



September 7, 2023

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Dear Secretary Becerra,

On behalf of the American Academy of Family Physicians (AAFP), representing 129,600 family physicians and medical students across the country, I write to share several recommendations the Department of Health and Human Services (HHS) should consider in preparation for the commercial rollout of COVID-19 vaccines later this month.

The AAFP deeply appreciates the many actions taken by the Department and its agencies to support the development and distribution of COVID-19 vaccines over the last three years. Estimates suggest that the COVID-19 vaccination program prevented more than 18.5 million hospitalizations and 3.2 million additional deaths¹. Family physicians are eager to protect their patients from COVID-19, and the AAFP [believes](#) that all children and adults should have access to all recommended vaccines and the federal government continues to play a significant role in achieving this goal. We stand ready to support the Department's ongoing COVID-19 response.

Given that COVID-19 cases and hospitalizations are again on the rise in communities across the country, a smooth roll out of new COVID-19 vaccines is vital to protecting patients and families as quickly as possible. Evidence clearly demonstrates that primary care physicians are essential partners in this effort: Primary care physicians are the most trusted vaccines messengers and are patients prefer to get new vaccines from them.^{2,3,4} As we noted in an [earlier letter to the President](#), **we are concerned that transitioning the COVID-19 vaccine to the commercial market will create financial and operational challenges for physicians that will impact access to and utilization of COVID-19 vaccines.** We ask that you consider the following strategies to bolster COVID-19 vaccination efforts this fall:

- **Ensure distribution processes, payment rates, and manufacturing buy-back programs enable primary care practices to purchase and offer COVID-19 vaccines to their patients**
- **Facilitate timely, equitable access to vaccines for uninsured adults through the Bridge Access Program**

Reduce financial and operational challenges for physician practices offering COVID-19 vaccines

Family physicians and other health care professionals have faced significant financial hardships during the pandemic, in addition to worsening administrative burden. The federal government's

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centralized purchasing and distribution of COVID-19 vaccines facilitated access in many primary care settings. However, many physician practices experienced delays in receiving vaccine shipments (as compared to other vaccination sites) which in turn delayed vaccination for many patients, including those who were hesitant or in underserved areas. **To promote equitable and timely access to vaccines, we urge HHS to work with vaccine manufacturers and distributors to ensure primary care practices are prioritized in the distribution of new COVID-19 vaccines once they are approved by the Food and Drug Administration and recommended by the Advisory Committee on Immunization Practices (ACIP).**

Ensure payment rates for COVID-19 vaccines cover the cost of offering them

The AAFP is pleased Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) will provide coverage of new COVID-19 vaccines and we appreciate the administration reminding states of their obligation to cover the vaccine through September 2024. However, coverage alone will not guarantee access to the vaccine if physician practices struggle to purchase and offer new vaccines to their patients. **Payment rates that accurately reflect the market price of the vaccine itself, as well as the unique costs supplying and administering COVID-19 vaccines, are necessary to ensure access to COVID-19 vaccines in physician practices.** When selecting which vaccines to stock in their office, physicians report that the cost of vaccine, expense of maintaining vaccine inventory, and payer reimbursement rates are the most influential factors.⁵ The price of the COVID-19 vaccine is predicted to be between \$110 and \$130 per dose, which is significantly higher than many other vaccines.⁶ We appreciate the administration's efforts to encourage manufacturers to set fair prices for COVID-19 but remain concerned about the impact of these high prices on family medicine practices.

In addition to high prices, COVID-19 vaccines have unique expiration timelines, storage requirements, and other supply management concerns which require physician practice staff to spend more time preparing to correctly administer the COVID-19 vaccine. For example, this fall, vaccines for younger children will still only be available in multi-dose vials that require dilution, which means practices must ensure multiple patients will choose to be vaccinated within a 12-hour period or risk wasting costly doses. These additional operational costs and workflow modifications could preclude practices from offering vaccines if doing so risks practices' financial stability.

For these reasons, we [advocated](#) for the manufacture of single-dose vials to prevent vaccine wastage and are pleased more vaccines are expected to be available in single-dose vials this fall. Some formulations for the 2023-2024 vaccination season will be somewhat easier for physician practices to manage but will still require several specific practice considerations and additional expense, as detailed further below. **To reflect the unique costs of administering the COVID-19 vaccine, the AAFP strongly recommends that CMS:**

- **Clarify the enhanced Medicare payment rate for COVID-19 vaccine administration will continue through CY 2024 and ensure Medicare payments for vaccine shipments fully cover the cost of purchasing vaccines.**
- **Publish guidance for state Medicaid officials outlining available waivers and other levers states can use to ensure Medicaid payment rates for vaccine products and administration promote access to vaccines for Medicaid and CHIP beneficiaries without threatening physician practice stability**

- **Encourage marketplace and commercial health plans to adequately pay for COVID-19 vaccines and administration services.**

Mitigate the financial risks associated with furnishing COVID-19 vaccines

Flexible return policies are needed to enable physician practices to stock and maintain vaccine supply. When COVID-19 vaccines are distributed commercially, physicians must purchase vaccines upfront and are not paid until after the vaccine is administered to patients. This means that offering the COVID-19 vaccine will require a significant financial investment that is accompanied with financial risk—if a physician is unable to administer the vaccine before it expires, their costs are not eligible to be reimbursed.

