Opportunities and Challenges to Pharmacist Participation in the Vaccines for Children Program

Introduction

Adequate access to vaccines that protect children from COVID-19 and other vaccine-preventable diseases is critical to improving childhood vaccination rates. While most children are vaccinated in their medical home, the COVID-19 pandemic underscored the importance of making vaccines available in locations that are more convenient to families—schools, pharmacies, and at community events, for example. The Vaccines for Children (VFC) program ensures that children who are Medicaid-eligible, under-insured, uninsured, or Alaska Native or American Indian have access to vaccines at no cost to their families; however, most VFC vaccine providers are in traditional medical office settings or health departments. This limitation on VFC vaccine availability can result in disparities in access for children who qualify for the VFC program as they may not be able to access vaccines in pharmacies and other locations that have expanded/weekend hours, but only provide vaccines to children with commercial insurance. The Association of Immunization Managers (AIM) convened a work group of state and local immunization program managers and AIM staff to research and develop this white paper, which examines the opportunities and challenges to using pharmacists to expand access to childhood vaccinations through the VFC program. This paper was reviewed by representatives of the American Pharmacist Association and the National Association of State Health Pharmacist Associations.

Background

After the U.S. declared COVID-19 a federal and public health emergency (PHE) in March 2020, provider ordering of routinely recommended pediatric vaccines from the federally funded VFC program profoundly decreased due to parents complying with stay-at-home orders, a reduction in office-based appointment availability for well child care with a shift to telemedicine, and a surge of pediatric respiratory viruses that left pediatric healthcare providers overwhelmed and understaffed (Santoli, et al., 2020) (American Academy of Pediatrics, 2020). While routine childhood vaccination rates have recovered to some degree since 2020, catch-up vaccinations are not occurring to the degree needed to protect children and communities from a resurgence of vaccine-preventable diseases (CDC, 2024).

One survey revealed 41.3 percent of U.S. parents reported their youngest child had missed a well child visit due to the COVID-19 pandemic in 2020, and one-third of parents surveyed reported their child had missed a routine vaccination (Teasdale, et al., 2022). This decline in routine vaccination coverage also manifested in two consecutive years of decreasing coverage with state-required vaccines among children enrolled in kindergarten, accompanied by a significant two-year rise in non-medical vaccine exemption rates (CDC, 2024).

When children are left unvaccinated, vaccine-preventable disease outbreaks become a greater risk, especially in schools and congregate care settings. Globally, more than 25 million children missed out on basic childhood vaccinations in 2021, the highest number since 2008, and 6 million more than in 2019 (WHO, 2022). By the end of 2023, more than 30,000 measles cases

had been reported across 40 of 53 European countries, more than 21,000 of which required hospitalization (European Center for Disease Prevention and Control, 2024). As of July 11, 2024, a total of 167 measles cases were reported across 24 jurisdictions (CDC, 2024). If further outbreaks of vaccine-preventable diseases are to be avoided, it is critical that all children, regardless of insurance status, have access to vaccines at locations and times that are accessible to their caregivers and that make vaccination the easy choice for families.

The 2020 federal Public Readiness and Emergency Preparedness (PREP) Act allowed pharmacists in all states to administer vaccines to children as young as 3 years of age (HHS, 2020). This expanded access and relieved some of the strain placed upon pediatric medical offices during the COVID-19 pandemic. The high percentage of children who were vaccinated by pharmacists makes a case for pharmacist participation in the VFC program (Santibanez, et al., 2022). Every state in the United States allows pharmacists to administer vaccines to adults, but some have laws restricting what ages pharmacists are authorized to vaccinate and which vaccines they are authorized to administer. Participation by pharmacies in the VFC program presents benefits to the community but can pose significant challenges to pharmacists and their staff, as well as to the state and local immunization programs that administer the VFC program.

