NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

March 29, 2022

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Office of Infectious Disease and HIV/AIDS Policy
Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Submitted electronically via nvp.rfi@hhs.gov

RE: Vaccines Federal Implementation Plan Public Comment Opportunity

Dear Dr. Kim:

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment on the Office of Infectious Disease and HIV/AIDS Policy's (OIDP) request for written comments on the Vaccines Federal Implementation Plan (VFIP). NACDS appreciates OIDP's leadership in supporting immunization efforts in the United States (U.S.) through implementation of the Vaccines National Strategic Plan 2021-2025 (VNSP 2021-2025). NACDS is pleased to offer our support of this important work and to provide recommendations on the VFIP.

As committed partners in the effort to improve immunization rates in the U.S., we appreciate OIDP's recognition throughout the VNSP 2021-2025 and VFIP of the critical role community pharmacies and pharmacists play in expanding equitable access to vaccinations. We strongly support the 2021-2025 VNSP and VFIP's objectives, strategies, and actions that leverage pharmacies to deliver immunizations across the lifespan for all age groups by improving access to vaccines and strengthening the vaccine infrastructure. Specifically, we support and appreciate the inclusion of pharmacies and pharmacists as outlined prominently in the VNSP, in addition to the VFIP's recognition of the importance of pharmacists in addressing vaccine inequities and the promotion of vaccine confidence and acceptance; the critical role of pharmacies in enhancing access; the need to remove barriers to and incentivize vaccination in pharmacies; the effort to assess and seek to mitigate pharmacy barriers with respect to the Vaccines for Children (VFC); among others.

Prior to the COVID-19 pandemic, pharmacies had demonstrated tremendous effectiveness and value in improving vaccination access and uptake across the country. **Furthermore, the importance of pharmacies as an essential element of the nation's vaccination infrastructure has been significantly underscored throughout the COVID-19 pandemic. Please consider:**

- Pharmacies have administered more than 234 million COVID-19 vaccinations to date[1]
- Today, 2 of every 3 COVID-19 vaccine doses are provided at a pharmacy[2]
- More than 40% of those vaccinated at pharmacies were from racial and ethnic minority groups[3]
- About a third of children ages 5 to 11 who received a COVID-19 vaccination did so at a pharmacy[4]
- Half of pharmacy COVID-19 vaccination sites are located in areas with high social vulnerability[5]
- Pharmacies have provided more than 11,000 mobile COVID-19 vaccination clinics across the country[5]

[1] CDC, Federal Retail Pharmacy Program, *available at* https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html.
[2] White House, *available at* https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/02/fact-sheet-president-biden-announces-new-actions-to-protect-americans-against-the-delta-and-omicron-variants-as-we-battle-covid-19-this-winter/.
[3] GAO, Federal Efforts to Provide Vaccines to Racial and Ethnic Groups, *available at* https://www.gao.gov/assets/gao-22-105079.pdf.
[4] Biden Administration, *COVID-19 Vaccine for Children 6 Months – 4 Years Old Preliminary Considerations for Pediatric Planning*, Feb. 2022, *available at* https://www.aha.org/system/files/media/file/2022/02/covid-19-vaccine-for-children-6-months-4-years-old-preliminary-considerations-for-pediatric-planning.pdf.
[5] GAO, Federal Efforts to Provide Vaccines to Racial and Ethnic Groups, *available at* https://www.gao.gov/assets/gao-22-105079.pdf.

- Pharmacies provide more than 20,000 COVID-19 testing sites nationwide, and 70% of such sites are in areas with moderate to severe social vulnerability[6]
- Pharmacies and retail health clinics provide access to COVID-19 antivirals at thousands of locations nationwide

We thank you for the chance to offer recommendations aimed at increasing overall immunization rates across the country by broadly and comprehensively increasing the accessibility of vaccinations to Americans and strengthening the vaccine infrastructure. The following comments draw from similar tenets outlined in NACDS' 2019 comments in response to the VNSP 2021-2025 Request for Information (RFI); however, include recent experiences and learnings from pharmacies' participation in the COVID-19 pandemic response. NACDS supports the coordinated and expansive approach across the Department of Health and Human Services for the VFIP in order to achieve the goals and objectives described in the VNSP 2021-2025. We agree with the overall direction of the implementation plan and the clarity in identifying specific actions and Agency leads and supporting groups. Below we offer specific comments on the VFIP as well as the strategies and the identification of proposed actions.

