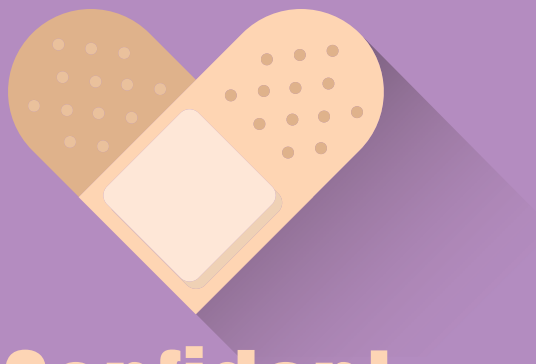
FINAL REPORT

Sustainability of PREP Act Changes to Vaccine Authority

Virtual discussion facilitated by NASPA and conducted on June 14, 2023



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SEPTEMBER 2023

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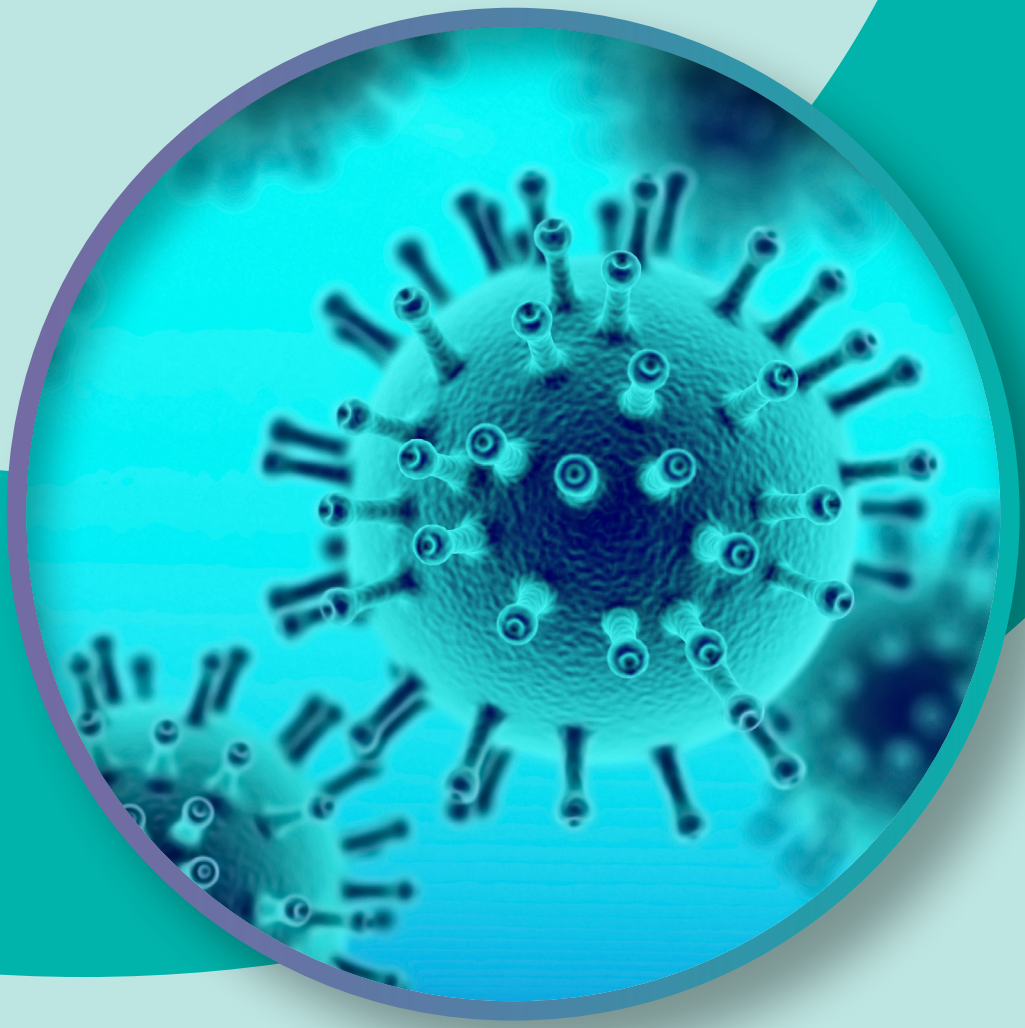

