brief discussion of the draft NPRM at the ACCV meeting on March 6, 2020, the draft NPRM was not on the agenda (*see https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/meetings/2020/accv-agenda-march2020.pdf),* and no members of the ACCV other than the then-Chair knew in advance that it would be discussed. One ACCV member commented at the meeting that she thought that the members were not permitted to discuss the draft NPRM. Several members stated that they had questions about the draft NPRM and wished to have further discussion (*see https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/meetings/2020/accv-march-meeting-minutes.pdf*).

At the May 18, 2020, ACCV meeting, three ACCV members expressed their concern that no HHS representative was present to explain the draft NPRM, provide scientific evidence in support, or discuss the recommendations with the ACCV members (*see https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/meetings/2020/accv-may-meeting-minutes.pdf*). It was highly unusual for HHS to propose a revision to the Table without sending an agency representative to discuss the proposal with the ACCV. The ACCV unanimously voted to oppose the proposed changes to the Table, and sent a recommendation to the Secretary opposing the draft NPRM for many reasons including: (1) No representative from HHS was made available to provide the evidence and reasoning behind the draft NPRM; (2) SIRVA and vasovagal syncope, though rare, are injuries caused by vaccines; (3) exposing vaccine administrators to civil liability could be a disincentive to vaccine administration and result in lower vaccination rates; and (4) the explanation in the draft NPRM did not meet the ACCV's guiding principles for recommending changes to the VICP Table (*see https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/reports/accv-recommendation-may-2020.pdf*).

On October 29, 2020, HHS published in the **Federal Register** a Notice that a hearing on the NPRM would be held on November 9, 2020, 85 FR 68540. Unfortunately, that **Federal Register** Notice incorrectly gave a deadline of October 26, 2020 (three days earlier than the Notice was published) for individuals to register to speak at the hearing, 85 FR 68540. A correction extending the deadline to November 5, 2020, was published in the **Federal Register** on November 6, 2020 (one day after the deadline), 85 FR 71046. Despite these notice issues, 26 individuals spoke at the public hearing; all were opposed to the NPRM (*see https://www.regulations.gov/document/HRSA-2020-0002-0373*).

The comment period for the NPRM closed on January 12, 2021, at 11:59 p.m. HHS received over 760 comments. Over 150 of those comments, more than 20 percent, were posted on the last day of the comment period or the next day, since some comments were received after normal business hours. Four business days later, on January 19, 2021, the **Federal Register** posted for public inspection the final rule amending the Table.

Both the final rule and the NPRM included the following instruction: ''In § 100.3, revise paragraph (a) and remove paragraphs (c)(10) and (13) and (e)(8). The revision reads as follows:'' Removing paragraphs (c)(10) and (c)(13) would strike the definitions of SIRVA and vasovagal syncope, respectively, from the QAI, and removing (e)(8) would strike the new vaccines category (Item XVII of the Table) from the Coverage Provisions section of the regulation. However, what followed the instruction was only subsection (a) and the Table itself, but not the rest of the regulation, including the revised (c) QAI and (e) Coverage Provisions, which are a critical part of the regulation, 86 FR 6267; 85 FR 43804. Furthermore, the version of the Vaccine Injury Table that is currently displayed on the eCFR includes a link titled ''Link to an amendment published at 86 FR 6267, Jan. 21, 2021.'' This link displays only the Vaccine Injury Table that was published in the final rule (*see https://www.ecfr.gov/cgi-bin/text-idx?SID=f5f03d551be5379a43b4de00614dafaa&mc=true&node=20210121y1.4*). However, it does not include the (b) Provisions that apply to all conditions listed, (c) QAI, (d) Glossary for purposes of paragraph (c), and/or (e) Coverage Provisions sections of the Table.

On January 20, 2021, the first day of the new Administration, the President's Chief of Staff sent a memorandum entitled ''Regulatory Freeze Pending Review,'' which, among other things, instructed federal agencies to, ''[w]ith respect to rules that have been sent to the OFR but not published in the **Federal Register**, immediately withdraw them from the OFR for review and approval'' (*https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/regulatory-freeze-pending-review/*). The final rule was published in the **Federal Register** on January 21, 2021, with an effective date of February 22, 2021, 86 FR 6249.

The Regulatory Freeze Memorandum also instructed federal agencies to consider delaying the effective date of rules published in the **Federal Register**, but which have not yet taken effect, for a period of 60 days so that the new Administration may review recently published rules for ''any questions of fact, law, and policy the rule may raise'' (*see https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/regulatory-freeze-pending-review/*).