The following comments build on the draft VFIP's outlined strategies and actions to further foster equity and support public access to vaccination, including at pharmacies, leveraging critical lessons learned during the COVID-19 pandemic.

NACDS Recommendations on VFIP

1. **Collaborate with states to support scope of practice expansion for pharmacists and their staff, including pharmacy technicians, to administer all recommended vaccines across ages and states**, in light of the demonstrated success of scope of practice flexibilities granted during the COVID-19 pandemic to comprehensively expand public access at pharmacies nationwide for a variety of pandemic-related care, including COVID-19 vaccinations, routine, and catch-up vaccines for individuals 3 years of age and older *(in alignment with Strategy 3.3.1 and contemplation of scope of practice barriers across different vaccinators).*

2. **Support consistent coverage and reimbursement of pharmacy-based vaccines that cover pharmacies' costs, vaccination administration, and counseling, including support for pharmacists as eligible providers in Medicare and Medicaid programs** *(in alignment with Strategies 4.1.1, 4.4.3, and 4.5.2 to promote vaccine access by incentivizing vaccination in pharmacies, promoting adequate payments for vaccinations by public and private health plans, and for vaccine counseling and administration, in addition to encouraging state Medicaid programs to continue implementing evidence-based policies to improve vaccination rates).*

3. **Coordinate with pharmacy stakeholders to mitigate undue barriers limiting the ability for pharmacies to participate in the Vaccines for Children (VFC) program** *(in alignment with Strategy 4.1.3 to expand the number of VFC sites and reduce barriers to provider enrollment and corresponding action to assess barriers in pharmacy enrollment in VFC and explore options to reduce barriers while maintaining sufficient quality assurance oversight and requirements).*

4. **Support the direct participation of pharmacies and pharmacists in value-based payment models** given their accessibility and expertise in promotion of public access to care, including for vaccination uptake, and their ability to support vaccine-related quality measures in such models *(in alignment with Strategy 4.4.4 Promote the use of vaccination as a quality measure in value-based payment models).*

[6] White House, *FACT SHEET: Biden Administration Announces Historic $10 Billion Investment to Expand Access to COVID-19 Vaccines and Build Vaccine Confidence in Hardest-Hit and Highest-Risk Communities*, *available at* https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/25/fact-sheet-biden-administration-announces-historic-10-billion-investment-to-expand-access-to-covid-19-vaccines-and-build-vaccine-confidence-in-hardest-hit-and-highest-risk-communities/.

5. **<u>Support the development of vaccine access programs for the uninsured at accessible care settings, including pharmacies</u>,** leveraging the lessons learned from the HRSA Uninsured Program, for example, which supported COVID-19-related care access for the uninsured during the pandemic *(in alignment with Strategy 4.5.3: to improve access to free vaccines for uninsured adults and corresponding action to implement activities that expand or develop systems that provide access to free vaccines for uninsured adults).*

6. **<u>Support bidirectional, interoperable Immunization Information Systems (IIS) with standardized requirements across states that foster visibility and communication to and from all providers and settings of vaccine delivery, including pharmacies</u>**, to improve the ability of vaccine providers to identify vaccination gaps and act on them *(in alignment with Strategies 4.1.1 and 4.3.1 to improve IIS reporting, interoperability across jurisdictions, and bidirectional communication with other health data systems, and the corresponding action to link vaccination records from pharmacies, specialty care practices, and non-health care settings with the patient's primary care doctor)*

<u>Background</u>

As the most accessible and most frequently visited[7,8,9] member of the healthcare team, pharmacists are particularly well positioned to continue expanding access to vaccination assessment, education, and delivery in neighborhoods across the country. Chain pharmacies have demonstrated their essential role in providing immunizations to millions of Americans and this role has been highlighted during the pandemic and recent flu seasons.

Ahead of initiating the nation's robust COVID-19 vaccination campaign, the Federal government leveraged and coordinated the accessibility, trust, broad sweeping footprint, and clinical and logistical expertise of pharmacies through the Federal Retail Pharmacy Program for COVID-19 Vaccination, a network of 21 retail pharmacy partners and independent and regional pharmacy networks with more than 41,000 locations nationwide, including long-term care pharmacies. This strong network of the nation's pharmacies has also been tapped recently to expand access to COVID-19 antivirals, and many of these same pharmacies participate in federal and state COVID-19 testing programs.