CDC Acknowledgment

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Overview

The coronavirus that emerged in 2019 (COVID-19) caused one of the worst global public health crises in modern times and one that has not fully abated. Pharmacists, public health organizations, and public health agencies in the United States continue developing strategies to bring COVID-19 disease and its virus variants under control, while also preparing for other communicable respiratory diseases and illnesses that increase the strain on public health resources and the health of communities.

On March 10, 2020, the Secretary of Health and Human Services (HHS) issued a declaration under the 2005 Public Readiness and Emergency Preparedness Act (PREP Act) to cover COVID-19 tests, drug therapies, and vaccines. Eleven amendments were added to the PREP Act since the issuance of the declaration, focused on expansion of health professional authority and liability coverage that resulted in expanded access to needed medical countermeasures. Of importance to the pharmacy team is the Seventh Amendment to the PREP Act.

The Seventh Amendment expanded the category of individuals authorized to administer COVID-19 vaccines to include pharmacists, pharmacy interns, and pharmacy technicians as health care providers and to provide immunity from liability. While the public health emergency for the country expired in May 2023, certain authorities were maintained to address ongoing public health needs. These authorities included PREP Act immunity from liability and authority for pharmacists, pharmacy interns, and pharmacy technicians to administer COVID-19 vaccines and seasonal influenza vaccines to those individuals ages three years and older through December 2024. This, however, does not authorize pharmacy team members to administer vaccines to children younger than three years of age and relies upon state laws and rules for that authority, which may be non-existent; yet some pharmacists are willing to administer vaccines to this age group.

The National Alliance of State Pharmacy Associations (NASPA) held a meeting on June 14, 2023, with state pharmacy executives to address obstacles pharmacists are encountering regarding the sustainability and expansion of pharmacy team member vaccination authority and to share information about COVID-19 immunization rates in the pediatric population; the participants also discussed insights and lessons learned from expanding vaccine access in the states following passage of the PREP Act.

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This meeting is one of several conducted by NASPA, whose focus was to build and strengthen relationships between state pharmacy associations and state immunization/public health managers and provide guidance to state pharmacy association executives in establishing collaboration in developing vaccine confidence and vaccine uptake within their jurisdictions, particularly related to COVID-19 and Vaccines for Children (VFC) program regulations. This session predominantly focused on COVID-19 and making permanent PREP Act authorities within state laws.

The meeting agenda included:

- COVID-19 Vaccine Coverage for Children presented by Michelle (Shelly) Fiscus, MD, FAAP, Chief Medical Officer, Association of Immunization Managers
- State Executive Panel: Successes/Challenges With Implementation of Expanded Vaccine Access
  - Brandy Seignemartin, PharmD, Executive Director, Alaska Pharmacists Association
  - Krista D. Capehart, PharmD, MSPharm, BCACP, FAPhA, AE-C, Director of Professional and Regulatory Affairs, West Virginia Board of Pharmacy
  - Aliyah N. Horton, FASAE, CAE, Executive Director, Maryland Pharmacists Association
- Facilitated Discussion/Questions
  - Mitchel Rothholz, BSPharm, MBA, President, Three-C Consulting Group

This report provides insights into the discussions and identifies potential next steps forward.

The presentation portions were introduced and facilitated by Joni Cover, JD, Vice President of Strategic Initiatives, NASPA.

Approximately 10,000 children become eligible for vaccinations per day.