Access to Routine Childhood Vaccinations

For nearly 30 years, the federal VFC program, authorized by section 1928 of the Social Security Act, has provided recommended childhood vaccinations to children from birth through 18 years who are Medicaid-eligible, un- or under-insured, or American Indian or Alaska Native (CDC, 2023). CDC estimates more than 472 million illnesses, 30 million hospitalizations, and more than one million deaths have been prevented by routine childhood vaccination among children born during the VFC era (CDC, 2022). The VFC program reduces financial barriers that prevent physicians and other healthcare providers from having vaccines available for eligible children at the time of scheduled visits. The VFC program requires enrolled providers to stock and offer all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) to eligible children, and the program provides those vaccines at no cost to the provider, individual, or family. The program also ensures providers have separate vaccine stocks for VFC-eligible and privately insured children to ensure vaccine availability. The Centers for Diseases Control and Prevention (CDC) distributes VFC vaccines through its contract with a centralized distributor that ships vaccines to public and private healthcare facilities enrolled in the VFC program. Medical providers enrolled in the jurisdiction's Medicaid program are permitted to charge Medicaid a vaccine administration fee to offset the costs involved with administering vaccines to patients covered under Medicaid. State Medicaid agencies set the administration fee, but the Centers for Medicare and Medicaid (CMS) establishes maximum fees (CMS, 2012). Providers may charge vaccine administration fees to non-Medicaid patients up to the maximum rate established by CDC (CDC, 2014). Since VFC vaccines are provided at no cost to providers, providers may not charge a fee for VFC vaccine products (CDC, 2023). Vaccines for privately insured children are purchased by the medical provider. The Affordable Care Act (ACA) requires commercial insurance companies to cover all ACIP-recommended vaccines without cost sharing unless the commercial policy was grandfathered by the ACA (KFF, 2024).

According to CDC, there are approximately 37,100 health care sites enrolled in the VFC program. Providers include, for example, those serving children and adolescents in private practices, public health clinics, federally qualified health centers (FQHCs), rural health clinics, school-based clinics, and some pharmacists, among others (CDC, 2024). Even though private

insurance and the VFC program cover the cost of vaccines, there are still significant health inequities around childhood vaccinations, and vaccination coverage can vary widely depending on race, ethnicity, age, and geography (DeSilva, Haapala, & Vazquez-Benitez, 2022).

While the majority of routine childhood immunizations are administered through the child's medical home, children who receive vaccines through the VFC program may experience decreased access to vaccines compared to children who are privately insured and who have healthcare providers who are routinely available during extended hours or who have multiple provider options. In response to the declared PHE, the federal Public Readiness and Emergency Preparedness (PREP) Act allowed pharmacists, pharmacy technicians, and pharmacy interns to provide COVID-19 and routine vaccinations to children ages 3 and older, preempting more restrictive state and local laws (U.S. Department of Health & Human Services, 2023). The expanded authorization to administer routine childhood vaccinations expired with the end of the COVID-19 PHE in May 2023; however, the authorization to administer COVID-19 and seasonal influenza vaccinations to children ages 3 years and older was extended through December 2024. Despite federal authorization, there has not been widespread participation of pharmacists in providing routine childhood vaccinations to either privately insured children or those who qualify for the VFC program. In some states, state/local legislation and/or corporate policies may prevent certain providers, like pharmacists, from administering all vaccines to all populations (NASPA, 2023). Additionally, pharmacists that do vaccinate children may elect to only vaccinate school-age children, and those that participate in the VFC program may elect to only provide select vaccines (such as influenza and COVID-19 vaccines) to children.

Pharmacists as COVID-19 Vaccination Providers

As of August 2023, more than 307 million doses of COVID-19 vaccine had been administered to children and adults through pharmacies participating in the Federal Retail Pharmacy Program (FRPP), a network of more than 41,000 pharmacy locations that provided COVID-19 vaccines supplied by the federal government (CDC, 2023). As participation in the FRPP required vaccine storage, handling, administration, and documentation processes and procedures that were closely aligned with those of the VFC program, FRPP pharmacies may have already met many of the requirements of the VFC program. According to an analysis of more than 39,000 responses to the National Immunization Survey- Child, COVID-19 Module and parent interviews in 2021 and 2022, pharmacies were the most common place for children ages 5-17 to receive a COVID-19 vaccination (Santibanez, et al., 2022). According to data from CDC's FluVaxView for the 2020-2021 influenza season, 12.3 percent of children ages 6 months through 17 years received a seasonal influenza vaccination at a pharmacy or store compared to 39.1 percent of adults. (CDC, 2021).

A study published in the Journal of the American Pharmacists Association demonstrated that nearly 90 percent of Americans live within five miles of a community pharmacy and 96.5 percent of individuals live within 10 miles of one. In rural areas, more than three quarters of pharmacies are franchises or independent pharmacies, compared to chain pharmacies representing nearly two thirds of pharmacies in cities (Berenbrok, Tang, & Gabriel, 2022).

