Via Electronic Submission to: www.regulations.gov

April 14, 2021

Tamara Overby, Acting Director
Division of Injury Compensation Programs
Healthcare Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room 08N146B
Rockville, MD 20857

Re: National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table (86 FR 14567)
HHS Docket No. HRSA-2021-0001

Dear Acting Director Overby:

The American Pharmacists Association (APhA) and the National Alliance of State Pharmacy Associations (NASPA) strongly support the Health Resources and Services Administration's (HRSA) proposal to rescind the final rule entitled "National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table," published in the Federal Register on January 21, 2021.[1] This ill-advised final rule would remove shoulder injury related to vaccine administration (SIRVA) and vasovagal syncope from the Vaccine Injury Table (Table). 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[2], including optimizing the manufacture, distribution, and administration of COVID-19 and other critical vaccinations.

Founded in 1852, APhA represents pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use, advancing patient care, and protecting public health. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

[1] 86 Fed. Reg. 6249.
[2] 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-COVID-19-Response-and-Pandemic-Preparedness.pdf

NASPA, founded in 1927 as the National Council of State Pharmacy Association Executives, is dedicated to enhancing the success of state pharmacy associations in their efforts to advance the profession of pharmacy. NASPA's membership is comprised of state pharmacy associations and over 70 other stakeholder organizations. NASPA promotes leadership, sharing, learning, and policy exchange among its members and pharmacy leaders nationwide.

APhA and NASPA strongly support HRSA's proposal to rescind the final rule for the following procedural and policy reasons:

Procedural Reasons

In 2017, HRSA conducted extensive literature reviews, consultations, and public deliberations that resulted in the decision to add SIRVA and vasovagal syncope to the Vaccine Injury Table. In contrast to this extensive process, HRSA did not fully engage with either the Advisory Commission on Childhood Vaccines (ACCV) or the public regarding its rationale behind its proposal to subsequently remove these conditions from the Table. As HRSA notes in its proposal to rescind the final rule, "HHS agrees that there is a legitimate question as to whether the ACCV received the full 90 days to make recommendations [to HRSA]"[3], as required by the Vaccine Act.

In addition, contrary to 42 U.S.C. § 300aa–14(c), HRSA did not provide the required 180 days for public comment on the proposed revisions to the Table. The proposed rule was published on July 20, 2020, and the comment period closed on January 12, 2021.[4] In addition, HRSA did not properly notify the public of the entire revised regulation, 42 CFR § 100.3(b)–(e), since 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. Finally, given that HRSA filed the final rule on January 19, 2021 and published it in the Federal Register on January 21, 2021 -- **only three and five business days after the comment period closed on January 12th, respectively** – leads APhA and NASPA to question whether HRSA adequately considered "the relevant matter presented" in the 772 comments on the proposed rule as required by the Administrative Procedure Act.[5]

Policy Reasons

In our comments on the proposed rule, APhA and NASPA joined the ACCV as well as the majority of the other commenters in strongly opposing the removal of SIRVA and syncope from the Table due to our concerns that 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

[3] 86 FR 14569.
[4] 85 FR 43794.
[5] 5 U.S.C. § 553(c).

provided by the National Vaccine Injury Compensation Program (VICP).[6] While pharmacists and other immunizers are currently protected from liability for vaccine administration by the Public Readiness and Emergency Preparedness Act (PREP Act), that protection ceases at the conclusion of the declared COVID-19 public health emergency and might not cover all vaccinators in states with different training requirements.

As noted above, the fact that HRSA published the final rule only a few days after the comment period closed shows that the agency rushed to finalize this rule without adequate time to carefully consider the implications of its action. As we stated in our comments on the proposed rule, SIRVA and vasovagal syncope are "vaccine-related injuries" that Congress intended to be compensable under the VICP.

Despite the final rule's contentions to the contrary, the scientific record supporting the addition of SIRVA and syncope to the Table in 2017 has not materially changed. The final rule represents an abrupt about-face in policy without sufficient scientific and medical evidence to support the changes. This final rule threatens our nation's vaccine R&D, vaccine administration, and adverse event reporting efforts. It is bad public policy and APhA and NASPA therefore strongly support rescission of the final rule.

Furthermore, our organizations dispute HRSA's conclusion in the final rule that removal of SIRVA and syncope from the Table is necessary in order to incentivize proper administration technique. More than 400,000 pharmacists have been trained to administer vaccines for patients of all ages. They are educated regarding appropriate vaccination technique in accordance with CDC guidelines, and the management of potential adverse events such as syncope. Appropriate vaccination technique is reinforced through continuing education programming and other sources of information. Pharmacists take their responsibility to properly administer vaccines very seriously, and the removal of SIRVA and syncope from the Vaccine Injury Table will not further incentivize them to use proper technique. Having SIRVA and syncope within the Table keeps the potential of the injury in front of providers. Removing them might discourage providers from vaccinating if they are concerned about being sued in court for these vaccine injuries.

APhA and NASPA believe that HRSA's proposal to rescind this final rule will help to preserve widespread access to vaccines and provide compensation to victims of vaccine injuries. Our members are actively participating in the nationwide COVID-19 vaccine administration effort and look forward to continuing to work on vaccination and other public health initiatives with HHS and the Biden Administration.

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[6] See APhA and NASPA Comments to HRSA on Revisions to the Vaccine Injury Table, Jan. 12, 2021, available at: https://aphanet.pharmacist.com/sites/default/files/audience/APhAandNASPACommentstoHRSAonRevisionstotheVaccineInjuryTable_FINAL_1-12-2021.pdf

Thank you for heeding our concerns by proposing to rescind the final rule. We strongly support rescission. If you have any questions or require additional information, please contact Karin Bolte, JD, APhA's Director of Health Policy, at kbolte@aphanet.org or by phone at (202) 558-2727.

Sincerely,

Ilisa BG Bernstein, PharmD, JD, FAPhA
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