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COVID-19 Vaccine Coverage for Children

Michelle (Shelly) Fiscus, MD, FAAP, Chief Medical Officer, Association of Immunization Managers (AIM), a membership organization for immunization managers from the 64 CDC-funded state and local jurisdictions, provided demographic and updated information about immunization rates for COVID-19 in the pediatric population as well as insights and lessons learned from AIM's eight regional meetings. These meetings involved many vaccine stakeholders, including pharmacy, from 63 of the 64 jurisdictions. A pediatrician by training, and board member of the American Academy of Pediatrics, Dr. Fiscus stated that she **"believes that pharmacists should be able to vaccinate kids. Not every pediatrician feels that way, but at the end of the day, we need to do what's right for patients, and it is better being vaccinated than not being vaccinated."** She also shared possible solutions and approaches to address reasons why children are not being vaccinated against COVID-19.

Dr. Fiscus provided the following demographics regarding the population under 5 years of age in the United States:

- 3,659,289 U.S. births in 2021.
- Approximately 10,000 children become eligible for vaccinations per day.
- Each week, approximately 7,000 children (6 months to 4 years of age) are vaccinated.
- During January 1–June 13, 2023, about 1.6 infants have become eligible for vaccination.
- Only around 260,000 vaccinations have been given to all children ages 6 months to 4 years during January 1–June 13, 2023.
- About 220 COVID-19 deaths per year among infants and children aged 0–4 years (compared with about 75 deaths per year in this age group for varicella).

Lack of access, as reported by Vaccine Equity Planner, demonstrates COVID-19 vaccine deserts by:

- Age.
- Uninsured rate.
- Population density.
- Social vulnerability.
- Transportation.

Access is more problematic in rural areas but is also seen within urban and suburban areas.

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Reasons for the lack of access, vaccine deserts, and why not all pharmacists and medical practices are vaccinating children are complicated. Among them include the following:

- Understaffing.
- COVID-19 fatigue.
- Large minimum vaccine order sizes.
- Too many different vaccine preparations (11 different preparations).
- Complicated storage and handling.
- Administrative burdens.
- Parent lack of interest in COVID-19 vaccines.
- Misinformation and disinformation.
- Lack of provider confidence in discussing COVID-19 vaccines and making strong recommendations.
- Lack of pharmacist confidence in vaccinating young children.
- Uncooperative children.
- COVID-19 vaccine has not been incorporated into the well-child visit.
- Feeling that “someone else will do it.”

Take personal responsibility that the “someone who has to do it” is you.

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An overview of pediatric COVID-19 vaccination rates was provided. Highlights included:

- A small percentage of parents had children 6 months old to 4 years old vaccinated when this age group initially became eligible for vaccination.
- Vaccinations were done primarily by physicians.
- Pharmacists vaccinated approximately 15% of those aged 3 years and older.
- Pharmacists who did not vaccinate opted not to for the same reasons as some other providers.

Dr. Fiscus shared potential solutions for closing these vaccination gaps. These solutions included:

- Address the issues associated with understaffing of health care professionals.
- Find motivation to get children vaccinated and motivate parents through conversation.
- Resolve the large minimum order requirement.
- Recognize that the number of different preparations is resolving with the newer formulations of COVID-19 vaccines.
- Inform providers that, in practice, storage is easier than it was previously thought to be.
- Provide additional training and support to increase pharmacist confidence in discussing COVID-19 vaccines and making strong recommendations.
- Take personal responsibility that the “someone who has to do it” is you.

Find motivation to get children vaccinated and motivate parents through conversation.

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COVID-19 Vaccine Coverage for Children Discussion: Summary

Pharmacists have numerous reasons for not administering more vaccines to the pediatric population. These include pushback from organized medicine and concerns about disrupting the medical home. However, there are many children who do not have medical homes or access to one, and pharmacists can be a great resource to address these access gaps. Barriers in the VFC program are a big reason for pharmacies not vaccinating children. Some states are not allowing pharmacies to enroll in VFC, and for those that do, pharmacy enrollment is not widespread. One barrier is that each VFC jurisdiction can make its own rules around the Centers for Disease Control and Prevention (CDC) VFC rules. Through discourse and discussions with public health, educating them about the training and knowledge of pharmacists and pharmacist capabilities, some naysayers at the state level have changed their thinking and are having open dialogue with pharmacy practitioners.

Dr. Fiscus noted that about two-thirds of the managers across the 64 jurisdictions are new and do not know the CDC rules and why certain requirements are in place. Through its state, local, and territorial chapters, AIM is working with these jurisdictions to help them align with CDC requirements and discussing with immunization programs about meeting and engaging pharmacists. She indicated that jurisdictions and states are hearing the message. AIM is facilitating the sharing of practice examples between state jurisdictions. Dr. Fiscus also described an immunization program manager who was initially skeptical about pharmacists becoming VFC providers but changed her perspective after talking with a VFC pharmacist, learning about pharmacists' education and practice. This program manager is now supportive of pharmacists becoming VFC providers.

Another challenge Dr. Fiscus identified for the VFC program is the variability of interpretation and implementation of CDC requirements and state jurisdictions attaching additional requirements for providers, which increase administrative burdens. As an example, she reported that one jurisdiction requires a VFC provider to be open 4 days a week; in this situation, mobile clinics would be challenged in meeting the requirement because they do not hold regular office hours. Nearly two-thirds of the immunization program managers have been hired since the COVID-19 outbreak began and do not know how and why the state jurisdiction differences were put in place. This provides an opportunity for these differences to be addressed. For example, the differences in requirements were addressed with the Colorado Pharmacists Society, which reported that the state requires pharmacists to follow CDC rules and that legislation had passed for reimbursement of pharmacists. While the administrative barriers are a challenge, and flexibility is needed to gain provider support, addressing differences can improve VFC program uptake.

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State Executive Panel: Successes/Challenges With Implementation of Expanded Vaccine Access

The panel presented reports about recent activity in their states and shared lessons learned about sustaining and expanding vaccine access from pharmacy teams in the states with respect to the PREP Act. The panel also elaborated on the importance of collaboration and communication with state public health/immunization programs, pharmacists/pharmacy associations, and state legislators/regulators.

Brandy Seignemartin, PharmD, *Executive Director, Alaska Pharmacists Association (AKPhA)*

The groundwork is laid for pharmacists to be VFC providers in Alaska. AKPhA worked to pass HB145, which allows pharmacists to prescribe and administer vaccines and conduct tests waived under the Clinical Laboratory Improvement Amendments with no age restrictions. The bill also allows certified pharmacy technicians to administer vaccines. AKPhA is working with the state's Department of Health, University of Alaska Anchorage College of Health/ Idaho State University College of Pharmacy, and the state's Board of Pharmacy to implement this new authority. Discussions are ongoing to get pharmacies enrolled in the VFC program. The reimbursement for VFC providers is at a level that could sustain practices, but they must overcome the administrative burdens.

AKPhA is also working with the Alaska Primary Care Association, which has a federal workforce development grant, to develop an apprenticeship program for pharmacy technicians and provide free didactic training to be eligible to sit for the national certification exam. Additionally, AKPhA is working with high schools in a technical program to prepare students to become certified as pharmacy technicians when they turn 18 years old. The current Board of Pharmacy rule requires that a person has to be at least 18 years old and a high school graduate to be a pharmacy technician. AKPhA is working with the Alaska Board of Pharmacy to update the rules so that individuals in these programs can work in the pharmacy and earn hours toward certification requirements.

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Krista D. Capehart, PharmD, MSPharm, BCACP, FAPhA, AE-C, *Director of Professional and Regulatory Affairs, West Virginia Board of Pharmacy*

In addition to her position at the West Virginia Board of Pharmacy, Dr. Capehart works at the West Virginia University School of Pharmacy. She described the positive experience representatives of these institutions had at the AIM Vaccine Access Cooperative (VAC) meeting. West Virginia requires that the Boards of Pharmacy, Medicine, and Osteopathic Medicine must agree to changes made to state immunization rules. Dr. Capehart shared that there has been dialogue and consensus among the West Virginia Boards of Pharmacy, Medicine, and Osteopathic Medicine. The West Virginia legislature passed PREP Act recommendations for all CDC-recommended vaccines for individuals ages 3 years and older with parental consent and promotion of well-child visits. Rules have been drafted and approved by the Board of Medicine and the Board of Osteopathic Medicine. This lowers the age for patients to receive vaccine administration without a prescription from 17 years of age to 3 years of age. Those rules will be filed as an emergency rule and will go into effect upon adoption. Additionally, all pharmacy technicians in West Virginia are required to be immunization certified. The state was awarded a grant and will be using that funding to train and certify more technicians as immunization providers.