Many pharmacies operate seven days a week and typically have longer business hours than physicians' offices. Not only are pharmacists some of the most accessible healthcare providers, even in rural areas, but they also have invaluable knowledge about vaccines and medications. Historically, pharmacies do not require appointments for vaccinations; however, there have been

significant staffing shortages across all healthcare fields, which has hindered the ability of some pharmacies to offer walk-in vaccinations since the COVID-19 pandemic (Roth, Greene, & Fiscus, 2022).

Examining Benefits and Challenges with Pharmacist Participation in the VFC Program

Improving routine childhood vaccination coverage requires the involvement of all vaccination providers in a jurisdiction. When children miss routine vaccinations, they are more susceptible to preventable diseases and the public health threat from those diseases increases.

Benefits of Pharmacist Participation in the VFC Program

- **Expanded access for children and families**
  While most routine childhood vaccinations are administered in the medical home, pediatricians, family medicine physicians, and other pediatric health care providers were hard hit by the pandemic and suffered staffing shortages that have been slow to recover. According to a primary care survey conducted by the Larry Green Center, as of March 2023, only 19 percent of primary care practices surveyed reported they were fully staffed, and 60 percent reported having open staff positions they could not fill. Thirty-five percent of those surveyed said they continued to receive new patient requests from those who lost their practice due to closure (The Larry A. Green Center, 2023). Expanding the network of pharmacies enrolled in the VFC program could help alleviate the strain on primary care medical practices and increase vaccination rates, particularly for children and adolescents who do not have a medical home or have a hard time getting in to see their primary care provider (Roth, Greene, & Fiscus, 2022). Additionally, pharmacies provide weekend and evening hours, providing working parents with additional opportunities to seek vaccination for their children. Some pharmacists coordinate with local medical providers to ensure access to vaccinations after clinic hours. This expanded access allows parents to get their children vaccinated outside of clinic hours, while at the same time providing an opportunity for pharmacists to remind parents of the importance of preventive care for children. Pharmacists also partner with local health departments and schools to offer vaccinations at sites where families are present, increasing convenience and removing access barriers (NASHP, 2023).

- **Potential to reduce inequity**
  There is inequity between vaccination rates of privately insured children and those covered by Medicaid or who are uninsured (KFF Health News, 2022). Without pharmacist participation in the VFC program, children who qualify for VFC vaccines can generally only be vaccinated in their medical home (which likely requires an appointment), at a health department (open "government" hours), or at a Federally Qualified Health Center (FQHC). Unless pharmacists participate in the VFC program, VFC-eligible children cannot be vaccinated in pharmacies, creating inequity in access to preventive services.

- **Improved immunization Information system (IIS) data collection**
  Many states require vaccinating pharmacies to report their administered vaccine doses to the state's immunization information system (IIS). As pharmacies can provide access to vaccines in areas where there is not medical care, their reporting to the IIS may illustrate where care gaps exist and indicate areas of low coverage or higher risk for transmission of vaccine-preventable diseases.

If we are to see improvement of routine child vaccination coverage and find ways to reduce burden on pediatric offices, we will need to recruit pharmacists to participate in the VFC program, but many challenges exist.

Challenges to Vaccinating Children in Pharmacy Settings

- **Legislation and Policy**
  One of the greatest challenges to enrolling pharmacies as VFC providers is the limitation placed on pharmacists by many state laws around the ages pharmacists can vaccinate and which vaccines they may administer. Additionally, corporate pharmacy policies may limit the ages to which pharmacists may administer vaccinations. The PREP Act temporarily circumvented state legislative barriers when it expanded authority for pharmacists, pharmacy technicians, and pharmacy interns to administer routine childhood, COVID-19, and seasonal influenza vaccines to children as young as 3 years old. With the end of the public health emergency in May 2023, pharmacist authority to provide routine childhood vaccinations reverted to existing state laws (except for the authorization to administer COVID-19 and seasonal influenza vaccinations, which was extended to December 2024). While many states have moved to codify the PREP Act and thereby preserve pharmacist authority to vaccinate children, some states have not (Bonner, 2023). As a result, the access to routine childhood vaccinations through pharmacies that had been present for much of the pandemic may no longer be available. Pharmacist associations have lobbied for changes to these restrictions with varying degrees of success as they are often met with opposition from medical associations concerned about expansion of pharmacist scope of practice and decreased engagement between patients and their medical home.

