



December 3, 2020

[Submitted electronically via NVP.RFI@hhs.gov]

David Kim, MD
Office of Infectious Disease and HIV/AIDS Policy (OIDP)
Office of the Assistant Secretary for Health (OASH)
Office of the Secretary (OS)
U.S. Department of Health and Human Services

Re: Vaccines National Strategic Plan 2021–2025

Dear Dr. Kim:

The American Pharmacists Association (APhA) is pleased to submit these comments regarding the draft Vaccines National Strategic Plan 2021–2025. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, specialty pharmacies, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

There are no greater public health priorities today than defeating the COVID-19 pandemic and protecting our nation from other vaccine-preventable diseases like the seasonal flu. We need all-hands-on-deck to improve Americans' access to life-saving vaccines during these difficult times. Pharmacists stand ready, willing, and able to work with our colleagues across the health care continuum to end this pandemic as soon as possible and continue our efforts to improve public health

For that reason, we appreciate the recent action by the OASH authorizing pharmacists to order and administer COVID-19 (ages 3 and older)¹ and Advisory Committee on Immunization Practices (ACIP)-recommended childhood vaccines (ages 3-18),² as well as qualified pharmacy technicians and State-authorized pharmacy interns under certain conditions,³ where this authority did not already exist. This has enhanced the position of community pharmacies and pharmacists as primary access points for patients to receive preventive immunizations and pharmacist-provided patient care services and we strongly urge HHS to make these authorizations permanent.

As valued and vital members of the immunization neighborhood we are committed to consistent collaboration, coordination, and communications with other health care professionals and stakeholders to address the public health needs of our patients and communities. Nearly every pharmacist in America has prior experience vaccinating patients. Pharmacists are also the nation's most accessible health care professionals, with 90 percent of Americans living within five miles of a

¹ HHS. Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act. September 3, 2020, <https://www.hhs.gov/sites/default/files/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf>

² HHS. HHS Expands Access to Childhood Vaccines During COVID-19 Pandemic. August 19, 2020, <https://www.hhs.gov/about/news/2020/08/19/hhs-expands-access-childhood-vaccines-during-covid-19-pandemic.html>

³ HHS. Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing, October 20, 2020, <https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf>

community pharmacy. And, every survey ranks pharmacists as one of America's most trusted professions.

To assist OASH and OIDP to maximize the use of pharmacists to increase vaccine access and immunization rates, APhA respectfully submits the following recommendations on the goals, objectives and strategies of the draft Vaccines National Strategic Plan 2021–2025 below:

Goal 2: Maintain the highest possible levels of vaccine safety.

Objective 2.1 Minimize preventable vaccine-related adverse events.

Strategies: 2.1.2 Promote education and training for health care providers on recognizing, managing, and preventing vaccine- and vaccination-related adverse events.

APhA Comments: While immunizations are overwhelmingly safe and effective, patients can occasionally experience adverse reactions or injury following vaccination. Ready access to reliable, accurate and practical information for providers supports their ability to provide optimal care related to vaccinations. In response, APhA has created an extensive library of educational programs and resources to support pharmacist and pharmacy team member ability to identify and manage adverse reactions and patient expectations related to immunizations. With the expected authorization of the COVID-19 vaccines(s), HHS should fully fund and implement education and training for pharmacists and other immunizing professionals on recognizing, managing, and preventing vaccine- and vaccination-related adverse events. Such training will be necessary to ensure patients are made aware of potential adverse events and to ensure patients return for second doses, if necessary. With the experiences of COVID-19, public expectations for transparency and access to evidence-based information will be heightened.

Strategies: 2.2.1. Strengthen integration of systems that track vaccine administration and adverse events associated with vaccines.

APhA Comments: It will be critical to identify any adverse event signals with accuracy and expediency. The national Vaccine Adverse Event Reporting System (VAERS) and state immunization information systems are important tools to detect concerning safety signals and track administered doses. These programs must receive the necessary resources to enable real-time, efficient, and interoperable reporting processes—including vaccinations and potential referrals with every member of patients' health care teams. Thus, all pharmacists providing vaccinations should have access to integrated electronic health record (EHR) systems. It is also important to note adverse events reported to VAERS are not necessarily side effects caused by vaccination. Prioritization of accurate and timely reporting of any adverse events due to COVID-19 and other vaccine administration will assist healthcare personnel, including pharmacists, in providing the best care and prevention services to their patients and ensure individuals feel empowered regarding their self-care decisions. In addition, identified trends, gaps and issues should be utilized to develop educational resources and practice tools to improve the delivery of immunization services.

