American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

AAP Headquarters
345 Park Blvd
Itasca, IL 60143
Phone: 630/626-6000
Fax: 847/434-8000
www.aap.org

Reply to
AAP Washington Office
601 13th St NW, Suite 400N
Washington, DC 20005
Phone: 202/347-8600
E-mail: kids1st@aap.org

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Ashish Jha, MD
Coordinator, White House Coronavirus Response Team
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear Dr. Jha:

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, I write to urge the administration to consider the needs of infants, children and adolescents as the federal government prepares to transition COVID-19 vaccines into a new stage of the pandemic. We also urge you to ensure that the unique needs of children are addressed as we shift from a federally purchased distribution system to one where COVID-19 vaccines are purchased through the commercial marketplace. We also request to meet with you at your earliest convenience to discuss the recommendations in this letter.

The Academy applauds the federal government for its work throughout the past three years guiding the development of safe and effective COVID-19 vaccines. We are grateful that infants and children under the age of 5 years now have access to COVID-19 vaccines – the last population group to benefit from these vaccines. We also look forward to having the bivalent booster shots authorized for children aged 5-11 years in the near future.

Commercializing COVID-19 vaccines now – when most adults have received the vaccines but most younger children have not – has the potential to leave children behind. Since the COVID-19 vaccines became available to Americans in January 2021, the vaccines were provided at no cost to medical providers to administer them, and with no cost sharing for patients receiving them. This system has facilitated clinician ability to administer the vaccines, which has led to vaccination of a substantial percentage of American adults. However, if a switch to commercialization of COVID-19 vaccines happens soon, clinicians who vaccinate children will face challenges that adult clinicians did not have to face. Specifically, clinicians who administer COVID-19 vaccines to infants and children will need to pay for some of the vaccines upfront, with no guarantee that they will be able to recoup the costs of this investment. This could result in inequitable coverage of COVID-19 vaccines for adults and children, with the population that waited longest to have access to the vaccines at risk for facing access challenges with some clinicians unable to purchase the vaccines because of the costs associated with stocking them. As such, we urge the administration to purchase enough COVID-19 vaccine for children now so the vaccines can be provided at no cost to pediatric clinicians, even as the country switches to commercialization of COVID-19 vaccines.

In addition, there are numerous administrative burdens associated with providing COVID-19 vaccines that need to be addressed in order to ensure that pediatricians and other pediatric clinicians can continue to offer COVID-19 vaccines to their patients. Administering COVID-19 vaccines, as well as routine immunizations, has become increasingly complex, requiring clinicians to dedicate additional time for counseling patients and families, staying abreast of ordering logistics and vaccine labeling, maintaining storage space and borrowing requirements, and following the different messages on

wastage for COVID-19 and routine vaccines. There are several issues that we urge the administration to act on to make it easier to administer COVID-19 vaccines to children.

Flexible ordering policies for COVID-19 vaccines

To begin with, providing more flexibility when ordering COVID-19 vaccines can help pediatric practices better manage the administration of vaccines to their patients. For example, one of the challenges facing pediatric clinicians is the minimum number of vials that they are required to order – often more than they actually need at the time of order. Many practices do not have the refrigerator space to accommodate the number of vials and different types of vials required per order, especially as they need to store COVID-19 and other publicly purchased vaccines separately from privately purchased vaccines. Lowering the number of minimum vials per order—the AAP recommends 10 doses per order—can help practices order the right amount of vaccine and not worry about expiring vials.

Single-dose vials and pre-filled syringes

We urge the administration to work with vaccine manufacturers to allow pediatric practices to receive COVID-19 vaccines in single dose vials or pre-filled syringes, as this will help reduce the amount of wasted COVID-19 vaccine vials that are not fully used. Pediatric offices are only able to order multi-dose vials at this point in time, which poses two competing challenges for pediatricians. On one hand, they can open a vial and risk wastage by the end of the day; on the other, they can decline to vaccinate a willing patient because they do not want to waste any of the vaccine in the vial. Many pediatric offices struggle with this choice daily, especially as publicly administered immunization systems like the Vaccines for Children (VFC) program emphasize no wasting of vaccines. Moving to commercial purchase and distribution of COVID-19 vaccines will exacerbate these challenges, as pediatricians are more likely to be financially liable for wastage. If commercialization of COVID-19 vaccines proceeds without the availability of single-dose options, plans must be put in place to protect clinicians against the risk of loss or many clinicians will be forced to stop providing COVID-19 vaccines.