- **Finance**
  Financial challenges can hinder the ability of pharmacists to participate in the VFC program. In many jurisdictions, pharmacists cannot enroll as Medicaid providers and cannot receive payment for the administration of VFC vaccines (Immunize Colorado, 2021). Some Medicaid programs have payment restrictions on pharmacists that provide influenza vaccinations to children. If payment is not received to offset the costs of administering vaccines, pharmacies participating in the VFC program do so at a financial loss to their practice. Additionally, while all VFC providers are required to provide the vaccines they carry to all eligible individuals regardless of the patient's ability to pay, pharmacists may be at higher risk than most medical providers due to the walk-in services they provide, putting pharmacies at greater financial risk when they are not able to seek payment for vaccines administered to the uninsured. In some states, pharmacists are required to bill for the administration of VFC vaccines as a medical claim, rather than through their point-of-sale system. This means that individual pharmac*ists*, rather than the pharmac*ies*, are required to be contracted and credentialed with each Medicaid managed care organization (MCO) they intend to bill. This is a time-consuming and laborious process, for both pharmacists and the MCOs. Additionally, pharmacists are required to purchase additional software to file medical claims, which adds additional administrative cost. Pharmacists, like medical providers, also have a limited and strained workforce after the increased demands put on them through the COVID-19 pandemic. Services like COVID-19 testing, anti-viral medication dispensing, and COVID-19 vaccination already require additional staff, making it difficult to also provide routine immunization services for children. If vaccination protocols (physician standing orders) are needed for pharmacists to vaccinate, this can cause additional burdens and stress on the pharmacy.

- **VFC Policies and Oversight**
  VFC enrollment and participation comes with challenges that affect not only pharmacists, but also pediatricians and other provider offices with limited staff. The VFC Operations Guide is provided to immunization program managers by the CDC and outlines the federal methods and expectations for implementing the VFC Program. Per the guide, "Pharmacists are eligible to enroll in the VFC program if state law grants them the authority to administer vaccines by prescription, vaccine protocol, or prescribing" (CDC, 2024). Policies that follow CDC requirements are to be developed by the immunization programs, and the programs are responsible for the oversight and enforcement of the policies. This means there is variability between the policies of the 64 CDC-funded immunization programs because the policies are developed and implemented at the jurisdiction level. Inconsistencies across jurisdictions in policies and procedures for vaccine borrowing, storage and handling, restitution and replacement, and other core components of the VFC program make participation especially difficult for chain pharmacies that operate in more than one state to successfully participate in the VFC program. These challenges can be mitigated, to some extent, by pharmacy chains employing regional managers and experts in laws and board regulations across state lines.

  Other challenges include having designated staff to implement and oversee the pharmacy's VFC program, administer vaccines, manage vaccine inventory, and make sure that proper billing practices are in place to prevent unintentional fraud or abuse of the program through administration of VFC vaccines to non-eligible individuals. The misconceptions or concerns about punishment or fines associated with mismanagement of VFC vaccines and opinions expressed by pediatricians and other providers that vaccinations should only be provided through a child's medical home may also contribute to the hesitancy pharmacists have about enrolling in the VFC program.

- **Training**
  Through the PREP Act, any licensed pharmacist was eligible to provide COVID-19 and routine childhood vaccinations to children as young as 3 years old if the pharmacist met all the requirements laid out in the Act. These requirements included 20 hours of practical training approved by the Accreditation Council for Pharmacy Education (ACPE), a current certificate in basic cardiopulmonary resuscitation, and a minimum of 2 hours of ACPE-approved, immunization-related continuing education courses (HHS, 2020). While the required training programs contain comprehensive information on adult and pediatric vaccinations as well as hands-on training, some pharmacists may feel they do not have the training and level of comfort needed to vaccinate young children, who are often uncooperative and require vaccination techniques that differ from those used to vaccinate older children and adults.

  Additional VFC program training is required for any staff responsible for management or administration of VFC-supplied vaccines. Required training topics include vaccine storage and handling, ordering and inventory management, documentation and reporting requirements, and eligibility screening and documentation requirements. CDC developed the *You Call the Shots* immunization training course that consists of a series of modules that discuss vaccine-preventable diseases and explain the latest recommendations for vaccine use. Immunization programs may require jurisdiction-developed training in addition to the federal VFC program requirements (CDC, 2023).