Aliyah N. Horton, FASAE, CAE, *Executive Director, Maryland Pharmacists Association*

In Maryland, three bills were introduced, of which HB 693 passed; SB 372/HB 1232 failed. HB 693 allows pharmacy technicians, with appropriate training, to administer influenza, COVID-19, and pneumonia vaccines to patients aged 18 years and older and respiratory syncytial virus and shingles vaccinations to individuals aged 50 years and older. SB 372/HB 1232 sought to codify provisions of the PREP Act, which authorized a licensed pharmacist to order and administer pediatric vaccinations to individuals ages 3 years and older. Efforts to get this expanded authority have been ongoing since 2021.

The Maryland Department of Health planned to release a report in December 2022 on the impact of the change in vaccination policy under the PREP Act. The report was completed but not delivered to the General Assembly, which was one of the reasons SB 372/HB 1232 did not pass. No response was provided regarding why the report was not delivered. There is ongoing discussion between the Maryland Pharmacists Association and the Department of Health after the recent AIM VAC meeting to increase efforts to engage pharmacies within the VFC program. Up to this point, the Department of Health cited a lack of time to address the issue, however the AIM VAC meeting may have opened new opportunities.

Coordination of issue priorities among pharmacy groups is essential to move bills forward. For those needing to get immunization legislation passed, the following experience from the 2023 Maryland session may help avoid some issues.

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From an overarching approach, the key factors are:

- Public/constituent support.
- Political will—leadership, committees, coalition.
- Consensus building.
- Effective communication among stakeholders.
- Strategic timing.
- Skilled legislators—committed champions.
- Procedural knowledge—ability to maneuver.
- Political alignment/environment.
- Addressing opposition.
- Persistence and adaptability.

Regarding the Maryland experience, the observations were:

- Pediatricians and other groups' testimony did not support the expansion of pharmacist authority. More supporters from within pharmacy and outside of pharmacy (immunization coalition, etc.) were needed to testify in support of the bill.
- Many new members of committee leadership and coalitions appeared not to have information about the bills. They were not comfortable moving forward on changes to the practice act. Pharmacy did not have the legislative leadership within committees. Legislators in red districts of the state were hesitant and not willing to move forward anything concerning vaccinations.
- The word "caregiver" in the bill caused hesitation. The bill said a caregiver could authorize pediatric vaccination, but legislators were not aware of the definition of caregiver, which was perceived as a babysitter.
- Several political disagreements regarding vaccinations were ongoing, particularly with requiring state agency staff to be vaccinated.
- Pharmacy's champion in the House of Delegates was appointed to a state Senate seat, so the bill's authors scrambled to obtain a new House member to represent the bill, who was not as supportive.
- Pharmacy stakeholders have to support the bill and make it a high priority.
- The House Health Committee needs to be in consensus; if even one member objects, a bill will not move forward. Republicans pushed back on the bill.
- The Maryland Department of Health report not being delivered to the House Health Committee was a big concern and had an unfavorable impact. Committee members did not think they had enough information to move forward.

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State Executive Panel Discussion: Summary

Discussion centered on these questions: **Were there conversations with public health and immunization managers about going forward to expand pharmacy's role in providing vaccinations, and how were those interactions?**

West Virginia had conversations with public health, stating that those conversations were a vital part of the process, as well as working closely with state health officers. Alaska did not have official support of public health; however, public health did assist. Maryland indicated that it needs to have those conversations in the future, explaining that the Maryland Association of Chain Drug Stores took the lead, as the state pharmacy association was focused on its payment bill; (the state pharmacy association was able to get the Secretary of Health to sign the payment bill). The consensus coming out of this panel was its recognition of the importance of open communications and engagement with public health and other stakeholders to reach common ground for the good of public health and access to vaccinations.