Goal 3: Increase knowledge of and confidence in routinely recommended vaccines.

Objective 3.1 Counter vaccine mis- and disinformation and increase public support for the individual and societal benefits of vaccination.

Strategies: 3.1.3. Invest in communication sciences and community engagement to delivery compelling messages on vaccines and vaccinations by trusted messengers.

APhA Comments: Due to the trusting relationships between pharmacists and their patients, pharmacists have ample opportunities to advance public health through immunization advocacy. Pharmacists are important members of the immunization neighborhood, and that trust will be important in addressing vaccine hesitancy for our nation’s vulnerable populations—which is an invaluable asset that should be emphasized in the Vaccines National Strategic Plan.

APhA strongly recommends that HHS implement a fully-funded component for pharmacists and other accessible health care practitioners to conduct coordinated and consistent community- based education and outreach campaigns supporting recommended vaccinations. These campaigns should focus on eliminating stigma, addressing vaccine hesitancy, and improving prevention and health outcomes for high priority and vulnerable patient populations.

Objective 3.2 Increase provider capacity to promote knowledge of the benefits of immunization and increased vaccine acceptance by the public.

Strategies: 3.2.1. Strengthen vaccine curricula in medical, nursing, pharmacy, and allied health education.

Strategies: 3.2.2. Develop partnerships with health professional societies, health professional training programs, and licensing and certification boards to strengthen communications and training of health care professionals about the importance of vaccines and best practices for vaccine counseling and administration.

APhA Comments: APhA strongly urges the Vaccines National Strategic Plan to include a steady funding stream to maintain a quality vaccine curriculum provided by professional associations like APhA and its partnering organizations. For example, HHS could sign a memorandum of understanding with national immunization professional organizations, such as APhA, who provide professional immunization training programs. For example, APhA has trained more than 360,000 pharmacists through its Pharmacy-Based Immunization Delivery certificate training program, based on national educational and practice standards for immunizations from CDC, APhA and other reputable entities. This practice-based curriculum represents a fusion of science and clinical pharmacy. The program, which emphasizes a health care team approach, seeks to foster the implementation of interventions that will promote disease prevention and public health. This program has prepared pharmacists to assume the role of educator, facilitator and/or administer of recommended vaccines.

Objective 3.3 Ensure key decision- and policymakers receive accurate and timely information on vaccines and strategies to promote vaccine uptake

APhA Comments: APhA agrees there is also a great need for key decision-makers to have information on vaccine benefits and risks; economics; and public knowledge, attitudes, and benefits. In particular, many key decision makers may not know the key role that pharmacists play in providing immunization. Accordingly, APhA recommends the Vaccines National Strategic Plan also encourage HHS to work with Congress, CMS and health plans to add a pharmacist modifier on vaccination administration claims to provide greater visibility into the scope and outcomes of the services pharmacists currently provide. In addition, plan strategies should encompass the identification and addressing of system barriers to the optimization of immunization rates including policies related to scope of practice, payment/reimbursement and access to recommended vaccines.

Objective 3.4 Reduce disparities and inequities in vaccine confidence and acceptance.

APhA Comments: Dr. Julie Morito, Executive Vice President at the Robert Wood Johnson Foundation and former Commissioner of Chicago's Department of Health, recommended leveraging existing public health immunization infrastructure, including pharmacists and pharmacies, to reduce disparities and inequities in vaccine confidence and acceptance. Dr. Morito noted that Chicago utilized pharmacists and pharmacies as part of 800 provider sites for distribution of the H1N1 vaccine in traditionally underserved areas as a model to improve health equity and build on public trust.⁴ Utilization and sustaining of accessible and trusted healthcare providers within identified communities is critical for address inequities and health disparities.

Goal 4: Increase access to and use of all routinely recommended vaccines.

Objective 4.1 Increase the availability of vaccines in a variety of settings.

Strategies 4.1.1. Remove barriers to and incentivize vaccination in non-health care settings such as schools, workplaces, places of worship, community centers, and pharmacies, as well as in specialty health care settings (e.g., cancer treatment centers).

APhA Comments: We request that the language of this strategy be modified by removing pharmacies from your description of non-health care settings. A variety of health care services are provided within pharmacies related to medications, disease management, and preventive services, and would be more appropriate for inclusion under specialty health care settings or other location within the plan where healthcare providers are highlighted.