- **Vaccine Storage and Handling**
  Immunization programs can implement requirements in addition to CDC's requirements for vaccine storage and handling, some of which may be challenging for pharmacists to implement and are inconsistent from state to state. Pharmacy chains in multiple states are held to federal requirements as well as jurisdiction-level requirements for any jurisdiction in which they operate. State variability can be frustrating and confusing and may hinder participation in the VFC program by pharmacists.

  Entities that provide vaccinations should monitor vaccine storage unit temperatures using a "temperature monitoring device" or "TMD." For VFC providers, CDC requires a specific type of TMD called a digital data logger (DDL), a small electronic device that continuously monitors the vaccines' environment using an external sensor probe, and most immunization programs require the use of a DDL (CDC, 2023). Most pharmacies use purpose-built commercial vaccine refrigeration and freezer units that have sophisticated integrated temperature monitoring, but jurisdiction immunization programs may not be familiar with the capabilities of that technology and may still require a separate DDL. This requirement places pharmacists in the position of using duplicative equipment to monitor vaccine temperatures and can cause confusion when the integrated monitor and external DDL show differing temperatures.

  A long-held common misperception that may present a barrier to participation in the VFC program is the belief that VFC vaccine stock must be stored in a unit separate from other vaccine stock held at a facility, thus creating a perceived disincentive for VFC enrollment among pharmacies. However, a separate unit to store only VFC vaccines is not a condition of enrollment in the VFC program. Separation of vaccine inventories does not require the purchase or use of a VFC-only storage unit if the existing unit meets the minimum specifications required for VFC vaccine storage. VFC-supplied vaccines must be visually separated from other vaccine inventories, which can be done by utilizing separate shelves within one storage unit, colored bins, or markings that clearly indicate the vaccine is to be administered only to VFC-eligible individuals. The purchase or acquisition of a vaccine storage unit is only necessary if there is no unit on-site that currently meets the minimum requirements for VFC vaccine storage. A second storage unit is only needed if there is not enough room to store vaccine inventory at its largest volume (e.g., flu and back to school seasons) in a unit without over-crowding.

- **Vaccine Ordering and Inventory Management**
  The VFC program requires all VFC providers to stock and administer privately purchased vaccines for administration to their non-VFC-eligible patients. In some jurisdictions, state, local, or other public funds are used to purchase these vaccines from the CDC federal contracts at the same cost CDC pays per dose. In these jurisdictions, providers are permitted to order most or all vaccines at no cost, reducing or eliminating the financial burden of purchasing expensive privately purchased vaccines. These jurisdictions are referred to as either "universal" or "universal-select" purchase states. Fourteen of the 64 CDC-funded immunization programs are universal vaccine purchase states (Center for American Progress, 2023). Universal states provide all ACIP-recommended vaccines to enrolled providers, while universal-select states provide some, but not all, ACIP-recommended vaccines for administration to non-VFC-eligible individuals. In jurisdictions that do not receive state or local funding for vaccine purchase, and in those that are universal-select states, VFC-enrolled providers must purchase vaccines for their non-VFC-eligible patient populations. While most

vaccine manufacturers offer extended payment terms and opportunities to return expired vaccines for account credit, the financial burden of commercial vaccine purchase can be a barrier to VFC program participation, especially for independent pharmacies in rural areas that may not serve a large population of privately insured children.

- **Accountability and Reporting**
  There is extensive oversight of CDC's management of the VFC program as a taxpayer-funded entitlement program. As such, participation in the VFC program requires a high degree of provider accountability and detailed reporting of publicly supplied vaccines at the dose-level. This means accounting for a vaccine dose through its lifespan: from the time the dose is ordered by the provider, submitted to CDC by the immunization program, fulfilled by the manufacturer directly or at a CDC distribution center, packaged and shipped to the provider site, received, and verified by someone at the facility and appropriately stored, and administered to the patient.