Purchasing COVID-19 vaccines is particularly challenging due to low demand in many communities and because they expire faster than other vaccines, even when refrigerated. One brand of refrigerated COVID-19 vaccines expires in 30 days while refrigerated injectable inactivated influenza vaccines have a standard expiration date of June 30.⁷ This shorter shelf life requires additional management by practice staff and may preclude practices from stocking and offering this vaccine because wasting any doses will negatively impact practices financially. While one manufacturer plans to allow returns of expired doses, it is unclear whether distributors or other manufacturers will also allow for physician practices to return expired doses, and whether practices will receive a full refund (as opposed to a credit for future purchase). **We urge HHS to encourage manufacturers to establish invoicing and return policies that enable family physicians to stock COVID-19 vaccines with less financial risk.**

Remove barriers for physicians participating in the Vaccines for Children program

The Vaccines for Children (VFC) program provides vaccines to approximately half of all children living in the United States and has proven successful in increasing vaccination rates. Under the VFC program, participating clinicians must also carry commercial vaccine stock for their non-VFC patients for vaccines they receive through the VFC program. Thus, adequate commercial payment rates and robust buy-back programs are also needed support physician practices' participation in this essential program.

Other longstanding administrative and operational challenges have precluded family physicians from participating in VFC. For example, VFC vaccines must be labeled and stocked separately from vaccines the practice has purchased for non-VFC patients. **The AAFP urges HHS to clarify and ease storage requirements and allow borrowing between VFC and private vaccine stock during at least a six-month transition period.** These flexibilities will promote participation in VFC and enable practices to offer vaccines to patients of all ages by easing storage capacity and operational practice challenges.

Provide distinct payment for vaccine counseling

Physicians are the public's most trusted source of vaccine and health related information and can support improved adult vaccination rates.^{8,9,10} In addition to the cost of acquiring and administering the vaccine, physicians spend time counseling patients on the need for a new COVID-19 vaccine, annual influenza vaccines, new respiratory syncytial virus vaccines, and other recommended immunizations. Increasing public distrust in vaccines means that it often takes more time to fully

address patient questions and concerns related to all vaccines. There are also times when vaccine counseling occurs independent of vaccine administration, particularly given that some recommended adult vaccines are only covered under Medicare Part D and therefore physician practices face barriers to offering them to Medicare beneficiaries. However, there is no Medicare payment for counseling unless the patient is vaccinated. Providing separate payment for vaccine counseling will improve vaccination rates by enabling clinicians to spend more time counseling patients even when they cannot offer certain vaccines.

CMS requires state Medicaid agencies and Medicaid managed care plans to cover and pay for vaccine counseling separate from administration for children up to age 21, but this requirement does not extend to Medicare, adult Medicaid beneficiaries, or those enrolled in plans administered by private payers. **The AAFP strongly urges HHS to require coverage of separate vaccine counseling for all ACIP-recommended vaccines across all public programs and for all beneficiaries, including when counseling is provided via audio-only or audio/video telehealth.**

Ensure timely, equitable implementation of the Bridge Access Program

The AAFP strongly supports the Centers for Disease Control and Prevention (CDC) Bridge Access Program, which will provide no cost COVID-19 vaccines to uninsured patients this fall. To improve access to information about the program and facilitate vaccination referrals, **we recommend that HHS publish locations for the Bridge Access Program on vaccines.gov and ensure it is easily searchable.** Family physicians are viewed as a trusted source of COVID-19 information in the communities they serve and making this information available as soon as possible will make it easier to direct eligible patients to these sites earlier in the fall.

We understand that the CDC is modifying existing Community Access to Testing (ICATT) contracts with retail chains to facilitate distribution of vaccines to pharmacies in low access areas with low vaccination coverage¹¹. While these contracts will reach many communities, we urge HHS to ensure there is equitable access in rural areas. A 2022 study found that only 25% of rural counties have a chain pharmacy, and the majority (over 70%) of rural counties are served by independent and franchise pharmacies.¹² **We recommend that the CDC take steps to ensure there is a Bridge Access Program site in every rural community.** The AAFP appreciates the CDC's recent efforts to accelerate contract processes to ensure timely and equitable access to the latest COVID-19 vaccines.