Labeling and dosing schedules

Single dose vials or pre-filled syringes can help alleviate the confusion resulting from same-colored caps for COVID-19 vaccine for different age groups. Relatedly, improved labeling of COVID-19 vials can help minimize any possible errors in administering the vaccines. The Academy also encourages the administration to work with the manufacturers to simplify the dosing schedules so that Pfizer and Moderna vaccines can be interchangeable and ease the need for medical providers to stock both brands. Many pediatric practices currently store eight types of COVID-19 vaccine: two each (Pfizer and Moderna) for the 6 months to 4 years, 5 to 11 years, 12 years and older, and the bivalent boosters for those 12 and older. With a bivalent booster for children aged 5-11 expected to be available soon, this demonstrates the challenges associated with both administering and storing COVID-19 vaccines for infants, children, and adolescents.

Ordering and cancelling vaccine orders

As we anticipate moving to the commercialization of COVID-19 vaccines there are several additional recommendations regarding ordering and billing for the vaccines that AAP urges the administration to work with manufacturers and insurers to implement. First, we encourage the continuation of weekly supplies of COVID-19 vaccines. Most routine vaccinations are not available that quickly, but this ordering schedule has been helpful to pediatric offices as demand for COVID-19 vaccine is unpredictable. The ability to quickly replenish COVID-19 vaccine stock as needed has been beneficial and should continue. It can also help with storage and waste if practices are allowed to cancel orders that have not shipped in anticipation of decreased demand. In addition, once commercialization is in effect, manufacturers must allow a flexible return policy so that unused COVID-19 vials can be returned at no cost to the medical provider. Returning expired vaccines is a routine process for other vaccines and the same accommodation should be made for COVID-19 vaccines.

Longer invoice and payment schedules

With regard to billing and payment for COVID-19 vaccines, the Academy recommends the ability for practices to have longer invoice and payment schedules. Most routine vaccines have a 90-day billing cycle from receipt of invoice to when payment is due on the order. Because of the uncertainty involved with administering COVID-19 vaccines the Academy recommends a 180-day invoice schedule. This will give time for insurance companies to load the proper vaccine codes into their system and assign payment for vaccine administration that practices can then use to pay for COVID-19 vaccine shipments from the manufacturers. Additionally, to ensure a smooth transition, the Academy urges the federal government to ensure that all insurers upload vaccine codes and be ready to pay for all COVID-19 vaccines by a certain date before commercialization is initiated. Even more helpful would be for the federal government to continue federal purchase of COVID-19 vaccines for children for as long of a period as vaccines were purchased for adults. While COVID-19 vaccines could be purchased by the government for children eligible for the VFC program in a commercialization scenario, the administration must consider the financial implications of vaccination for privately insured children. Finally, the Academy would also encourage pricing guidelines for manufacturers so that the cost of COVID-19 vaccines is not exorbitant for pediatric practices to afford. The research and development costs for the COVID-19 vaccines have already been paid and pricing should reflect this reality.

Vaccine counseling and federal investment in promoting COVID-19 and routine 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 58 percent of adolescents have received their primary series of COVID-19 vaccine, only 31 percent of children aged 5-11 years have received their primary series and just 8 percent of children 4 and under have received their first shots. Based on conversations pediatricians have had with their patients and families around the country, we 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. Pediatricians are trusted messengers on vaccines and having these conversations during office visits and in a medical home is the most appropriate setting for these discussions. However, this also means that it will take longer for a majority of younger children to get vaccinated, and pediatric clinicians will need to remain engaged with their families and have the vaccines available to administer when families decide they are ready. We urge the administration to ensure payment for vaccine counseling for both COVID-19 vaccines and routine immunizations, whether a vaccine is administered or not. We also encourage the federal government and insurers to continue providing COVID-19 vaccines at no cost to patients, as any copayment or deductible requirement will pose a barrier for families choosing to vaccinate their children. As we look to increase both COVID-19 and routine immunization rates, we would also encourage the federal government to increase funding for a public health campaign to promote the need for routine immunizations at a national level, as well at a more targeted community level, that can reach populations with lower vaccination rates.

