



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

May 14, 2020

Advisory Commission on Childhood Vaccines
Division of Injury Compensation Programs
5600 Fishers Lane, 08N146B
Rockville, MD 20857

Tamara Overby
Acting Director, DICP
Executive Secretary, ACCV
5600 Fishers Lane, 08N146B
Rockville, MD 20857

via email: toverby@hrsa.com

Re: HRSA Proposed Vaccine Rulemaking Making Dramatic Changes in Scope of the National Vaccine Injury Compensation Program

Dear Ms. Overby and Members of the Commission:

I. Introduction

The National Association of Chain Drug Stores (NACDS) thanks the Advisory Commission on Childhood Vaccines (ACCV) for the opportunity to comment on a draft HRSA Notice of Proposed Rule Making (NPRM) that would seek to remove two injuries, syncope and shoulder injuries related to vaccine administration (SIRVA), from the Vaccine Injury Table. NACDS urges ACCV to recommend that HRSA not proceed with the NPRM, as the HRSA proposal would likely result in dramatically negative public health consequences by significantly reducing Americans' access to vaccinations. Especially in this time of nationwide pandemic and associated health care crises, we believe it would be unwise to adopt such a health policy change. Ironically, the HRSA proposal would limit access to vaccinations, which are the only potential preventative treatment that could halt the spread of the coronavirus.

II. The NPRM is Not Supported by Medical Literature

HRSA's NPRM asserts that the medical literature and scientific community almost uniformly agree that SIRVA is caused by the administration of the vaccine and not the antigen itself. HRSA makes this assertion despite HRSA's own longstanding opinion and abundant medical and scientific research to the contrary, including by

the National Academy of Medicine.¹ Considering the paucity of scientific and medical evidence to support HRSA's NPRM, we urge ACCV not to support HRSA's proposal.

III. The NPRM is Not Supported by Underlying Statutory Law

We believe that HRSA's NPRM draws unsubstantiated conclusions and is contrary to Federal statutes. The NPRM would shift the liability for SIRVA and syncope injuries back to vaccine administrators and vaccine manufacturers in clear contradiction of federal vaccine statutory law.

We must disagree with HRSA's statement that federal statutes exclude the "administration of vaccines." In issuing the NPRM, HRSA seems to ignore several provisions of the Vaccine Act. 42 U.S.C. § 300aa-11 specifically provides protection for "administration" of a vaccine. Section 11(a)(2) of the Act explicitly states, "No person may bring a civil action for damages in an amount greater than \$1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death **associated with the administration of a vaccine** after the effective date of this part..." Likewise, Section 11(3) clearly states, "No vaccine administrator or manufacturer may be made a party to a civil action . . . for damages for a vaccine-related injury or death **associated with the administration of a vaccine** after the effective date of this part." Further, Section 11(b)(2) plainly states "Only one petition may be filed **with respect to each administration of a vaccine.**" These are just a sample of the 17 instances in which Congress used the term "administration of the vaccine" in the Vaccine Act. Taking into account a comprehensive view of relevant federal law, we find no legal basis to support HRSA's NPRM.

Upon taking a closer analysis of 42 U.S.C. § 300aa-17, we must similarly challenge HRSA's assertion that monetary payment for negligence in the administration of a vaccine should be borne by the vaccine administrator, not the Vaccine Fund. Congress specifically envisioned instances where there might be negligence on the part of vaccine administrators and vaccine manufacturers, and they expressly provided a provision in the Act to deal with such circumstances. In Section 17 of the Act, the Vaccine Act's Subrogation provision, Congress places on the Secretary of HHS the responsibility to recoup Vaccine Trust Funds that were paid to a claimant for the negligence of a vaccine administrator or manufacturer. Clearly, Congress instructed HRSA, and not the vaccinated patient, to pursue potential claims against an administrator.

¹ See e.g., Atanasoff S., et al.; "Shoulder injury related to vaccine administration (SIRVA)," *Vaccine*, 2010 Nov 29;28.

IV. Policy Considerations

The NPRM mentions three policy justifications. First, HRSA implies that the NPRM is needed because under the present regime, vaccine administrators, such as doctors, nurses, and pharmacists have no incentive to properly administer vaccines because they know that they are protected by the VICP. We can assure HRSA that health care providers, including pharmacists, are highly trained, skilled professionals that seek to provide high quality care to their patients, and are not likely to be reckless or negligent in the care they provide because of their knowledge of liability protection. HRSA's logic seems to imply that medical malpractice insurance should be abolished to incentivize doctors not to be intentionally neglectful in the care they provide. Frankly, we find HRSA's implication to be uninformed about the ethical duties of health care providers.

Second, HRSA states that they want to preserve Vaccine Trust Funds to be available for other more-meritorious cases. HRSA seems to have taken on the role of the judiciary in pre-determining which cases have merit and which do not. Obviously, this is not a proper role for HRSA; and this justification is deficient. Moreover, as noted above, Congress has directed HRSA to avail itself of the Act's Subrogation provision. HRSA could recoup funds paid in SIRVA and syncope claims if in fact all instances are actually caused by health care provider recklessness or negligence, as HRSA suggests.

Finally, HRSA's third justification for this reversal defies salutary public health policy, as well as contravenes Congressional intent. HRSA argues that it is concerned that payouts from the VICP may lead to the conclusion that vaccines are not safe and that the Vaccine Program statistics will be used as justification by such people for not getting vaccinated at all. Considering the tremendous health benefits of vaccines, we have grave concerns about basing vaccine policy on what vaccine opposers might argue. Tragically, HRSA's proposal would actually lead to fewer vaccines being offered, thus handing a victory to those who oppose sound, science-based health policy.

Should HRSA move forward with proposing and finalizing this rule, the outcome may ultimately cripple our nation's vaccine provider infrastructure by exposing doctors, nurses, and pharmacists to billions of dollars in lawsuits. If the proposed changes area approved, it is highly likely the cost of malpractice insurance will skyrocket, thus strongly discouraging health care providers from providing vaccines. At this time of national pandemic, we believe the Administration should be looking to implement policies that encourage vaccination by making vaccination services more readily available to Americans, such as at our Nations' approximately 60,000 pharmacies.

V. Potential Alternatives

HRSA expresses concern in the NPRM about limited VICP funding available to pay all legitimate claims. Rather than depriving patients that have suffered syncope and SIRVA of their rightful opportunity for compensation under the Vaccine Act, we would suggest that ACCV recommend that HRSA explore other potential solutions that could include increasing the VICP funding allocation or reviewing VICP claim payouts in general.

VI. Conclusion

We urge ACCV to carefully consider our legal and policy concerns detailed in this letter and reject HRSA's proposal to remove SIRVA and syncope from the vaccine injury table. If we can provide further assistance or clarification, please do not hesitate to contact Kevin Nicholson, RPh. JD, Vice President, Public Policy at knicholson@nacds.org.

Sincerely,

/S/

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer