Shoulder Injury Controversy Generates Opportunity to Modernize the Vaccine Injury Compensation Program

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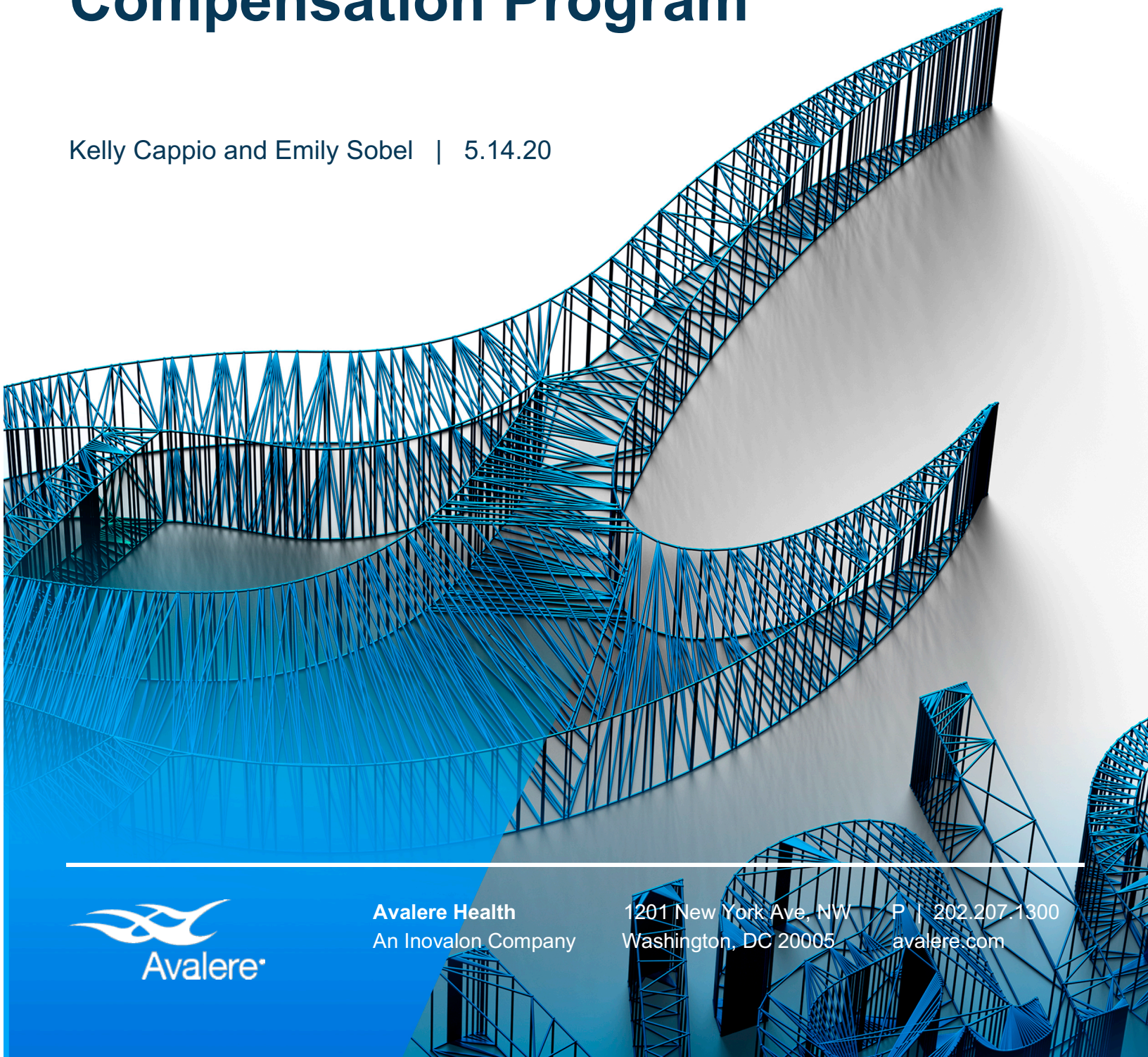

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Table of Contents

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A proposal to eliminate shoulder injuries from the list of vaccine-related conditions that warrant federal compensation through the National Vaccine Injury Compensation Program (VICP) highlights the administrative challenges posed by these claims and provides an opportunity to consider reforms to modernize the program. For 3 decades, the VICP has operated as a simple and efficient system through which people with vaccine injuries, which are rare, can receive compensation. In providing this function, VICP has also helped stabilize the vaccine supply and facilitated vaccine access.