Facilitated Discussion/Questions

Facilitator/presenter: Mitchel Rothholz, RPh, MBA, President, Three-C Consulting Group

Mitchel Rothholz opened the discussion with a brief overview of the VFC program and how pharmacists helped address vaccine issues during the pandemic. He described the purpose of the VFC program and reiterated that VFC covers only a portion of the childhood population. States that tie authority for pharmacists to administer childhood vaccinations to VFC are restricting access to vaccinations unnecessarily. Mr. Rothholz provided the following overview of the VFC program:

- More than half of young children and one-third of adolescents in the United States are eligible to receive vaccinations from the VFC program.
- CDC estimates that VFC vaccinations prevented over 400 million illnesses, more than 26 million hospitalizations, and 930,000 deaths among children born in the last 25 years.
- CDC estimates that every dollar invested in childhood vaccination ultimately saves over 10 dollars.
- Pharmacies (as of April 2023) account for 0.6% of VFC providers. This was an increase from 2021. Among the 37,385 VFC providers, there are 223 pharmacies in the program. The total number of VFC providers has decreased 2.5% since 2021.
- The categories of the 223 pharmacy VFC providers are: independent (101), regional chains (97), health system/medical group (24), and other (1). Notably, there are not any national pharmacy chains identified as VFC providers.
- COVID-19 showed when all providers work together, barriers are removed, and vaccine access and delivery are increased. There are numerous opportunities for pharmacy engagement.

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What have we learned, and what is needed moving forward?

- The "immunization neighborhood" was brought to life during the COVID-19 pandemic.
- Sustaining community-based providers now will ensure continuing access for the next pandemic or public health emergency. Pharmacy providers are stressed and stretched to the limit.
- Communities need to regain the losses on childhood vaccination rates that occurred during the COVID-19 pandemic.
- Health equity and social determinants of health need to be addressed, optimizing the influence and access pharmacy teams have within their communities.
- Pharmacists are a source of credible information and can help vaccine contemplators increase their vaccine confidence.
- Rural areas have a need for increased vaccine access.
- Every pharmacy does not need to be involved in the VFC program, but those that want to should be allowed. The intent of the PREP Act authority was to address a public health crisis and optimize the accessibility of pharmacy and abilities of pharmacy staff to address those needs.

Facilitated Discussion/Questions: Summary

Panelists and participants shared further thoughts about the challenges within the scope of the PREP Act, particularly regarding VFC, while also raising questions and possible actions that state pharmacy associations may want to pursue. The primary focus of the discussion centered on pharmacists wanting to participate in the VFC program and the obstacles to doing so.

Among the impediments mentioned facing pharmacists wanting to get into VFC program activities were Maryland's Department of Health excluding pharmacist participation; Colorado limiting the number of pharmacists in its VFC pilot; pharmacists' resistance to participating; and political factors.

In Texas, politics became the barrier. Although pharmacy legislation to expand immunization authority passed both houses of the state legislature, anti-vaccine language and several anti-vaccine bills were added in the Senate, causing the pharmacy legislation to ultimately die because issues could not be resolved in conference committee. A participant from Texas also noted that pediatricians were insisting that pharmacists must take VFC patients, even though not every physician takes VFC patients, nor do all physicians take Medicaid patients. While 90% of pharmacies fill Medicaid prescriptions, many pediatricians nonetheless feel that pharmacists only want to accept work with high-profit administration rates, rather than provide health care to uninsured/underserved children. Because of the negative presentation by pediatricians, support from Democrats, who often support pharmacists, was lost. In Maryland, the physicians' lobbyist said pharmacists need to be in the VFC program in order to administer vaccinations. Even though some pharmacists want to participate in the VFC program, the state's Department of Health said they cannot.

