

June 27, 2023

Rochelle P. Walensky, MD, MPH
Director, Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road
Atlanta, GA 30329

Dear Dr. Walensky:

On behalf of the American Academy of Pediatrics (AAP), a non-profit professional organization of more than 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of all infants, children, adolescents, and young adults, and the Association of Immunization Managers (AIM), a non-profit association representing the nation's 64 immunization program managers, we write to urge the administration to consider the needs of participating providers in the Vaccines for Children (VFC) program, as well as their patients, as the Centers for Disease Control and Prevention (CDC) prepares to include COVID-19 vaccines in the VFC program.

The AAP and AIM applaud the federal government for its work throughout the past three years guiding the development, distribution, and administration of safe and effective COVID-19 vaccines. It is nothing short of amazing that over 270 million Americans have received a COVID-19 vaccine since they became available in 2020. Now that we are entering a new phase of the COVID-19 pandemic, with the expected transition of COVID-19 vaccines from being fully purchased by the federal government to instead becoming available in the commercial market, it is important to acknowledge that there are real challenges that must be overcome to make this transition successful.

The VFC program has been extremely successful in increasing vaccination rates for America's youth, particularly rates among Black and Hispanic youth. Both AAP and AIM strongly support the program, which provides vaccines to approximately half of America's children. It is imperative, however, to relieve some of the administrative burden currently associated with the VFC program to help participating providers successfully administer COVID-19 vaccines to their patients. Our organizations encourage CDC to allow additional flexibility in various VFC participation requirements.

Allow a ramp up period for VFC providers

Under the VFC program, participating providers must also carry commercial vaccine stock for their non-VFC patients for vaccines they receive through the VFC program. This requirement is challenging for VFC providers to implement from a financial perspective. In essence, beginning to offer commercial COVID-19 vaccine will come with the same challenges as beginning to offer a new vaccine product.

To begin with, the anticipated cost of COVID-19 vaccines, along with a potentially high minimum order size and multiple presentations, would require providers to invest significant up-front capital costs to stock these vaccines. Many participating VFC providers may not be able to afford these upfront costs. In addition, there is currently little demand for COVID-19 vaccines, especially in younger-aged eligible patients, which may lead to additional financial risk for practices if purchased vaccines cannot be used because demand does not materialize before the ordered doses expire. In addition, with any new vaccine product, there is a significant delay for payers to update their payment systems in order to accept and correctly pay for claims that are submitted. Even with a 3-month lead time, payers have been historically inconsistent in implementing such changes so that payment occurs seamlessly from the start. Some practices intentionally delay implementation of new vaccine products until they are certain that there is a business case for purchasing the vaccine.

Due to the issues outlined above, there is a real concern that requiring all VFC providers to immediately purchase and provide commercialized COVID-19 vaccine to private-pay patients when these vaccines become covered by VFC would likely result in providers dropping out of VFC altogether, which would have the effect of reducing, rather than improving, access to all vaccines. As such, we urge CDC to allow a “ramp up” period of between six and twelve months where VFC providers may gradually begin to acquire and administer VFC and-commercial COVID-19 vaccine. This flexibility will allow time for payment systems to be updated so there is less financial risk on practices. Alternatively, CDC could provide a guarantee to physicians who do order the vaccine immediately that they will be made whole should their submitted claims not be paid appropriately.

Ease storage requirements and allow borrowing between VFC and commercial COVID -19 vaccine stock

In order to facilitate a successful transition to VFC coverage of COVID-19 vaccines, our organizations urge the CDC to clarify that public and private COVID vaccine stock may be stored in the same refrigerator as long as they are clearly labeled and not mixed together. There remains a widely circulated myth that vaccines must be physically separated. While we eagerly await single-dose vials for those younger than age 12, there will still be onerous storage requirements for different vaccines for different age groups. Pediatricians simply do not have the capacity in their storage units to store redundant quantities of COVID-19 vaccines in all of its various preparations. Storing COVID-19 vaccines for each separate age group, along with the usual immunizations covered by the recommended childhood vaccination schedule, is currently stressing the storage capacity of VFC providers.

In addition, our organizations encourage the CDC to ease borrowing requirements between public and private stock for the COVID-19 vaccine in all states. With the uncertainty of demand for COVID-19 vaccines, possibly large upfront costs of purchasing commercial stock, and large numbers of COVID-19 vaccines to store, participating VFC providers should be able to borrow from one stock to another to efficiently respond to ebb and flow in demand. We urge CDC to allow practices to order excess VFC stock during a six-month ramp up period so that practices may borrow VFC stock for private-pay patients with borrowed vaccine to be returned by the end of this period. We would also urge CDC to permit VFC providers to swap from either public or private stock when good faith efforts are made to determine a child’s insurance status, but an inadvertent error was made in classification. Together, we are committed to ensuring accountability for these suggested practices.

Allow vaccine counseling payment in VFC and continue federal investment in promoting COVID-19 immunizations

As we move into the commercialization stage, we also have to realize that the nation still has a long way to go to achieve acceptable COVID-19 vaccination rates for infants and children. While 62 percent of adolescents have received their primary series of COVID-19 vaccine, only 33 percent of children aged 5-11 years have received their primary series and just 11 percent of children aged 2-4 years and 9% of children younger than 2 have received their first shots. Based on conversations with patients and families around the country, our organizations know that many parents have not vaccinated their children because of misinformation and disinformation they have heard about the safety of COVID-19 vaccines. As such, it often takes many conversations before a family chooses to have their child vaccinated. Consequently, we urge the federal government to ensure payment for vaccine counseling for both COVID-19 vaccines and routine immunizations in the VFC program for all VFC eligible children, whether a vaccine is administered or not. We also encourage the federal government to continue funding for a public health campaign to promote the need for COVID-19, as well as routine, vaccinations, particularly messaging to populations with lower vaccination rates.

Encourage manufacturers to provide flexibility with ordering, package size and return policies

In addition to a ramp up period mentioned above, our organizations urge CDC to encourage manufacturers to extend their initial invoice due dates to 180 days from vaccine delivery to allow practices to be paid by insurers before their commercial COVID-19 vaccine invoices are due. In addition, we would appreciate any urging from CDC for

manufacturers to ship COVID-19 vaccine in small minimum order sizes (e.g.,10 doses), and to implement return policies similar to that of influenza and other childhood vaccines, which allow expired vaccines to be returned for full credit.

To reiterate, the AAP and AIM applaud the efforts by the federal government to help develop COVID-19 vaccines, as well as purchase and provide the vaccines at no cost to medical providers and children and adults across the United States. As we prepare to have COVID-19 vaccines distributed through the VFC program, we urge the CDC to consider the recommendations outlined here to ensure a successful transition for participating VFC providers and preservation of the VFC program infrastructure and vaccine access for all children. As always, the AAP and AIM stand ready to partner with the CDC to further the uptake of COVID-19 vaccines through the VFC and keep children and their families safe.

Warmest regards,



Sandy L. Chung, MD, FAAP
President, American Academy of Pediatrics



Claire Hannan, MPH
Executive Director, Association of Immunization Managers