  Many jurisdictions utilize the IIS for vaccine ordering, inventory accountability, and reporting requirements. Laws or policies governing data reporting to the IIS, patient consent laws, or jurisdiction-level implementation of IIS reporting requirements for VFC-enrolled providers vary by jurisdiction. Reporting of administered doses to an IIS is not a requirement of the federal VFC program but a reporting requirement often implemented through the VFC Provider Agreement at the jurisdiction level. In many cases, vaccine doses administered by a pharmacist are automatically electronically reported to the jurisdiction's IIS via a connection with the pharmacy's existing software program; however, small independent pharmacies, especially those in more rural areas, may not have the ability to report electronically to the IIS. Those pharmacies are required to enter vaccine administration information into the IIS manually, which may impose significant burden on pharmacy staff.

- **Logistics of Vaccinating Young Children**
  Unlike medical offices that provide care for children, most pharmacies were not designed in a way that promotes a comfortable space to administer or receive vaccinations. Many pharmacies have undergone improvements or renovations that were necessary to allow for social distancing and space for individuals seeking COVID-19 testing, treatment, or vaccination services; however, there are additional considerations for providing vaccination services to children.

  It is vital to have a private space in or near the pharmacy for patient privacy when administering vaccines. This is particularly important when it comes to pediatric patients, especially the younger ones, because there needs to be room for the parent(s) and caregiver(s) and potentially the patient's sibling(s), as well. Some parents want to be present when their child is vaccinated, while other parents may not want to be present because of the stress and anxiety that goes along with watching their child receive a vaccination. Pharmacies may not have the physical space to accommodate such preferences. Worried parents may become stressed when hearing their child cry, which may affect their ability to assist the pharmacist with the vaccination of their child. Not only is crying stressful for the parent/caregiver and the person vaccinating, it also may cause stress to others in and around the pharmacy. Additionally, infants and toddlers receive vaccinations in the thigh, rather than the arm. This means the pharmacy needs space to lay a child down while vaccinating them or a place for a parent to sit and hold the child in their lap.

Vaccinating children takes more time than vaccinating adults, not only with the vaccination itself, but also with reporting requirements. The PREP Act requires pharmacists to inform the child's pediatrician, if available, of any vaccination(s) given, as well as recommend to the parent or caregiver that the child see their medical provider for a well-child visit. Additionally, children receive several vaccines over the span of their childhood, so it is important that the pharmacist review the patient's record in the IIS and/or other records to ensure the child is getting the correct vaccines at the appropriate time.

- **Increased Burden on Immunization Programs**
  Increasing the number of enrolled providers in the VFC program, regardless of the type of provider, impacts the immunization programs charged with overseeing compliance with VFC regulations. Since the pandemic, immunization programs are stretched and have new staff who are not familiar with program operations outside of a pandemic. Turnover among key staff in immunization programs is high, which impacts continuity of operations and knowledge transfer from veteran staff.

  The rapid onboarding of the more than 41,000 pharmacies enrolled in the FRPP during the pandemic made it impossible for the federal government, which had direct oversight of the program, to conduct site visits with each pharmacy partner. However, immunization programs must adhere to CDC guidance and processes for enrolling new provider sites in the VFC program. Pharmacies that have more than one location typically prefer to enroll all locations at the same time to alleviate changes to workflows or processes for individual locations. Every individual location that will order, administer, or store VFC vaccines is required to participate in an enrollment site visit prior to being authorized to receive and administer VFC vaccines. The number of locations looking to enroll and the geographical logistics with visiting each location are factors that immunization programs must consider when enrolling pharmacies and setting realistic expectations about the time the enrollment process will take from start to finish. After enrolling the new sites, immunization program staff are required to conduct at least one site visit at each VFC location every 24 months.

Considerations

The VFC program has implementation and oversight requirements for immunization programs and enrolled providers to ensure vaccines are viable and available to eligible children and that programs and providers are good stewards of this publicly funded resource. Immunization programs must implement the VFC program and ensure compliance with federal requirements; however, immunization programs also have discretion to implement additional requirements or policies for participating in the VFC program or other publicly funded vaccine programs. Immunization programs that wish to recruit pharmacists to participate in the VFC program may want to evaluate current jurisdiction-specific VFC policies and consider removing or updating requirements that exceed federal requirements, thus potentially decreasing the barriers to pharmacist participation due to burdensome or inconsistent policies for VFC across states.