We believe broad access to pharmacists' immunization services for all patient populations is fundamental to achieving equitable accessibility to vaccines to our nation's vulnerable populations and to combat vaccination rates that have plummeted nationally since late March when COVID-19 cases started increasing. Accordingly, as mentioned above, we strongly urge the Vaccines National Strategic Plan to include recommendations to make the new immunization authorizations granted to pharmacists permanent. It is also important to note that data shows there are approximately 21,767 independent pharmacies and 22,812 large national chains.⁵ Additional analysis shows that 20.5% of zip codes that have a pharmacy do not have a chain drug store, supporting the case for broad-based utilization of ALL community-based pharmacy practices under equitable distribution of vaccines.

In addition, implementation strategy needs to address barriers related to network inclusion of pharmacists and other accessible immunization providers, and the removal of increased patient out of pocket cost for utilizing these providers.

Strategies: 4.1.3 Expand the number of Vaccines for Children sites and reduce barriers to provider enrollment.

APhA Comments: Issues have arisen related to pharmacists' ability to enroll as Vaccines for Children (VFC) and Medicaid providers. States have stated they do not have the resources to enroll pharmacies as providers within these programs. Inability to enroll pharmacists limits the ability to

⁴ See, NASEM. Recording of the Third Committee Meeting Open Session. H1N1 Vaccine Sites, Chicago 20092010. August 10, 2020, available at: <https://www.nationalacademies.org/event/08-07-2020/committee-on-equitable-allocation-of-vaccine-for-the-novel-coronavirus-committee-meeting-3>

⁵ 2019 NCPA Digest, Changing the Pharmacy Payment Model.

optimize the value afforded by the Amendment's authority. Without an adequate/reasonable payment structure in place, providers will not be able to sustain their ability to provide vaccines to patients. Accordingly, APhA urges the Vaccines National Strategic Plan to include specific recommendations and guidance HHS can provide to our nation's pharmacists and public health in the states to expand the number of Vaccines for children sites and pharmacist enrollment.

Objective 4.2 Reduce disparities and inequities in access to and use of routinely recommended vaccines across the lifespan.

Strategies 4.2.1. Support continued research on racial and ethnic, age, social, economic, cultural, and other factors that contribute to disparities in vaccination rates, and develop targeted interventions to address them.

APhA Comments: APhA agrees with the need to support continued research on race and ethnicity, age, social, economic, cultural, and other factors that contribute to disparities in vaccination rates and develop targeted interventions to address them. Special attention should be paid to establishing vaccination as a routine part of preventive care from trusted providers..

Objective 4.3 Strengthen data infrastructure, including Immunization Information Systems, to track vaccine coverage in the United States and conduct surveillance of vaccine-preventable diseases.

Strategies 4.3.1. Improve Immunization Information System reporting, its interoperability across state lines, and bidirectional communication with other health data systems.

APhA Comments: The ongoing COVID-19 pandemic brought to light gaps in the immunization infrastructure, especially around Immunization Information Systems (IIS), which can provide timely and accurate vaccination data, and must be used to support any mass immunization efforts around COVID-19. Accountability measures should be highlighted to expand the incorporation of vaccinations and the use of IIS into quality improvement programs. IIS must be enhanced to meet new and changing data standards and access to IIS must be expanded to more providers and settings, including pharmacists and pharmacies, across the health care system. For providers serving multiple jurisdictions consistent reporting, access and interoperability requirements are a must. In addition, seamless and efficient processes for reporting and accessing IIS data is critical in the provision of coordinated immunization services, no matter where the patient gets immunized.

Strategies 4.3.2. Use interoperable health information technology including electronic health records, electronic case reporting, and health information exchange networks to characterize and improve monitoring of vaccine-preventable diseases.

APhA Comments: Currently, some IIS face challenges and policy barriers that limit their ability to maximize their use. IIS should encompass all vaccinations received during each person's lifetime, contain a person's consolidated immunization history, and fully meet the standards recommended by the CDC and American Immunization Registry Association (AIRA) to support clinicians in efforts such as administering multidose vaccines. There must also be coordination, interoperability, and bidirectional communication between the IIS and electronic health records, electronic case reporting, and health information exchange networks, including any new technologies created around Covid-19 distribution. The Vaccines National Strategic Plan should prioritize the completeness of, and communication between, IIS and EHRs to monitor vaccine coverage and efforts to support the adoption of interoperable health information technology and EHRs for immunization.

Strategies 4.3.4. Provide additional resources, training, and incentives to improve IIS reporting by adult vaccine providers.

APhA Comments: APhA agrees that additional resources for training, technical assistance, and incentives to improve IIS are needed.