The AAFP strongly supports the decision to include federally-qualified health centers (FQHCs) in the Bridge Program. Many family physicians across the country work in FQHCs providing comprehensive, longitudinal primary care to low-income and other underserved patients, making FQHCs essential to ensuring equitable access to new COVID-19 vaccines. FQHC sites played a critical role in providing equitable access to previous COVID-19 vaccines, delivering nearly 26 million COVID-19 vaccine doses between January and June 2021.^{13,14} **We therefore strongly recommend HHS work across agencies and states to prioritize contracting efforts with FQHC sites, and ensure distribution processes and payment rates support FQHCs in offering vaccines to their patients.**

Thank you for your time and consideration of these important issues. We believe these strategies will strengthen COVID-19 vaccination efforts and equip family physicians to offer timely, equitable access

to COVID-19 vaccines. Should you have any questions, please contact Meredith Yinger, Senior Manager of Federal Policy at myinger@aafp.org or (202) 235-5136.



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American Academy of Family Physicians, Board Chair

Cc: Centers for Disease Control and Prevention
Centers for Medicare and Medicaid Services
Administration for Strategic Preparedness and Response
Food and Drug Administration
White House Office of Pandemic Preparedness and Response and Domestic Policy Council

¹ Fitzpatrick M, Moghadas S, et al. Two Years of U.S. COVID-19 Vaccines Have Prevented Millions of Hospitalizations and Deaths. The Commonwealth Fund, Blog, December 13, 2022. Available: <https://www.commonwealthfund.org/blog/2022/two-years-covid-vaccines-prevented-millions-deaths-hospitalizations>

² Darius Tahir, KFF Health News, "Few Firm Beliefs and Low Trust: Americans Not Sure What's True in Age of Health Misinformation," August 22, 2022. Available: <https://kffhealthnews.org/news/article/few-firm-beliefs-low-trust-health-misinformation-kff-poll/>

³ Kaiser Family Foundation. COVID-19 Vaccine Monitor. June 2021. Available at: <https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-june-2021/>

⁴ Edelman. 2022 Trust Barometer Special Report: Trust and Health. Available at: <https://www.edelman.com/sites/g/files/aatuss191/files/2022-08/2022%20Trust%20Barometer%20Special%20Report%20Trust%20and%20Health%20with%20Talk%20Track.pdf>

⁵ Hutton DW, Rose A, et al. "Importance of reasons for stocking adult vaccines." American Journal of Managed Care. November 2019. Available: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9004468/>

⁶ <https://www.reuters.com/business/healthcare-pharmaceuticals/us-health-department-asks-reasonable-prices-updated-covid-shots-2023-07-13/>

⁷ Hesse EM, Hibbs BF, Cano MV. Notes from the Field: Administration of Expired Injectable Influenza Vaccines Reported to the Vaccine Adverse Event Reporting System — United States, July 2018–March 2019. MMWR Morb Mortal Wkly Rep 2019;68:529–530. DOI: <http://dx.doi.org/10.15585/mmwr.mm6823a3e>

⁸ Darius Tahir, KFF Health News, "Few Firm Beliefs and Low Trust: Americans Not Sure What's True in Age of Health Misinformation," August 22, 2022. Available: <https://kffhealthnews.org/news/article/few-firm-beliefs-low-trust-health-misinformation-kff-poll/>

⁹ Kaiser Family Foundation. COVID-19 Vaccine Monitor. June 2021. Available at: <https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-june-2021/>

¹⁰ Edelman. 2022 Trust Barometer Special Report: Trust and Health. Available at: <https://www.edelman.com/sites/g/files/aatuss191/files/2022-08/2022%20Trust%20Barometer%20Special%20Report%20Trust%20and%20Health%20with%20Talk%20Track.pdf>

¹¹ Centers for Disease Control and Prevention. CDC's Bridge Access Program. Last reviewed July 13, 2023. <https://www.cdc.gov/vaccines/programs/bridge/index.html#vaccines>

¹² Berenbrok L, Tang S, et al. Access to community pharmacies: a nationwide geographic information systems cross-sectional analysis. Journal of the American Pharmacists Association, July 2022. Available at: [https://www.japha.org/article/S1544-3191\(22\)00233-3/fulltext](https://www.japha.org/article/S1544-3191(22)00233-3/fulltext)

¹³ Crane JT, Pacia D, Fabi R, Neuhaus C, Berlinger N. Advancing COVID Vaccination Equity at Federally Qualified Health Centers: a Rapid Qualitative Review. Journal of General Internal Medicine. 2022 March. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8722741/>

¹⁴ Cole MB, Raifman JR, Assoumou SA, Kim J. Assessment of Administration and Receipt of COVID-19 Vaccines by Race and Ethnicity in US Federally Qualified Health Centers. JAMA Network Open. January 2022. Available at: <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2787771>