Below are several considerations for immunization programs wishing to encourage and better equip pharmacists to be successful participants of the VFC program:

- **Vaccine Storage and Handling**
  Vaccine storage and handling requirements, especially around reporting and documentation, can be redundant or administratively burdensome. For example, some immunization

programs require providers to document the current temperatures of vaccine storage units twice daily as well as the minimum and maximum temperatures at least once per day. CDC requires the recording of minimum and maximum temperatures only once each day, in the morning or at the start of the clinic day, using either a paper temperature log with manual records or via the use of a DDL. Immunization programs could consider requiring temperature data be submitted at specified intervals (i.e., weekly, monthly, etc.), that place less burden on pharmacy staff. Additionally, immunization programs could consider becoming familiar with temperature-monitoring technology incorporated in commercial-grade vaccine storage units and allowing pharmacies to use these integrated digital data loggers to monitor VFC vaccines. VFC programs could also consider consulting with CDC's vaccine storage and handling experts (izcoldchain@cdc.gov) to verify if a unit is capable of meeting VFC temperature monitoring device requirements.

Immunization programs could consider reviewing their vaccine storage and handling policies, identify where they deviate from CDC requirements, and consider ways to reduce the burden placed upon pharmacists and other VFC providers.

- **VFC Site Visit Frequency**
  One of the most critical, yet complicated, requirements of the VFC program is compliance with proper vaccine storage and handling. The Office of the Inspector General (OIG) conducts periodic assessments of the VFC program and in 2012 reported that 76 percent of provider offices studied had documentation of vaccines exposed to inappropriate temperatures (HHS Office of Inspector General, 2012). The OIG also assesses compliance with site visits, which CDC requires immunization programs (IPs) to conduct with VFC-enrolled providers at least once every 24 months. IPs must also perform unannounced storage and handling-only visits with a minimum of 5 percent of enrolled providers each year to help ensure vaccines are maintained under the conditions needed to assure their safety and efficacy (Office of Inspector General, 2023). However, some jurisdictions complete site visits with providers annually in addition to storage and handling visits. Aligning with the CDC guidelines is a way to alleviate the burden on immunization program staff as well as pharmacy staff and allow more resources for enrolling new providers, including pharmacies, in the VFC program. Immunization programs can consider clearly communicating their capacity to enroll multiple sites and manage expectations from the start. For example, chain pharmacies may want to enroll all sites in the VFC program; however, if that is not feasible for the immunization program, that could be communicated to program enrollees and a long-term plan for enrollment developed. Immunization programs could also consider appointing a staff member to specialize in pharmacies since the nuances of pharmacy VFC enrollment and operations may be complicated compared to other provider types. Immunization programs may also consider establishing a connection with their state pharmacy association to help answer system-wide questions about pharmacies in their state, including nuances in policies and laws.

- **Vaccine Replacement Models and Borrowing**
  Pharmacists have expressed that increased participation in the VFC program could be achieved if changes are made to the CDC's policy on vaccine replacement models. Vaccine replacement models are designed to alleviate the need to maintain both a private and public vaccine inventory by permitting the administration of privately purchased vaccine to all individuals, which is then replaced dose-for-dose with VFC-supplied vaccine for any vaccines administered to VFC-eligible individuals. Though replacement models are allowed,

jurisdictions must submit detailed policies and procedures for implementing a vaccine replacement model to CDC and demonstrate that the jurisdiction can ensure each dose reported by the provider was in fact administered to an eligible individual. This is a burdensome process for both VFC program participants and immunization programs and therefore not frequently pursued. Vaccine replacement is not allowed for influenza vaccine, which constitutes a large portion of vaccines administered by pharmacies participating in the VFC program.

Most IIS can track inventory at the dose level and record changes to vaccine inventory, including the adding and removing of doses to or from inventory as well as when doses are changed from public to private funding sources. Consideration could be given to standardizing vaccine source designations in IIS to ensure patient eligibility is appropriately documented (e.g., vaccine is state funded, federally funded, or commercially acquired).