In addition to providing hundreds of millions of COVID-19 vaccinations, pharmacies provided nearly 40 million influenza vaccinations during the 2021-2022 season.[10] Last flu season, for example, pharmacies provided 14 million more flu shots compared to other providers. Chain pharmacies have helped lead the way in being a primary healthcare access point for Americans, including many vulnerable and hard to reach populations, which has helped to address disparities in access to vaccines especially during the COVID-19 pandemic. The literature continues to unequivocally demonstrate that community-based pharmacies are integral to improving vaccination uptake and access.

For example, studies demonstrate that extending pharmacist authority to more broadly provide immunizations has improved vaccination coverage.[11] Pharmacies have also been shown to be a cost-effective healthcare setting for providing immunization services.[12] For these reasons, the Centers for Disease Control and Prevention (CDC) has continued to support pharmacists as fully recognized vaccine-providers.[13] Not only does care improve while avoidable total costs decrease, but patients experience greater choice in healthcare options that are accessible for them when pharmacists can offer and sustain vaccine delivery.

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[7] Manolakis PG, Skelton JB. Pharmacists' Contributions to Primary Care in the United States Collaborating to Address Unmet Patient Care Needs: The Emerging Role for Pharmacists to Address the Shortage of Primary Care Provider. Am J Pharm Educ. Dec 2010. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3058447/

[8] Hemberg N, Huggins D, et al. Innovative Community Pharmacy Practice Models in North Carolina. North Carolina Medical Journal. June 2017. http://www.ncmedicaljournal.com/content/78/3/198.full

[9] Wright, D, Twigg, M. (2016). Community pharmacy: an untapped patient data resource. Integrated Pharmacy Research and Practice. 5:19-25

[10] https://www.cdc.gov/flu/fluvaxview/dashboard/vaccination-administered.html

[11] Drozd EM, Miller L, et al. Impact of Pharmacist Immunization Authority on Seasonal Influenza Immunization Rates across States. Aug 2017. Clinical Therapeutics. doi: 10.1016/j.clinthera.2017.07.004. https://www.ncbi.nlm.nih.gov/pubmed/28781217

[12] Burson, R., Buttenheim, A., Armstrong, A. et al. (2016). Community Pharmacies as Sites of Adult Vaccination: A systematic review. *Human Vaccines & Immunotherapeutics*, 12:12, 3146-3159.

[13] https://stacks.cdc.gov/view/cdc/50403/cdc_50403_DS1.pdf

Given this strong evidence base, we are pleased that the OIDP has included strategies and actions throughout the VNSP 2021-2025 to assess and address barriers that prevent broader public access to vaccinations administered by pharmacists and at pharmacies. NACDS offers the following specific recommendations on the VFIP aimed at increasing overall immunization rates across the country by broadly and comprehensively increasing the accessibility of vaccines to Americans and strengthening the vaccine infrastructure.

NACDS Recommendation 1:
Collaborate with states to support scope of practice expansion for pharmacists and their staff, including pharmacy technicians, to administer all recommended vaccines across ages and states, in light of the demonstrated success of scope of practice flexibilities granted during the COVID-19 pandemic which comprehensively expanded public access at pharmacies nationwide for a variety of pandemic-related care, including COVID-19 vaccinations, routine, and catch-up vaccines for individuals 3 years of age and older *(in alignment with Strategy 3.3.1 and contemplation of scope of practice barriers across different vaccinators).*

The comprehensive ability for pharmacies nationwide to effectuate critical access to vaccinations, testing, and antivirals across communities throughout the COVID-19 pandemic have largely been made possible by flexibilities granted during the Public Health Emergency. Specifically, federal actions taken under the Public Readiness and Emergency Preparedness (PREP) Act leveraged pharmacies, including pharmacists, pharmacy technicians, and pharmacy interns, to provide enhanced public access to COVID-19 vaccines, routine and catch-up vaccines. For reference, the key flexibilities granted for pharmacies under the current PREP Act declaration are outlined in Appendix A.

