DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 100

RIN 0906–AB24

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

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

ACTION: Final rule; withdrawal.

SUMMARY: This action rescinds in its entirety 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 April 22, 2021, the January 21, 2021 Final Rule, published in the **Federal Register** at 86 FR 6249, which was delayed at 86 FR 10835 on February 23, 2021, is withdrawn.

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:

I. Background

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 it was first enacted in 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 of Health and Human Services (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 [1] (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),[2] 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 reached a conclusion, based upon review of the evidence, whether 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 from proposing a revision to the Table's list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided, or to the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition, or death, ''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)). The Advisory Commission on Childhood Vaccines (ACCV) advises and makes recommendations to the Secretary on issues relating to the operation of the VICP (*see generally* 42 U.S.C. 300aa–19). Further, once the proposed revision is published, the Vaccine Act requires the Secretary to provide for a public hearing and at least 180 days of public comment (42 U.S.C. 300aa–14(c)(1)). To add a new category of vaccines to the Table, that category also must be recommended for routine administration to children or pregnant women by the Centers for Disease Control and Prevention (CDC), be made subject to an excise tax by Federal law, and be added to the VICP by the Secretary within two years of the CDC's recommendation (42 U.S.C. 300aa–14(e)).

HHS added Shoulder Injury Related to Vaccine Administration (SIRVA) and vasovagal syncope to the Table in March 2017, following an extensive, multi-year process that involved nine HHS workgroups comprising HRSA and CDC medical staff reviewing the 2012 Institute of Medicine report, ''Adverse Effects of Vaccines: Evidence and Causality,'' [3] as well as other then-newly published scientific literature not contained in the report (82 FR 6294–95). The ACCV considered the proposed changes to add SIRVA and vasovagal syncope to the Table in its meetings on March 8, 2012, September 5, 2013, December 5, 2013, June 5, 2014, and September 4, 2014 (80 FR 45134). On July 29, 2015, a notice of proposed rulemaking (NPRM) was published (80 FR 45132), which provided a 180-day public comment period that resulted in the receipt of 14 written comments; 13 from individuals and one from a national organization (82 FR 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, on January 19, 2017, HHS issued the final rule that added SIRVA and vasovagal syncope to the Table, with an effective date of February 21, 2017 (*Id.* at 6294). Pursuant to a January 20, 2017 memorandum from the Assistant to the President and Chief of Staff, titled ''Regulatory Freeze Pending Review,'' the effective date of the final rule adding SIRVA and vasovagal syncope to the

[1] *https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/vaccine-injury-table.pdf.*

[2] These requirements generally include that: (1) The person bringing the petition qualifies as a petitioner under the Vaccine Act; (2) the petitioner filed the petition within the statute of limitations; (3) the individual who sustained the vaccine-related injury has not collected a prior award or settlement of a civil action for the vaccine-related injury (or no prior award or settlement of a civil action was made on their behalf); (4) the vaccine was administered within the United States or its trust territories; and, (5) the individual who sustained the vaccine-related injury suffered the residual effects or complications of the injury for more than six months, died, or was hospitalized and underwent surgical intervention in response to the vaccine-related injury. *See generally* 42 U.S.C. 300aa–11(b)–(c), 300aa–16(a)–(b).

[3] *https://www.ncbi.nlm.nih.gov/books/NBK190024/.*

Table was delayed until March 21, 2017 (82 FR 11321).

On July 20, 2020, HHS published an NPRM proposing to amend the Table by removing SIRVA, vasovagal syncope, and the new vaccines category, Item XVII (85 FR 43794). A final rule amending the Table was published on January 21, 2021 (86 FR 6249). Pursuant to the Regulatory Freeze Memorandum dated January 20, 2021, and after a brief public comment period, effective February 22, 2021, HHS delayed the effective date of the January 21, 2021 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 January 21, 2021 Final Rule to determine whether its promulgation raised any legal issues, including but not limited to (1) whether the 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 QAI 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). On March 17, 2021, HHS published an NPRM to rescind the January 21, 2021 Final Rule (86 FR 14567).

Summary of the Final Rule

This final rule rescinds the January 21, 2021 Final Rule entitled ''National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table'' (86 FR 6249), which, if it were to go into effect, would amend the provisions of 42 CFR 100.3 by removing SIRVA, vasovagal syncope, and the new vaccines category (Item XVII) from the Table.