An as-yet-unpublished US Department of Health and Humans Services (HHS) Notice of Proposed Rulemaking (NPRM) to remove both Shoulder Injury Related to Vaccine Administration (SIRVA) and vasovagal syncope from the program's Vaccine Injury Table (Table) began circulating among stakeholders in March. The draft NPRM marks the latest flashpoint in the ongoing controversy surrounding SIRVA. While still miniscule compared to the overall number of vaccines administered annually in the U.S., the increasing volume of SIRVA claims is overwhelming the VICP process, creating a backlog of cases and delaying compensation.

On May 18, the Advisory Commission on Childhood Vaccines (ACCV), which advises the HHS Secretary on the VICP, will hold a special meeting to discuss the proposal. Regardless of whether the proposed rulemaking is finalized, certain reforms could resolve the challenges associated with SIRVA and more broadly strengthen the VICP.

The VICP Process

Congress established the VICP under the National Childhood Vaccine Injury Act of 1986 (the Vaccine Act) to provide fair and timely compensation to children injured by vaccines and to limit liability for vaccine manufacturers and healthcare providers. A growing number of lawsuits in the 1970s and 1980s led many manufacturers to exit the vaccine market, and lawmakers were concerned this would result in increased product liability insurance costs and vaccine prices, destabilization of production and supply, and, ultimately, a resurgence of vaccine-preventable diseases.

To be covered under the Program, vaccines must be licensed by the Food and Drug Administration (FDA) and recommended by the Centers for Disease Control and Prevention (CDC) for routine administration to children or pregnant women. Vaccines must also be subject to a 75-cent excise tax on each dose, which funds awards to petitioners through the Vaccine Injury Compensation Trust Fund (Trust Fund). As of March 2020, the Trust Fund was valued at about $4 billion.

Under the VICP, vaccine injury petitions are filed against HHS by petitioners in the Office of Special Masters of the U.S. Court of Federal Claims (CFC). The petitions and supporting documents (e.g., medical records, affidavits) are reviewed by the medical staff of the HHS Health Resources and Services Administration (HRSA) on a first-in, first-out basis. HRSA submits the medical reviews to Department of Justice (DOJ), which represents HHS. Cases

may either be dismissed, conceded, settled by DOJ, or heard by one of eight court-appointed Special Masters. A Special Master's decision is appealable to the CFC by the petitioner, then to the U.S. Court of Appeals for the Federal Circuit, and ultimately, to the US Supreme Court.

To be compensated under the VICP, petitioners must establish that a vaccine-related injury or death has occurred, either by proving a vaccine caused or significantly aggravated an injury, or by demonstrating the occurrence of an injury enumerated in the VICP's Vaccine Injury Table. For injuries included on the Table, petitioners are not required to prove causation, thus reducing their burden of proof.

What Is SIRVA?

SIRVA was first identified by HRSA medical reviewers in a 2010 research paper describing 13 claims of adult shoulder injuries filed through the VICP between 2006 and 2010. The authors proposed the cause of the conditions was incorrect administration of a vaccine into and around the bursa of the shoulder, resulting in an inflammatory reaction. These findings were confirmed in 2011 by the National Academy of Medicine (NAM), formerly the Institute of Medicine, who recommended SIRVA be included in the Vaccine Injury Table, which occurred in March 2017.

In January of this year, HRSA and CDC published a follow-up review of SIRVA claims filed since 2010. They found that the majority involved influenza vaccines, and that the most common place of vaccination was a pharmacy or store (35.3%), followed by a doctor's office (30.9%). The authors concluded that healthcare providers should "be aware of proper injection technique and anatomical landmarks when administering vaccines."

Impact of SIRVA on VICP

Over the past decade, the number of claims filed through the VICP has nearly tripled from 448 petitions in Fiscal Year (FY) 2010 to 1,282 petitions in FY 2019. SIRVA claims have accounted for more than half (54%) of all petitions during the last two fiscal years.

The nature of SIRVA cases and their inclusion on the Table have necessarily contributed to the high volume of claims. In the draft NPRM, HHS wrote, "the sheer prevalence of shoulder injuries and low burden of proof placed on petitioners have made it attractive to file SIRVA petitions, even when such claims are dubious." Some attorneys specifically advertise their services for SIRVA cases, as the VICP pays attorneys' fees regardless of whether claims are deemed compensable.

Two notable policy changes may have also contributed to the rise in SIRVA claims. Following the 2009-2010 H1N1 influenza pandemic, the CDC issued a universal recommendation for influenza vaccination in all persons six months of age and older in the US, expanding previous recommendations to include healthy adults ages 18-49. Additionally, states' scope-of-practice

laws have expanded in the past decade, enabling pharmacists to administer certain vaccines. With flu vaccines widely recommended and available across diverse settings of care, there are more opportunities to administer vaccines to patients but also increased potential for administration error.

The increasing volume of petitions is overwhelming the VICP process and hindering the program's ability to fulfill its mandate of providing compensation to vaccine-injured people in a prompt and straightforward manner. The wait time for an initial HRSA medical review of any petition—only the first step in the VICP process—is nearly 10 months. Resources for HRSA, DOJ, and the Court to administer the program are constrained by annual appropriation levels set by Congress. Further, the Vaccine Act limits the number of Special Masters to eight, and the wait time for cases to be heard by Special Masters can be several years. The result is a backlog of claims and significant delays in compensation.

Justification for Proposed Removal of SIRVA from Table

In the draft NPRM, HHS bases its proposal to remove SIRVA from the Vaccine Injury Table on the following arguments:

- **Evolving Science:** Since SIRVA was added to the Table in 2017, additional scientific research has shown that SIRVA is most likely the consequence of poor injection technique rather than the vaccine antigen, suggesting that most cases of SIRVA likely are preventable.

- **Program Scope:** Based on a more accurate reading of the Vaccine Act, the Table should only include injuries associated with the vaccine itself, not injuries resulting incorrect administration.

- **Fault vs. No-Fault Injuries:** The VICP is designed for injuries that cannot be predicted in advance and can occur without fault, unlike SIRVA. Removing the no-fault compensation for SIRVA claims would better incentivize providers to take appropriate precautions.

- **Impact on Resources:** The growing volume of SIRVA petitions and awards reduces funding available for children and others who suffer injuries intended to be covered under the VICP.

- **Safety Misconceptions:** Vaccination opponents cite the amount of funding awarded to SIRVA petitioners as evidence that vaccines are not safe, even though those awards are not actually associated with vaccines or antigens.

Opponents of SIRVA's removal from the Table disagree with HHS's interpretation of the Vaccine Act, and they also assert that if state courts become the only venue available for bringing SIRVA claims, healthcare provider malpractice insurance costs will rise, potentially leading some providers to forego vaccine administration.

Should healthcare providers face medical malpractice suits related to SIRVA, there could be an adverse impact on immunization access if fewer providers are willing to administer vaccines due to liability concerns. However, this public health impact must be weighed against the practical considerations of adjudicating an increasing number of SIRVA claims in the VICP.

Resolving SIRVA Challenges in the VICP

Several reforms could be considered to address the issues created by SIRVA claims, including common-sense policy changes to improve the program's functioning and alleviate workload issues, should SIRVA remain on the Table.

1. **Standardize SIRVA Award Amounts and Cap Attorneys' Fees**
   To reduce the number of "dubious" claims and move legitimate injury claims through the program more efficiently, the U.S. Government could standardize SIRVA award amounts for damages. The standards could account for differences in injury severity (e.g. shoulder injuries requiring surgery would be awarded more than injuries requiring little to no medical intervention).