Collectively, these actions helped unleash pharmacy teams from onerous and unnecessary federal and state barriers that have historically prohibited them from providing such services to populations more broadly, including vaccinations. The flexibilities granted under the PREP Act were instrumental in driving better health and fostering equity across communities, supporting pharmacies to meet the dynamic needs of the nation throughout the pandemic.

Without these flexibilities, the existing patchwork of state rules and regulations for pharmacy vaccinations can create significant patient access barriers, especially in states that have yet to modernize their statutory limits. While not all barriers have been abolished during the pandemic, pharmacies have leveraged these temporary flexibilities effectively to operationalize broader delivery of care services, including vaccinations, especially for vulnerable and underserved populations. For example, the expansion of flexibilities that allow pharmacists to vaccinate children and adolescents attributed to a significant increase in available providers and access that further broadened critical outreach efforts to improve vaccine coverage. In fact, the CDC noted recently in its esteemed *Morbidity and Mortality Weekly Report* that pharmacists were vital in the efforts to vaccinate children aged 5 to 11, especially in areas with high social vulnerability, by addressing high initial demand for COVID-19 vaccine during evenings, weekends, and over holidays when other providers may have been less available.[14] These government actions supporting pandemic-related care have been paramount in helping smooth the complexity of state-by-state rules and regulations for pharmacy personnel as for example, prior to the pandemic, pharmacies often had limited ability to offer vaccination access for younger individuals. Therefore, the flexibilities granted under the current PREP Act declaration have made a meaningful difference in the ability for pharmacies to support a strong and coordinated pandemic response.

However, while the impact and value of these flexibilities to improve care access, foster equity, and promote health for the nation extends beyond the current COVID-19 pandemic emergency, the flexibilities granted under the PREP Act offer only temporary solutions. Therefore, NACDS continues to advocate for federal and state governments and agencies to consider statutory and regulatory mechanisms to preserve long-term access to testing, vaccination, and therapeutics at pharmacies permanently, to strengthen the nation's healthcare infrastructure and capacity, and in preparation for any future public health crises, emergencies or disasters. Similarly, as part of the VFIP, NACDS encourages collaboration with states to secure this important progress to enhance vaccine access and infrastructure in the long-term. Specifically,

[14] https://www.cdc.gov/mmwr/volumes/71/wr/mm7110a4.htm?s_cid=mm7110a4_w

NACDS recommends collaboration with states to support scope of practice expansion for pharmacists to order and administer, and their staff, including pharmacy technicians, to administer, all recommended vaccines across ages and states, at a minimum for individuals 3 years of age and older - as has been authorized under the current PREP Act declaration.

NACDS Recommendation 2:
Support consistent coverage and reimbursement of pharmacy-based vaccines that cover pharmacies' costs, vaccination administration, and counseling, including support for pharmacists as eligible providers in Medicare and Medicaid programs and within private insurance plans *(in alignment with Strategies 4.1.1, 4.4.3, and 4.5.2 to promote vaccine access by incentivizing vaccination in pharmacies, promoting adequate payments for vaccinations by public and private health plans, and for vaccine counseling and administration, in addition to encouraging state Medicaid programs to continue implementing evidence-based policies to improve vaccination rates).*

Although pharmacies are providing essential accessibility to vaccinations, testing, and therapeutics, restrictive or omissive coverage and billing support at the state and federal levels have led to instances where pharmacies may not be adequately compensated for providing clinical care, undermining patient access. These barriers were present prior to and exacerbated during the pandemic. Such barriers hinder scalability, sustainability, and further healthcare access expansion for the public. Some key flexibilities were initiated during the pandemic to smooth these needless barriers, such as Congress requiring health insurers to cover COVID-19 vaccination and costs consistently, without out-of-pocket expenses. Please see Appendix B for additional flexibilities that proved beneficial.