HHS is rescinding the January 21, 2021 Final Rule for both procedural and policy reasons. HHS had already been alerted, and commenters to the March 17, 2021 NPRM reiterated, that members of the public believe that the promulgation of the January 21, 2021 Final Rule was irregular in its haste, and that HHS did not fully engage with either the ACCV or the public regarding its rationale behind the July 20, 2020 NPRM and its proposed amendments to the Table. The promulgation of the January 21, 2021 Final Rule stands in contrast to the extensive, multi-year process HHS followed to add SIRVA and vasovagal syncope to the Table in March 2017.

Specifically, the July 20, 2020 NPRM stated that HHS provided its proposal to remove SIRVA, vasovagal syncope, and Item XVII from the Table to the 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'' (85 FR 43799 & n. 19). However, the draft 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*). In the past, when HHS has proposed a revision to the Table, it has sent 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 Notification that a hearing on the July 20, 2020 NPRM would be held on November 9, 2020 (85 FR 68540). Unfortunately, that **Federal Register** Notification 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 (*Id.*). 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 notification issues, 26 individuals spoke at the public hearing; all were opposed to the NPRM (*see https://www.regulations.gov/document/HRSA-2020-0002-0373*).

Both the January 21, 2021 Final Rule and the July 20, 2020 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 (13) would strike the definitions of SIRVA and vasovagal syncope, respectively, from the QAI, and removing paragraph (e)(8) would strike the new vaccines category (Item XVII of the Table) from the Coverage Provisions section of the regulation. What followed the instruction was paragraph (a) and the Table itself. The rest of the regulation, including the revised paragraph (c) QAI and paragraph (e) Coverage Provisions, which are a critical part of the regulation (86 FR 6267; 85 FR 43804), were not included in the instruction and therefore were not included in the revised regulations set out following the instruction. 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 January 21, 2021 Final Rule (*see https://www.ecfr.gov/cgi-bin/text-idx?SID=f5f03d551be5379a43b4de00614dafaa&mc=true&node=20210121y1.4*). It also does not include paragraph (b) Provisions that apply to all conditions listed, paragraph (c) QAI, paragraph (d) Glossary for purposes of paragraph (c), and/or paragraph (e) Coverage Provisions sections of the Table, because those revisions were not included in the instruction and therefore were not included in the

revised regulations set out following the instruction.

As a policy matter, HHS is rescinding the January 21, 2021 Final Rule because it is concerned that it would have a negative impact on vaccine administrators, which would be at odds with the Federal Government's efforts to increase confidence in vaccinations in the United States, particularly in light of efforts to respond to the Coronavirus Disease 2019 (COVID–19) pandemic, as detailed in the March 17, 2021 NPRM. On March 16, 2021, the then-Acting Secretary issued a Seventh Amendment to the Public Readiness and Emergency Preparedness (PREP) Act Declaration to, among other things, add additional categories of qualified people authorized to prescribe, dispense, and administer COVID–19 vaccines authorized by the U.S. Food and Drug Administration, including dentists, EMTs, midwives, optometrists, paramedics, physician assistants, podiatrists, respiratory therapists, and veterinarians (86 FR 14462).

Given this unprecedented vaccination effort and the concern that the January 21, 2021 Final Rule's revisions to the Table could negatively impact the COVID–19 vaccination campaign, as well as other campaigns such as annual influenza vaccination efforts, and the January 21, 2021 Final Rule's associated procedural issues, HHS is rescinding that rule.

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 removal of SIRVA and vasovagal syncope from the Table for 30 days, which would result in logistical and legal uncertainty regarding injuries allegedly received, petitions filed, and petitions adjudicated during that 30-day period. That same uncertainty also applies to the status of 42 CFR 100.3(b)–(e) during such period, given the January 21, 2021 Final Rule's conflicting instructions regarding these provisions. For these reasons, HHS finds there is good cause to make this final rule effective before the January 21, 2021 Final Rule goes into effect on April 23, 2021.

II. Analysis and Responses to Public Comments

The March 17, 2021 NPRM provided a 30-day comment period, and HRSA received 121 comments during that time, none of which supported the January 21, 2021 Final Rule. HRSA received comments from: Nurses and patients; law and other graduate school students; petitioners' attorneys (including a former member of the ACCV), law firms, and a bar association; a Member of Congress; a biotech trade association; pharmacist and drug store associations; a national drug store chain; non-profit organizations; and other individuals. While the Secretary only sought public comment on rescinding the January 21, 2021 Final Rule, many commenters offered comments beyond the scope of the request. We have summarized the relevant comments received, all of which support rescinding the January 21, 2021 Final Rule, and provided our responses below.

Comment: Several commenters supported the rescission of the January 21, 2021 Final Rule because they believe that rule did not adequately consider the recommendations of the ACCV or the public, or because they had other concerns regarding the January 21, 2021 Final Rule's promulgation. Several commenters pointed out irregularities in how HHS consulted with the ACCV as required by 42 U.S.C. 300aa–14(d). For example, then-ACCV Vice Chair raised concerns about the fact that the draft NPRM he received was marked privileged and confidential, and that he had ''never been given permission by anyone from HHS or anywhere else to talk about that document prior to the March 2020 meeting.'' He went on to state ''a discussion about the Proposed Rule was not on the agenda, and we [the ACCV] had absolutely zero notice that the Proposed Rule was going to be a topic of [consideration], even if the privileges and confidentiality had been waived by HHS.''

In addition, some commenters noted that HHS received more than 760 comments, the vast majority of which were opposed to the July 20, 2020 NPRM, and that more than 150 of those comments were posted on the last day of the comment period. These commenters contended that HHS did not address various substantive comments in the January 21, 2021 Final Rule. For example, one commenter pointed to six specific comments (three from petitioners' attorneys, one from an orthopedic surgeon, one from a commercial pharmacy, and one from a biotechnology trade association) that ''were substantial and challenged key premises of the [July 20, 2020] NPRM'' to which the January 21, 2021 Final Rule did not adequately respond.

Response: HHS agrees that there were irregularities in how HHS consulted with the ACCV, and there is a legitimate question as to whether the ACCV received the full 90 days to make recommendations. HHS also shares the commenters' other concerns related to the January 21, 2021 Final Rule's promulgation, as detailed above, including whether all public comments were adequately considered and addressed as required by the APA. Given the numerous concerns that have already been raised and the questions that surround the January 21, 2021 Final Rule's promulgation, HHS agrees that rescinding that rule is proper.[4]

Comment: Many patients and individuals supported the rescission of the January 21, 2021 Final Rule because they stated they had suffered SIRVA or other injuries related to vaccinations and wanted others to be able to submit petitions for their own alleged SIRVA injuries. Some individuals raised concerns about COVID–19 vaccines and expressed their view that any potential vaccine-related injuries from that vaccination should be covered by the Program.

Response: The VICP was created in the 1980s, after lawsuits against vaccine companies and health care providers threatened to cause vaccine shortages and reduce U.S. vaccination rates, which could have caused a resurgence of vaccine preventable diseases. HHS understands the important role the VICP plays by allowing any individual, of any age, who received a covered vaccine and believes he or she was injured as a result, to seek compensation. HHS regrets that it is unable to comment on individual pending or potential claims for compensation. Further, HHS notes that COVID–19 vaccines are covered countermeasures under the Countermeasures Injury Compensation Program (CICP),[5] not the VICP. As long as Item XVII is included on the Table, for a new category of vaccines to be

[4] One commenter expressed concern regarding the following sentence in the March 17, 2021 NPRM: ''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.'' HHS wants to clarify that the quoted sentence was intended merely to be a hypothetical statement.

[5] The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the CICP to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of covered countermeasures identified in and administered or used under a PREP Act declaration.

covered under the VICP, the following three things must happen: (1) Congress must enact an excise tax on the vaccine, (2) the CDC must recommend it for routine administration to children or pregnant women, and (3) the Secretary must publish a notice of coverage in the **Federal Register** (*see* 42 CFR 100.3(a), (e)(8)).

Comment: Many commenters supported the rescission of the January 21, 2021 Final Rule because they believe it contravenes the science surrounding SIRVA. For example, a group of registered nurses stated: ''Shoulder injury related to vaccine [administration] (SIRVA) and vasovagal syncope are legitimate vaccine-related injuries that should remain on the Vaccine Injury Table. The 2011 Institute of Medicine Report provided convincing evidence through extensive literature reviews that vaccine administration had a causal relationship with both SIRVA and vasovagal syncope. It is necessary that the Vaccine Injury Table [retain] injuries proven by evidence that have the potential to adversely affect American lives.''

Response: HHS is rescinding the January 21, 2021 Final Rule before it goes into effect in part so that the agency can have sufficient time to carefully and methodically consider the state of the science regarding SIRVA since it last completed its comprehensive review of the literature before adding SIRVA to the Table in March of 2017.

Comment: Various commenters supported the rescission of the January 21, 2021 Final Rule because they disagreed with the policy and legal rationales outlined in that rule. For example, some commenters argued that the cited financial considerations in the July 20, 2020 NPRM and the January 21, 2021 Final Rule did not support the removal of SIRVA and vasovagal syncope from the Table because these two injuries have minimal impact on the compensation funds available. Further, some commenters posited that the stated legal basis for removing SIRVA and vasovagal syncope from the Table, *i.e.,* that the VICP only covers injuries attributable to the contents of a vaccine, and for removing Item XVII from the Table, *i.e.,* that the item was contrary to law, represented changes in HHS's interpretation of the Vaccine Act that HHS did not adequately explain.

Response: HHS agrees that compensation paid for SIRVA and syncope claims under the VICP are not currently threatening the solvency of the Vaccine Injury Compensation Trust Fund.[6] Additionally, HHS agrees that the legal interpretation outlined in the January 21, 2021 Final Rule represented a change from HHS's historical interpretation of the Vaccine Act.[7] Such a change in interpretation would deserve a more thorough review and public discussion by HHS with the ACCV and the general public than occurred during the development of the January 21, 2021 Final Rule.

Comment: Some commenters supported the rescission of the January 21, 2021 Final Rule because removing Item XVII from the Table would significantly lengthen the process of adding any new vaccine in the future—such as COVID–19 vaccines—to the Table for coverage under the VICP. Other commenters supported moving coverage for COVID–19 vaccines to the VICP from the CICP.

Response: HHS agrees that, without Item XVII on the Table, the process for adding a vaccine to the Table could be more drawn out. With Item XVII in place, if HHS were to want to add a vaccine to the Table, it could do so if (1) Congress enacts an excise tax on the vaccine, (2) the CDC recommends it for routine administration to children or pregnant women, and (3) the Secretary publishes a notice of coverage in the **Federal Register** (*see* 42 CFR 100.3(a), (e)(8)). The January 21, 2021 Final Rule stated incorrectly that, if Item XVII were removed from the Table, notice and comment rulemaking to add a new vaccine to the VICP would *require* that any proposed addition of a new vaccine to the Table be presented to the ACCV for its consideration for 90 days prior to publication of an NPRM, with a 180-day comment period for the NPRM, and a public hearing.[8]

As stated above, COVID–19 vaccines are covered countermeasures under the CICP, not the VICP. For COVID–19 vaccines to be covered under the VICP, the process described above would have to occur.

Comment: Many commenters supported the rescission of the January 21, 2021 Final Rule because they are concerned that it would be particularly detrimental to vaccine administrators, which would be at odds with the Federal Government's efforts to increase COVID–19 vaccinations, influenza vaccinations, and routine childhood vaccinations, the latter of which have significantly dropped during the pandemic. For example, the American Pharmacists Association and the National Alliance of State Pharmacy Associations commented that ''during a pandemic is not the time to make changes to the Vaccine Injury Table, when we are working as a nation to implement the Administration's National Strategy for the COVID–19 Response and Pandemic Preparedness, including optimizing the manufacture, distribution, and administration of COVID–19 and other critical vaccinations.'' Another comment pointed out that many states are already suffering from nursing shortages, and increasing nurses' risk of liability for vaccine administration could exacerbate that shortage. Commenters also expressed concern that removing SIRVA and vasovagal syncope may increase vaccine hesitancy as individuals who already distrust vaccinations may decide to avoid being vaccinated if they believe they will not be compensated for SIRVA or vasovagal syncope injuries.

Response: Although the COVID–19 vaccine is not covered under the VICP, HHS recognizes that any action taken that concerns administration of other vaccines could impact the Federal Government's efforts to combat COVID–19.[9] For example, as discussed above,

[6] The Vaccine Injury Compensation Trust Fund provides funding for the VICP to compensate vaccine-related injury or death petitions for covered vaccines administered on or after October 1, 1988. Funded by a $.75 excise tax on vaccines recommended by the CDC for routine administration to children or pregnant women, the excise tax is imposed on each dose of a vaccine.

[7] Prior to the addition of SIRVA to the Table, SIRVA was a recognized vaccine injury in the VICP, with the Court of Federal Claims awarding compensation to petitioners based on a finding of causation in fact. *See, e.g., Vessey* v. *Secretary of HHS,* No. 14–556V, 2014 WL 5408975 (Fed. Cl. Sept. 26, 2014); *Grant* v. *Secretary of HHS,* No. 13–743V, 2013 WL 6913004 (Fed. Cl. Dec. 11, 2013); *Simpson* v. *Secretary of HHS,* No. 13–068V, 2013 WL 2454365 (Fed. Cl. May 9, 2013); *Godlewski* v. *Secretary of HHS,* No. 12–396V, 2012 WL 6830374 (Fed. Cl. Dec. 17, 2012); *Gainey* v. *Secretary of HHS,* No. 09–597V, 2010 WL 2483748 (Fed. Cl. May 12, 2010); *Ali* v. *Secretary of HHS,* No. 09–660V, 2010 WL 1010027 (Fed. Cl. Feb. 26, 2010).

