



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 42 CFR Part 100

### RIN 0906-AB24

## National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table; Delay of Effective Date

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

**ACTION:** Final rule; delay of effective date

**SUMMARY:** In accordance with the Presidential directive as expressed in the memorandum of January 20, 2021, from the Assistant to the President and Chief of Staff, entitled “Regulatory Freeze Pending Review,” this action delays until April 23, 2021, the effective date of the rule entitled “National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table,” published in the Federal Register on January 21, 2021 (January 21, 2021 Final Rule).

**DATES:** As of February 22, 2021, the effective date of the January 21, 2021 Final Rule, published in the *Federal Register* at 86 FR 6249, is delayed for 60 days, from February 22, 2021 to April 23, 2021.

**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](mailto:vaccinecompensation@hrsa.gov); or by telephone at (855) 266-2427.

### SUPPLEMENTARY INFORMATION:

#### I. Background

HHS published a notice of proposed rulemaking on July 20, 2020 (85 FR 43794), and a final rule on January 21, 2021 (86 FR 6249). The January 20, 2021 Final Rule amended the

provisions of 42 CFR 100.3 by removing Shoulder Injury Related to Vaccine Administration (SIRVA), vasovagal syncope, and Item XVII from the Vaccine Injury Table. The January 20, 2021 memorandum from the Assistant to the President and Chief of Staff, entitled “Regulatory Freeze Pending Review,” 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.” The memorandum notes certain exceptions that do not apply here. On January 20, 2021, the Office of Management and Budget (OMB) also published OMB Memorandum M-21-14, Implementation of Memorandum Concerning Regulatory Freeze Pending Review, which provides guidance regarding the Regulatory Freeze Memorandum. See OMB M-21-14, Implementation of Memorandum Concerning Regulatory Freeze Pending Review, <https://www.whitehouse.gov/wp-content/uploads/2021/01/M-21-14-Regulatory-Review.pdf>. OMB M-21-14 explains that pursuant to the Regulatory Freeze Memorandum, agencies “should consider postponing the effective dates for 60 days and reopening the rulemaking process” for “rules that have not yet taken effect and about which questions involving law, fact, or policy have been raised.” *Id.*

On February 12, 2021, HHS published a notice of proposed rulemaking, proposing, after a brief public comment period, to delay the effective date of the January 21, 2021 Final Rule for 60 days, from February 22, 2021, to April 23, 2021. HHS did so to determine whether the January 21, 2021 Final Rule’s promulgation raises any legal issues, including but not limited to (1) whether the Advisory Commission on Childhood Vaccines (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.

HHS received 29 comments on the notice of proposed rulemaking, most in support of the delay of the effective date to April 23, 2021, with only two anonymous comments against. After careful consideration of the comments received, HHS has decided to delay the January 21, 2021 Final Rule's effective date to April 23, 2021. HHS continues to believe that the delay is reasonable and will not be disruptive because the underlying rule has not yet been implemented or taken effect.

Section 553(d) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) requires that Federal agencies provide at least 30 days after publication of a final rule in the Federal Register before making it effective, unless good cause can be found not to do so. HHS finds that there is good cause for making this final rule effective less than 30 days after publication in the Federal Register given that failure to do so would result in the January 21, 2021 Final Rule going into effect before it can be reviewed by the new Administration pursuant to the Regulatory Freeze Memorandum and OMB M-21-14, and because the majority of public comments received support the delay and HHS's plans to more closely review the January 21, 2021 Final Rule's promulgation for both procedural and policy reasons.

## **II. Analysis and Responses to Public Comments**

In the notice of proposed rulemaking, HHS solicited comments regarding whether to delay the January 21, 2021 Final Rule's effective date for 60 days, from February 22, 2021, to April 23, 2021. We received 29 comments. The 27 comments in support of the delay of the effective date of the January 21, 2021 Final Rule to April 23, 2021, were from a broad range of patients, vaccine attorneys and legal clinics, biotech trade associations, pharmacist and drug store associations, and non-profit organizations. HHS only received two anonymous comments opposing the delay of the effective date of the January 21, 2021 Final Rule. HHS took into consideration comments on the underlying rule to the extent they shed light on the reasons commenters were for or against the delay; other comments that raised issues beyond the scope of the proposed rule delaying the effective date are not addressed here, but will be considered by

the agency in determining future actions related to the underlying rule. We have summarized the relevant comments received and provided our answers below.

Eight commenters, including the Biotechnology Innovation Organization, American Association for Justice, Walgreens, and the National Association of Chain Drug Stores, support delaying the January 21, 2021 Final Rule because they believe that the rule contravenes the purpose of the National Childhood Vaccine Injury Act. Thirteen commenters, including the National Community Pharmacists Association, the Vaccine Injured Petitioners Bar Association, the American Pharmacists Association, the National Alliance of State Pharmacy Associations, and various petitioners' attorneys, support the delay of the final rule because they believe the final rule did not adequately take into account the recommendations of the ACCV or the public. Four commenters, including a petitioner's attorney, supported the delay so that, pursuant to the Regulatory Freeze memorandum, the new Administration may review the rule and the comments submitted during that rulemaking process. Another commenter expressed concern with the promulgation of the final rule, specifically that the contents of the November 9, 2020 hearing have not been made publicly available, and as such supported the delay. Many commenters who said they had their own SIRVA injuries supported the delay. Finally, four commenters stated that the January 21, 2021 Final Rule contravenes the science surrounding SIRVA. HHS agrees that delaying the effective date of the final rule would provide the agency time to ensure the rule was properly promulgated and consider the other issues surrounding the rule.