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Moving Forward

The pharmacy profession needs to look at Medicaid vaccine immunization rates and address this as a potential barrier to provider engagement. Examples highlighting the need for review of Medicaid rates include Pennsylvania not updating its Medicaid vaccination rates since 2009, and the pharmacy association executive from Texas indicated that state's Medicaid rate had not been updated since 2004. Vaccination rates have changed prior to and since the pandemic and provide opportunities for pharmacy associations to engage with other health care providers who have a similar interest in addressing low vaccination rates. Participants suggested that the national pharmacy associations and CDC should look at the maximum VFC reimbursement rates the CDC has established for each state and highlight the variances; this information should be shared with the state pharmacy associations.

One participant stated, "We [pharmacists] don't have a doctor visit fee or a counter fee that gets added to this. We need to have fair reimbursement." Another agreed there is a need to pull data and start the discussion.

For states dealing with VFC barriers, a participant suggested that constructing an agreement for a VFC pilot could help. With only a couple of pharmacists to test, a pilot could demonstrate that pharmacists are trying to address health care gaps. A pilot could also demonstrate how to make the model viable in a pharmacy in order to gain pharmacist willingness to participate. The state agency in charge of VFC would need to understand that a pilot does not mean VFC requirements are being discarded; if anything, a pilot shows how the program can help pharmacists implement the requirements.

In response to physicians pushing for requiring pharmacies to enroll as VFC providers, participants suggested that "physicians should also be required to participate in Medicare Part D if they are going to vaccinate adult patients." Pharmacies that are willing to be VFC providers should have the opportunity to do so. States that have pharmacies as mandatory reporters as vaccinators should use that example to show how pharmacies can be responsible providers and part of the medical home and health team members. There also needs to be education of public health staff and providers that pharmacists would not have to vaccinate all children as VFC providers and could attend to, for example, adolescent patients only.

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Colorado mentioned that it currently has a pilot program; however, VFC limits pilot participation to only 5 to 10 pharmacies. Some pharmacy providers are concerned about the program's administrative burden on their practice. Is there some way to support these efforts, such as funding through CDC? How can state pharmacy associations support pharmacy participation in the VFC program?

Texas cited state restrictions in running a pilot of the VFC program. One commenter suggested that if there is a strong community pharmacy enhanced services network in the state, begin there for support. The topic also arose that although funding is unknown, the federal government recently released money for the CDC Bridge Access Program, and some states are receiving monetary support through that mechanism. Associations should ask their state whether there is funding available; now is the time to begin those discussions. State allocations may also be in Section 317 of the Public Health Services Act. Alaska acknowledged receiving some funding from immunization programs and recommends reaching out to those programs to see whether funds are available, building off Tennessee's example of obtaining grants from the state public health department.

For state health departments that are concerned about adequate staffing to onboard pharmacies as VFC providers, consider advocating for a discussion between the health department and the board of pharmacy since board inspectors are already visiting pharmacies for inspections. Could there be a memorandum of understanding between the two entities for conducting inspections?

NASPA indicated it could commit to having a follow-up call with AIM to see what can be done to help pharmacies interested in engaging with the VFC program get started, including putting together a step-by-step manual on applying to the VFC program. A beneficial step would be to review the federal requirements for VFC and the nuances for each state program.

Vaccination rates have changed prior to and since the pandemic and provide opportunities for pharmacy associations to engage with other health care providers who have a similar interest in addressing low vaccination rates.

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Appendix 1. Participants

Name (First)	Name (Last)	Position	Organization
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Chris	Federico	Association Volunteer	Rhode Island Pharmacists Association
Michelle	Fiscus	Association Staff Member	Association of Immunization Managers
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Debbie	Garza	State Pharmacy Association Executive	Texas Pharmacy Association
Katy	Gore	Association Staff Member	Association of Immunization Managers
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Mitchel	Rothholz	President	Three-C Consulting Group
Mike	Schwab	State Pharmacy Association Executive	North Dakota Pharmacists Association
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Megan	Witkowski	Association Staff Member	North Carolina Association of Pharmacists
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NASPA = National Alliance of State Pharmacy Associations.

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Appendix 2. Acknowledgments

Program Planning and Management

American Pharmacists Association (APhA)

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