Distinct from the vaccine replacement model is vaccine "borrowing" between VFC and commercially acquired stock. Borrowing refers to the use of a VFC-provided vaccine for the vaccination of a VFC ineligible patient or the use of a commercially acquired vaccine for the vaccination of a VFC-eligible patient when the appropriate vaccine dose is not available. For example, if a VFC ineligible patient needed a vaccine but the pharmacy did not have a commercially acquired vaccine dose available, the pharmacist could administer a VFC dose rather than leaving that child unvaccinated. The pharmacist would then need to "pay back" the VFC dose with a commercially acquired dose as soon as the stock was available to do so. There is concern, however, that by allowing borrowing of VFC vaccines, vaccine may not be available for VFC-eligible patients. Per CDC, "When allowing a single inventory and "virtually" identifying public stock, it is essential that VFC children are not left vulnerable and unable to obtain vaccines being supplied by the VFC program. Each provider must have a policy and process in place that ensures VFC children have uninterrupted access to all ACIP-recommended vaccines." Many jurisdictions forbid the borrowing of vaccine doses between VFC and commercial stock. Consideration could be given to allow borrowing and thereby permit pharmacists to vaccinate the patient who presents to them, even if the appropriate vaccine stock is unavailable at that moment.

Additional Considerations

- **Medicaid Policies for Provider Recognition and Payment for Vaccine Administration**
  Recognition of pharmacists as Medicaid providers varies across states. Such recognition results in financial incentives for participation in the VFC program because, as Medicaid providers, pharmacists can receive payment for vaccine administration to Medicaid patients.

- **PREP Act**
  The implementation of the PREP Act allowed for pharmacists, pharmacy technicians, and pharmacy interns to vaccinate children as young as age 3, regardless of state or local laws or policies otherwise limiting or prohibiting pharmacists from vaccinating children. Some jurisdictions have codified elements of the PREP Act that provide authority for pharmacists and pharmacy staff to administer all ACIP-recommended vaccinations to children.

- **Starting Small**
  To mitigate the impact of immunization program staffing shortages, programs may consider starting small by enrolling a limited number of pharmacies or implementing a pilot program, prioritizing areas with the greatest need such as Health Professional Shortage Areas (HPSAs), Medically Underserved Areas (MUAs), or other areas identified as having gaps in vaccination services or coverage (Roth, Greene, & Fiscus, 2022). Immunization programs may also consider using temporary or contracted positions to assist with the enrollment of multiple sites at the start of a pilot program or new initiative to enroll pharmacies in the VFC program.

- **Training**
  Many pharmacist associations developed training and courses to help pharmacists and staff become more comfortable with administering pediatric vaccines. Some pharmacies employ pediatric nurses with experience in improving needle stick comfort to help pharmacists and pharmacy technicians become more comfortable with vaccinating young children.

- **Historical Knowledge**
  Many rural pharmacies have tenured pharmacists and/or pharmacy technicians who can maintain institutional knowledge and serve as a resource to immunization programs and colleagues. Developing relationships with these professionals could be important to understanding context and developing solutions to longstanding challenges.

- **Connections between Pharmacy Leaders and Immunization Programs and Coalitions**
  Ensuring members of pharmacy boards, as well as chain and independent pharmacy network leaders, participate in state and local immunization coalitions and have regular touch points with jurisdiction immunization programs can help alleviate some of the myths and misunderstandings about the burden of participation in the VFC program.

- **Partnerships**
  Establishing partnerships between pharmacists and public health or health care providers, especially in areas where access to VFC vaccines may be limited, may help to expand coverage by providing additional access points for vaccination. For example, a mobile clinic that is a VFC provider could partner with a local pharmacy, using the pharmacy's parking lot to set up a vaccination clinic that is advertised by the pharmacy and supported by pharmacy staff. Pharmacists can also partner with school health programs that are enrolled in the VFC program or, conversely, pharmacists enrolled in the VFC program can support school located vaccination events.

Conclusion

Throughout the pandemic, pharmacists have proven to be important partners in the vaccination of children and can assist with getting children caught up on routine childhood vaccinations that were missed because of the COVID-19 pandemic. Because pharmacies are often the closest and most convenient vaccination location, encouraging pharmacists to participate in the VFC program can help to mitigate inequities in vaccination coverage.

To increase pharmacist enrollment in the VFC program, it is essential for immunization programs and pharmacists to work together to ensure there is compliance with VFC program requirements. Immunization programs need support to scale their workforce, enroll pharmacists,

conduct regular compliance site visits, and support routine vaccine ordering and management. Pharmacist participation in the VFC program could be encouraged by collaboration and regular communication with immunization programs.

It will continue to take all providers in the immunization neighborhood to get childhood vaccination coverage back to pre-pandemic levels and resume progress toward higher coverage rates. Despite the challenges, pharmacists are important partners in ensuring equitable access to affordable vaccines for children.

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