Two anonymous commenters opposed the delay of the final rule. One anonymous commenter stated the final rule should go into effect without delay for the reasons stated in the Department of Justice's (DOJ) May 15, 2020 letter. See <https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/hunt-letter-sirva.pdf>. That letter outlines DOJ's views with respect to the July 20, 2020 notice of proposed rulemaking (NPRM) (85 FR 43794), specifically the view that SIRVA should not be a compensable injury under the VICP, but does not discuss why the commenter opposes delaying the effective date of

the final rule. As such, HHS is unable to respond to this comment as it does not state why the commenter does not support the delay.

The other anonymous commenter asserted, without indicating the factual basis for the assertion, that the ACCV had been properly notified about the NPRM to remove SIRVA, vasovagal syncope, and Item XVII from the Table. Furthermore, the anonymous commenter pointed out that “HHS says it needs time to determine whether the ACCV ‘was properly notified of the proposed rule pursuant to 42 U.S.C. 300aa-14(c).’ 86 FR 9308, 9309 (Feb. 12, 2021) (the notice refers to 42 U.S.C. 300aa-14(c), but presumably it meant to refer to 300aa-14(d).)” HHS disagrees with this commenter’s views about the ACCV and is concerned that the ACCV may not have been properly notified. We also note that 300aa-14(c) discusses the process for promulgating regulations to revise the Table, but agree that section that 300aa-14(d) discusses the role of the ACCV in the regulation process more specifically. That subsection states the “Secretary may not propose a regulation under subsection (c) or any revision thereof, unless the Secretary has first provided to **the Commission** 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.” [emphasis added] Per the March 6, 2020 ACCV meeting minutes, found at <https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/meetings/2020/accv-march-meeting-minutes.pdf>, ACCV members said during the March meeting that, because the NPRM was marked as “privileged and confidential” and was not on the agenda for the meeting, they were uncertain whether they were allowed to discuss the NPRM at the ACCV meeting as a group. The fact that ACCV members were uncertain as to whether the ACCV as a group could discuss the NPRM at that meeting raises the issue about whether the ACCV as a whole actually was provided with the statutorily-required 90 days to provide its comments and recommendations on the NPRM. This sentiment was echoed in the May 18, 2020 meeting minutes, found at <https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/meetings/2020/accv->

may-meeting-minutes.pdf, where, for an example, an ACCV member raised the issue that “ACCV commissioners received this draft VICP NPRM in February of 2020, at that time commissioners were told it was privileged, confidential document that could not be discussed. It was not on the agenda for the March 6, 2020 meeting.” While the member acknowledged a brief discussion did occur, it remains clear that not all ACCV members believed they could discuss the NPRM during the March meeting. In a letter to the Secretary of HHS dated May 20, 2020, with the recommendation to oppose the proposed changes to the Table, the ACCV again expressed dissatisfaction with the ACCV recommendation process, stating, “During its March 6 Meeting, the Commission briefly discussed this draft NPRM; however, no representative from HHS was present to address questions from ACCV members, and discussion of the draft NPRM was not an agenda item. Therefore, ACCV members requested, among other things, a meeting with an HHS official to respond to their questions about the NPRM. Thus, the May 18, 2020 meeting was scheduled, but an HHS official who could respond to the ACCV's questions did not attend.” (See <https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/reports/accv-recommendation-may-2020.pdf>.)

That anonymous commenter also stated that the public was made aware of the entire revised regulation, including the qualifications and aids to interpretation and coverage provisions, because “the NPRM and the Final Rule provide: ‘In 100.3, revise paragraph (a) and remove paragraphs (c)(10) and (13) and (e)(8).’ 85 FR 43,804; 86 FR 6249, 6267 (Jan. 21, 2021).” The anonymous commenter said he or she believes it is sufficient to refer solely to the paragraphs being removed, and not spell out the entire revised regulation. However, the final rule says, “In § 100.3, revise paragraph (a) and remove paragraphs (c)(10) and (13) and (e)(8). The revision reads as follows...” After the “as follows,” the only text that is included is the Table itself, and not the revised qualifications and aids to interpretation and coverage provisions. Therefore, the language in the proposed and final rules is ambiguous because it implies that the entirety of the revised regulation is included, but then only includes the Table itself.

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, and this delay will permit HHS to clarify these seemingly conflicting instructions concerning 42 CFR 100.3(b)–(e).

### **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.

### **Impact of the New Rule**

This rule extends the effective date of the final rule titled “National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table” until April 23, 2021, to determine whether that rule’s promulgation raises any legal issues. This delay is reasonable and will not be disruptive because the underlying rule has not yet been implemented or taken effect.

### **Paperwork Reduction Act of 1995**

This rule has no information collection requirements.

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**Norris Cochran,**

*Acting Secretary,*

*Department of Health and Human Services.*