Objective 4.4 Reduce financial and systems barriers for providers to facilitate delivery of routinely recommended vaccines.

Strategies 4.4.1. Support adequate payments for vaccine counseling and administration to providers under public sector and private health plans.

APhA Comments: There must be adequate reimbursement from public and private payers to cover the cost of vaccine administration, handling, counseling and monitoring. Inadequate reimbursement discourages healthcare providers from proactively offering immunizations, and results in missed immunization opportunities and may result in declines of immunization rates.

Objective 4.5 Reduce financial and systems barriers for the public to facilitate access to routinely recommended vaccines.

Strategies 4.5.1. Remove co-pays, cost sharing, and other financial barriers by health care plans for all routinely recommended vaccines.

APhA Comments: Fixing structural inequities by removing co-pays, cost sharing, and other financial barriers by health care plans for all routinely recommended vaccines in vaccine coverage will provide a clear and direct financial and health benefit and will help to improve our national preparedness. In addition, financial barriers to patents should be removed for preventive services, such as immunizations

Strategies 4.5.2. Promote adequate payments for vaccines and vaccinations by public and private health plans to incentivize providers to vaccinate, thereby promoting access.

APhA Comments: The federal government should continue to encourage and promote adequate payments for vaccines and vaccinations by public and private health plans to incentivize providers, such as pharmacists, to vaccinate. Payments should keep pace with pharmacist and pharmacy costs, including for personal protective equipment (PPE). Sustaining existing community-health care providers is critical to our nation's ability to serve current and future public health needs.

Strategies 4.5.3. Expand systems that provide access to free vaccines for uninsured adults.

APhA Comments: There should be reliable Medicaid coverage of vaccines made available to adult populations across all states. Currently, access to vaccines under Medicaid varies, depending on where patients live and Medicaid eligibility status. Medicaid enrollees who are covered through Medicaid expansion programs are guaranteed access to all ACIP-recommended vaccines recommended with no cost sharing requirements. Not all vaccines recommended for adults are covered by traditional Medicaid programs, and those that are covered may have cost sharing requirements that put access to the vaccine out of reach for uninsured adults and other vulnerable patient populations.

Objective 4.6 Promote public-private partnerships to increase the capacity of the health system to deliver vaccines for routine use and protection during outbreaks.

APhA Comments: HHS has acknowledged the key role of pharmacists in administering vaccinations. APhA urges the Vaccines National Strategic Plan to make these temporary authorizations granted during the public health emergency permanent. The plans should also allow pharmacists, and other health care providers to practice at the top of their license in the community to meet vaccine demand, particularly acknowledging the forthcoming COVID-19 vaccines and the need to reach populations who are currently under-vaccinated. A strong immunization infrastructure will be essential for routine vaccine use and during public health emergencies.

Goal 5: Protect the health of the nation by supporting global immunization efforts.

Objective 5.2 Support global partners in efforts to combat vaccine misinformation, disinformation, and hesitancy worldwide.

Objective 5.3 Support global partners to strengthen immunization systems.

Objective 5.4 Increase coordination of global immunization efforts across federal agencies and with global partners.

APhA Comments: It is important now, more than ever, that communities and health professionals across the globe work together to continue to understand and mitigate the spread of coronavirus. Not having the U.S. influence and support could be detrimental to the health of patients around the world during this immediate crisis, and as we prepare for future pandemics. APhA supports collaborative efforts in the global fight against COVID-19 and vaccine-preventable conditions and applaud the dedication and collaborations worldwide in their efforts to mitigate, contain and prevent the spread of COVID-19 and potential future pandemics. HHS should work with stakeholder organizations to inform and share practice and policy best practices in the United States with global partners. In addition, HHS and CDC should evaluate and disseminate information from other countries to educate US practitioners on potential models to consider.

Conclusion

Thank you for the opportunity to provide feedback on the draft Vaccines National Strategic Plan 2021–2025 and consideration of our comments. We look forward to working with OASH and OIDP to maximize the use of pharmacists to administer lifesaving immunizations and services that will allow health care practitioners to work together to defeat the COVID-19 pandemic and improve immunizations and public health among our nation’s vulnerable populations. If you have any questions or require additional information, please contact Michael Baxter, Senior Director of Regulatory Policy, at mbaxter@aphanet.org or me at ibernstein@aphanet.org.
Sincerely,



Ilisa BG Bernstein, PharmD, JD, FAPhA
Senior Vice President, Pharmacy Practice and Government Affairs