Program flexibility in the Vaccines for Children (VFC) program

In order to raise the COVID-19 vaccination rates for infants and children, the AAP also encourages the Administration to allow COVID-19 vaccines to be distributed through the VFC program, which administers vaccines to approximately half of America's children. Having the ability to order COVID-19 vaccines through VFC will help pediatricians and other participating VFC providers order these vaccines in a similar fashion to other routine immunizations. It is imperative, however, to relieve some of the administrative burden currently associated with administering COVID-19 vaccines and participating in the VFC program. For instance, the Academy urges the federal government to relax current restrictions on storage of public and private vaccines in separate refrigerators. Stocking COVID-19 vaccines for each separate age group, along with the usual immunizations covered by the recommended childhood vaccination schedule, is stressing the storage capacity of participating VFC providers. Participating VFC providers should also be able to administer COVID-19

vaccines through VFC for all eligible children, and not have to refer those who qualify for VFC because they are underinsured to a federally qualified health center or a rural health clinic. It is important to be able to administer COVID-19 vaccines to children when they and their families are ready to be vaccinated and not have to refer them to another provider.

Appropriate payment for administration in the Vaccines for Children program
In addition to program flexibility, the AAP also encourages the Administration to ensure adequate payment levels for VFC providers to administer COVID-19 vaccines. Today, state Medicaid programs pay for the administration of COVID-19 vaccines to Medicaid enrollees, with payment rates at least matching the Medicare payment rate of $40 per COVID-19 vaccine administration. Medicaid payment for COVID-19 vaccine administration is supported by 100% FMAP coverage which will continue for one year after the end of the public health emergency. Once covered by VFC, though, Medicaid payment for COVID-19 vaccine administration to children will be limited by the VFC regional maximum charges; today's payment rate of at least $40 per administered dose exceeds the maximum regional charge for all states. The Academy urges the Administration to preemptively address the access and equity challenges that this change will pose, particularly considering that children are the population group that most needs increased immunization rates. We urge the Administration to revise the regional maximum charges in the VFC program to allow state Medicaid programs to continue to pay at least $40 per COVID-19 vaccine administered. Revising the regional maximum charge amount would also permit states to increase payment for the administration of routine childhood vaccines to account for the increased costs of vaccine storage, VFC program participation, and increased complexity of counseling patients and families about vaccine safety and efficacy.

Simply put, the nation's pediatricians need to be supported as we attempt to vaccinate our nation's youngest citizens against COVID-19. If there are too many financial and practical disincentives for pediatric clinicians to purchase, stock and administer COVID-19 vaccines, we will fail to meet the challenge. If pediatricians are not able to offer the COVID-19 vaccine to their patients due to administrative and other barriers, that will send the wrong message and add to the distrust that many parents have about these vaccines. As such, we urge the administration to do all they can to make it easier for pediatric clinicians to administer COVID-19 vaccines.

To reiterate, the AAP applauds 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. To have vaccinated at least 264 million Americans in a span of just under 2 years is nothing short of remarkable. As we transition from a federally purchased distribution system to one where COVID-19 vaccines are purchased through the commercial marketplace, we urge the Administration to consider the recommendations outlined here to ensure an equitable treatment of adult and childhood COVID-19 vaccines, as well as make it easier for medical providers to order, purchase, stock and administer COVID-19 vaccines. As always, the Academy stands ready to partner with the administration to further the uptake of COVID-19 vaccines and keep children and their families safe. We hope to meet with you as soon as possible to discuss these important issues.

Sincerely,

Moira A. Szilagyi, MD, PhD, FAAP
President

MAS/pmj