   Implementing caps on petitioner attorneys' fees would also help address the SIRVA burden and reduce any perverse incentives to bring these claims. According to HRSA, total attorney fees and legal costs for all compensated VICP cases increased 103% percent between FY 2015-2019, from $14.4 million to $29.2 million.

2. **Create National Certification Program for Vaccine Administrators**
   A promising way to address SIRVA is through standardized training and support for healthcare providers, which would help minimize the possibility of improper injection technique and prevent SIRVA from occurring. Further, provider-level accountability would ensure those who incorrectly administer vaccines can receive remedial training to correct their technique.

   Through the establishment of a national certification program, all vaccine administrators (e.g. physicians, pharmacists, nurses, medical assistants) could complete annual training on proper technique via online modules. To promote accountability, unique identification numbers could be assigned to immunizers through the certification program and then recorded in the electronic health record and immunization registries at the time of injection. They could also be included in VICP claims, thereby allowing for a process of notification and remedial training when SIRVA occurs.

Many professional and specialty societies already provide some level of training related to vaccine administration, and the CDC released a "Know the Site. Get It Right!" infographic for healthcare providers in 2017 to reinforce correct administration technique. Further, in the Senate's FY 2019 Labor, HHS Appropriation bill, the Committee included report language directing the CDC to "evaluate its outreach and provider education programs and identify additional efforts CDC should undertake to ensure proper vaccine administration."

Protecting and Modernizing the VICP

Broader changes could be made to protect the financial and administrative integrity of the VICP while also modernizing the program, regardless of whether SIRVA is removed.

1. **Address Inefficiencies in VICP Process**
   The primary bottlenecks affecting the timeline for adjudication of claims are HRSA medical reviews and Special Master hearings. To address the increased caseload and alleviate backlogs and delays in compensation, additional staff could be hired, a recommendation made in 2018 by the ACCV to the HHS Secretary. Through increased administrative funding for the VICP appropriated by Congress, HRSA and DOJ could add medical review staff and attorneys.

   Through a statutory amendment, the number of Special Masters could also be increased, as recommended by the ACCV. A bill that would double the number of Special Masters has been introduced in Congress but has gained little traction due to concern it would have limited impact as a stand-alone fix.

2. **Expand VICP to Cover Vaccines Recommended for Adults**
   Currently, only two CDC-recommended vaccines are not covered under the VICP: the shingles (herpes zoster) and pneumococcal polysaccharide vaccines. These vaccines, which are recommended only for use in adults, are excluded from the program due to the statutory requirement that covered vaccines be recommended by CDC for routine administration to children or in pregnant women.

   Although the VICP was originally intended to compensate for childhood vaccine injuries, the program now consists primarily of claims for adults. In FY 2019, 1,282 claims were filed in the VICP and over 90% of them (1,169) were filed for adult injuries. Given that the VICP is already adjudicating and compensating a majority of adult claims, and considering the robust pipeline of novel adult vaccines, policymakers could consider closing this liability gap to ensure that all vaccines are equally covered.

3. **Update Tax Code to Ensure Prompt VICP Coverage for New Vaccines**
   In 1987, Congress passed tax legislation to finance the Trust Fund through a 75-cent excise tax on each vaccine dose. The bill established a list of "taxable vaccines" covered under VICP in Section 4132(a)(1) of the Internal Revenue Code of 1986 that included vaccines recommended for routine use in children at the time. Since then, Congress has enacted legislation to impose an excise tax on seven additional types of vaccines.

   Going forward, Congress will need to pass tax legislation for any new first-in-class vaccines to ensure their inclusion in the VICP, which may prove difficult in the current political environment. Last year, bipartisan legislation was introduced to automatically apply the excise tax to any new vaccines once added to the Vaccine Injury Table. Such a change could benefit patients, healthcare providers, and vaccine manufacturers by expediting protections and remedies available under the VICP.

Conclusion

The proposed removal of SIRVA from the Table represents a complex and controversial change to the VICP. As discussions regarding the proposal continue, HHS's draft NPRM presents an opportunity to consider reforms that can ensure the VICP will continue providing the services it was designed to deliver without fueling public fears about vaccine safety or allowing preventable injuries to go unaddressed.

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