Pursuant to that direction, and after a brief public comment period, effective February 22, 2021, HHS delayed the effective date of the final rule until

April 23, 2021, so that the new Administration could review the final rule for ''any questions of fact, law, and policy the rule may raise'' (86 FR 10835). Specifically, HHS delayed the final rule to determine whether its promulgation raised any legal issues, including but not limited to (1) whether ACCV was properly notified of the proposed rule pursuant to 42 U.S.C. 300aa–14(c) and (d), and (2) whether the public was properly notified of the entire revised regulation, 42 CFR 100.3(b)–(e) (including the qualifications and aids to interpretation and the coverage provisions), given that both the proposed and final rules published in the **Federal Register** included only the revised Vaccine Injury Table itself, but not the entire revised regulation (*Id.* at 10835–36).

II. Discussion of Proposed Rescission

HHS proposes to rescind the final rule published on January 21, 2021, for both procedural and policy reasons. HHS has already been alerted to the fact that members of the public believe that the promulgation of the final rule was irregular in its haste, which stands in contrast to the extensive, multi-year process HHS followed to add SIRVA and vasovagal syncope to the Table in March 2017, and that HHS did not fully engage with either the ACCV or the public regarding its rationale behind the NPRM to subsequently remove these conditions from the Table. HHS agrees that the rule's promulgation further raises problematic issues related to the perceived procedural defects. Members of the public have raised concern that this Table modification was highly unusual because HHS failed to appear before the ACCV to discuss its proposed modification to the Table, and modified the Table over the opposition of the ACCV. Although HHS is not legally required to appear before the ACCV or accept the ACCV's recommendations, HHS acknowledges the ACCV's valid complaints that it was not able to fully engage in the process, which arguably runs counter to the ACCV's statutory purpose. Commenters and the ACCV itself pointed out that the method of transmittal of the NPRM to the ACCV and the manner in which it was introduced at the March 6, 2020 ACCV meeting raises concerns regarding whether the ACCV as a body had the full 90 days to make recommendations, as required by the Vaccine Act. HHS agrees that there is a legitimate question as to whether the ACCV received the full 90 days to make recommendations. Moreover, the paucity of time between the close of the comment period and the posting of the final rule for public inspection the day before the change in administration, with publication the day after, has raised doubts from the public regarding whether all public comments were sufficiently reviewed, considered, and responded to under Administrative Procedure Act (APA) standards. Given the numerous concerns that have already been raised and the questions that surround the final rule's promulgation, HHS proposes rescinding the final rule so that, if it chooses to proceed with removing SIRVA, vasovagal syncope, and the new vaccines category (Item XVII) from the Table, it does so with sufficient time to carefully and methodically review the policy, science, and law regarding these items and creates a transparent record of the process that clearly complies with all Vaccine Act and APA requirements.

As a policy matter, HHS also is proposing to rescind the final rule because it is concerned that it could have a negative impact on vaccine administrators, which would be at odds with the federal government's efforts to increase vaccinations in the United States to respond to the Coronavirus Disease 2019 (COVID–19) pandemic, as well as to make up for observed delays in routine vaccinations that have occurred during the pandemic.

The COVID–19 public health emergency was first declared on January 27, 2020, and continues to impact the nation.[1] On January 21, 2021, the White House published the National Strategy for the COVID–19 Response and Pandemic Preparedness (*see https://www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-COVID-19-Response-and-Pandemic-Preparedness.pdf*) (National Strategy). Goal 2 of the National Strategy is to ''Mount a safe, effective, comprehensive vaccination campaign,'' and provides:

> The United States will spare no effort to ensure Americans can get vaccinated quickly, effectively, and equitably. The federal government will execute an aggressive vaccination strategy, focusing on the immediate actions necessary to convert vaccines into vaccinations, including improving allocation, distribution, administration, and tracking. Central to this effort will be additional support and funding for state, local, Tribal, and territorial governments—and improved line of sight into supply—to ensure that they are best prepared to mount local vaccination programs. At the same time, the federal government will mount an unprecedented public campaign that builds trust around vaccination and communicates the importance of maintaining public health measures such as masking, physical distancing, testing, and contact tracing even as people receive safe and effective vaccinations.

(*Id.* at 8).

In carrying out the National Strategy, the federal government has taken a number of recent actions. It has increased access to vaccines by creating the Federal Retail Pharmacy Program for COVID–19 Vaccination to provide COVID–19 vaccinations in more locations through various non-federal partners (*see https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html/*). It is also taking steps to increase the number of vaccine administrators. As President Biden stated to NIH Staff on February 11, 2021, ''We're now allowing retired doctors and nurses to come back and administer shots. We're deploying federal vaccinators, and over the last three weeks, we put hundreds of new vaccinators in the field and are lining up thousands more. These include medical personnel from our Commissioned Corps at the Department of Health and Human Services, as well as personnel from FEMA, the Defense Department, and more departments to come.'' (*see https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/02/11/remarks-by-president-biden-to-national-institutes-of-health-staff/*). Although the COVID–19 vaccine is not part of the VICP, HHS is cognizant of the fact that any action taken that concerns administration of other vaccines could impact the National Strategy's goals and affect the federal government's efforts to combat COVID–19. It is partially due to this unprecedented vaccination effort and the concern that the final rule's revisions to the Table could negatively impact the vaccine administrators carrying out this massive campaign that HHS proposes to rescind the final rule.

HHS received comments in response to the February 12, 2021, NPRM that proposed to delay the effective date of the final rule that raised concerns from the public and interested organizations that the changes to the Table in the final rule would be particularly detrimental to vaccine administrators during the COVID–19 pandemic. For example, the American Pharmacists Association (APhA) and the National Alliance of State Pharmacy Associations (NASPA) supported delaying the final rule, and urged HHS to rescind it. APhA and NASPA stressed that, ''During a pandemic is not the time to make changes to the Vaccine Injury Table, when we are working as a nation to

[1] *See* ''Renewal of Determination That A Public Health Emergency Exists, ''which was first declared on January 27, 2020 and was last renewed on January 21, 2021, at *https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-07Jan2021.aspx.*

optimize the manufacture, distribution, and administration of COVID–19 and other critical vaccinations.'' (*see https://www.regulations.gov/comment/HRSA-2021-0001-0022*). These organizations further explained they opposed the ''removal of SIRVA and syncope from the Table because such a move would put a significant damper on vaccine research and development, the willingness of healthcare providers, including pharmacists, to administer vaccines, as well as the public's willingness to get vaccinated without the protections provided by the National Vaccine Injury Compensation Program (VICP).'' (*Id.*) Furthermore they stated, ''Removing [SIRVA and syncope] might discourage providers from vaccinating if they are concerned about being sued in court for these vaccine injuries.'' (*Id.*)

The National Association of Chain Drug Stores (NACDS) also supported delaying the final rule, and urged HHS to withdraw it, claiming it contained ''policies that will serve to inhibit vaccine availability thus leading to poorer public health outcomes.'' (*see https://www.regulations.gov/comment/HRSA-2021-0001-0017*).

Another commenter stated, ''The proposed Amendment to the Vaccine Injury Compensation Table is contrary to the purpose of the Act. It exposes doctors, nurses, health care workers and pharmacies to civil tort liability for administering a vaccine, which causes arm or shoulder injuries. The result will be more obstacles to the administration of vaccines as well as ultimately less Americans receiving vaccines availability thus leading to poorer public health outcomes.'' (*see https://www.regulations.gov/comment/HRSA-2021-0001-0004*).

HHS seeks comment by April 16, 2021 on the proposed rescission of the final rule, including on the issues raised above related to the final rule's promulgation and the impact the final rule could have on vaccine administrators.

III. Regulatory Impact Analysis

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that provide the greatest net benefits (including potential economic, environmental, public health, safety, distributive, and equity effects). In addition, under the Regulatory Flexibility Act, if a rule has a significant economic effect on a substantial number of small entities, HHS must specifically consider the economic effect of a rule on small entities and analyze regulatory options that could lessen the impact of the rule.

The Office of Information and Regulatory Affairs has determined that this rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866.

HHS has determined that no resources are required to implement the requirements in this rule because compensation will continue to be made consistent with the status quo. Therefore, in accordance with the Regulatory Flexibility Act of 1980 (RFA), and the Small Business Regulatory Enforcement Act of 1996, which amended the RFA, HHS certifies that this rule will not have a significant impact on a substantial number of small entities.

HHS has also determined that this rule does not meet the criteria for a major rule under the Congressional Review Act *or* Executive Order 12866 and would have no major effect on the economy or Federal expenditures. Similarly, it will not have effects on State, local, and tribal governments and on the private sector such as to require consultation under the Unfunded Mandates Reform Act of 1995. Nor on the basis of family well-being will the provisions of this rule affect the following family elements: Family safety; family stability; marital commitment; parental rights in the education, nurture and supervision of their children; family functioning; disposable income or poverty; or the behavior and personal responsibility of youth, as determined under section 654(c) of the Treasury and General Government Appropriations Act of 1999.

Paperwork Reduction Act of 1995

This rule has no information collection requirements.

Norris Cochran,

Acting Secretary, Department of Health and Human Services.

[FR Doc. 2021–05486 Filed 3–12–21; 4:15 pm]

BILLING CODE 4165–15–P