[8] Specifically, the January 21, 2021 Final Rule states: ''This final rule has zero impact on inclusion of the COVID–19 vaccine on the Table. The COVID–19 vaccine can separately be added to the Table, but the Department needs to follow the process specified in 42 U.S.C. 300aa–14(c)—(d) to do so. This includes that the ACCV recommend that the COVID–19 vaccine be added, or opine on the Department's recommendation to add the COVID–19 vaccine to the Table'' (86 FR 6251).

However, the process described in 42 U.S.C. 300aa–14(c)—(d) does not apply to adding vaccines to the Table; rather, it only applies to Table modifications that ''add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or [] change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition, or death.'' 42 U.S.C. 300aa–14(c)(3). Subsection 300aa–14(e)(2)—(3), by contrast, provides the process for adding new vaccines to the Table.

[9] *See* National Strategy for the COVID–19 Response and Pandemic Preparedness (Jan. 2021), available at *https://www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-*

on March 16, 2021, the then-Acting Secretary issued a Seventh Amendment to the Public Readiness and Emergency Preparedness (PREP) Act Declaration to, among other things, add additional categories of qualified people authorized to prescribe, dispense, and administer COVID–19 vaccines authorized by the U.S. Food and Drug Administration. HHS has determined it is not appropriate to remove categories of vaccines and types of injuries from the Table in the midst of the pandemic, especially in light of the Federal Government's unprecedented vaccination effort and data showing lower rates of routine immunizations during this period.[10] In addition, HHS agrees that the January 21, 2021 Final Rule's revisions to the Table could negatively impact the vaccine administrators carrying out this massive COVID–19 vaccination campaign by increasing their exposure to liability for administering non-COVID vaccines, without ample opportunity for vaccine administrators to engage in dialogue with HHS about their concerns. HHS agrees that removing compensable Table injuries, like SIRVA and vasovagal syncope, might run counter to public health goals and increase vaccine hesitancy because doing so could remove the possibility of an accessible and efficient forum for compensation for these injuries.

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 rescinds the final rule titled ''National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table.'' This rescission 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.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–08478 Filed 4–21–21; 8:45 am]

BILLING CODE 4165–15–P

COVID-19-Response-and-Pandemic-Preparedness.pdf.

[10] Santoli JM, Lindley MC, DeSilva MB, et al. Effects of the COVID–19 Pandemic on Routine Pediatric Vaccine Ordering and Administration — United States, 2020. MMWR Morb Mortal Wkly Rep 2020;69:591–593. DOI: *http://dx.doi.org/10.15585/mmwr.mm6919e2.*

DEPARTMENT OF TRANSPORTATION

Maritime Administration

46 CFR Part 310

[Docket No. MARAD–2020–0142]

RIN 2133–AB92

Admission and Training of Midshipmen at the United States Merchant Marine Academy; Amendment Providing an Emergency Waiver for Scholastic Requirements

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Final rule; response to comments on interim final rule.

SUMMARY: This final rule adopts, without change, an October 22, 2020, interim final rule (IFR) amending Maritime Administration (MARAD) regulations governing admission to the United States Merchant Marine Academy (USMMA). The amendments allow the MARAD Administrator to waive the requirement for USMMA applicants to have taken the College Board's Scholastic Aptitude Test (SAT) or the American College Testing Program (ACT) examination in the event of a State or national emergency. The ability to waive SAT and ACT requirements for prospective students is necessary to address testing disruptions caused by the coronavirus disease 2019 (COVID–19) pandemic and to provide for future emergencies.

DATES: This final rule is effective April 22, 2021.

FOR FURTHER INFORMATION CONTACT: Mitch Hudson, Office of the Chief Counsel, at (202) 366–9373 or *Mitch.Hudson@dot.gov.* The mailing address for the Maritime Administration, Office of the Chief Counsel is 1200 New Jersey Avenue SE, Washington, DC 20590.

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I. Executive Summary

Institutions of higher education across the Nation have been severely impacted by the coronavirus disease 2019 (COVID–19) pandemic, which has not only required them to adapt teaching methods and practices, but also admissions processes and criteria. USMMA, along with many other institutions, is faced with the dilemma