Despite the temporary changes enacted, however, numerous barriers remain. Specifically, pharmacies face numerous payment barriers and gaps in working to serve their patients with both public and private insurance, in addition to the individuals who may be uninsured or underinsured. For example, today, pharmacists generally lack a payment pathway/mechanism in Medicare Part B to provide clinical care to the communities they serve, with the exception of vaccinations and care provided "incident to" a physician's services. This challenge exists beyond Medicare, for commercially-covered individuals and within state Medicaid programs as well, when health plans do not recognize pharmacists or pharmacies as eligible providers of clinical care. This gap can have the effect of undermining the ability for the public to access key care interventions at pharmacies. For example, the lack of pathway for pharmacists to provide clinical care in Medicare Part B may have contributed to the lacking opportunity for pharmacists to be included as eligible to provide vaccine counseling, for example, like other healthcare providers for Medicare and Medicaid beneficiaries. Efforts are underway to help address this problem, including the recent introduction of HR 7213, the Equitable Community Access to Pharmacist Services Act.

Pharmacies, like other healthcare settings, and pharmacy personnel, including pharmacists, should be supported and reimbursed for the care they provide and the services they perform for their patients and communities, whether it is related to vaccinations, testing, therapeutics, or other care based on the needs of their patients, especially in instances of public health crises and emergencies. Pharmacies are in critical need of reliable, sustainable infrastructure to provide consistent public access to care more broadly. This infrastructure, in the form of a payment pathway or mechanism, across public and private programs, in addition for uninsured and underinsured populations, would help build on the lessons learned during the pandemic to establish more reliable and comprehensive public access to care at pharmacies. This care access was proven essential during the pandemic and should be maintained and built upon to reinforce response efforts to future public health challenges. Therefore, we encourage support for pharmacists as providers of clinical care, including vaccine-related care, in the VFIP. NACDS recommends consideration to include essential partners to help achieve this aim, including the Centers for Medicare & Medicaid Services (CMS), state Medicaid programs, and private insurers.

Beyond the clinical aspects of vaccination administration, such as counseling, patients have inconsistent insurance coverage across settings for vaccination itself.[15] This is important because out-of-pocket costs have been frequently

[15] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5741029/

cited as a barrier to vaccination, even as the most significant predictor of vaccine abandonment.[16] In fact, the Community Preventive Services Task Force, overseen by CDC, recommends interventions that reduce out-of-pocket costs based on strong evidence of effectiveness in improving vaccination rates, based on a systematic review of 20 studies.[17] Another study published in December 2018 found that mean out-of-pocket costs were higher for individuals who abandoned a shingles vaccine compared to those who did not. Data analyses indicated individuals with out-of-pocket costs of $80–$90 were 21% more likely, and those with out-of-pocket costs >$90 were 90% more likely to abandon than those with out-of-pocket costs <$80.[18]

Therefore, inconsistent insurance coverage of vaccinations, including at pharmacies, may greatly hinder patient access to vaccines and further limits the ability for pharmacies and other vaccine providers to more broadly improve vaccination rates. Medicare beneficiaries face challenges especially around cost-sharing for Part D vaccines at pharmacies, Medicaid coverage varies state by state, and there is variable coverage by commercial plans.[19] Despite the Affordable Care Act (ACA) mandate to cover vaccines without cost-sharing, this does not always apply to all plans (grandfathered plans) nor does it always apply to all settings (e.g. out of network physician practices, pharmacies).[20] Some reimbursement issues arise due to coverage for the product but not the administration of the vaccine by a pharmacist. Further, many insurers do not cover pharmacy-administered vaccines or cover only a limited selection of vaccines at pharmacies.[21] In fact, based on research conducted by the UCLA Center for Health Policy, expanding coverage of all adult vaccines as a pharmacy benefit of all public and commercial insurance plans would improve vaccination rates especially in patient groups with socioeconomic challenges at highest risk for vaccine-preventable disease, based on experience of the Medi-Cal program in California.[22] After the Medi-Cal program adopted such a policy in 2016, it saw significant increases in the number of doses administered. During 2016 and 2017, the number of flu, pneumococcal disease, and shingles vaccine doses administered to Medi-Cal participants increased by 44.4%.[23]

As such, NACDS urges for support of consistent coverage and reimbursement of pharmacy-based vaccines that cover pharmacies' costs, vaccination administration, and counseling, including support for pharmacists as eligible providers of care in Medicare and Medicaid programs and within private health insurance plans. Importantly, CMS worked to address Medicare reimbursement rates for vaccinations during the COVID-19 pandemic to better cover costs for vaccinators. These changes proved vital in supporting vaccine providers to foster enhanced access. Adequate payment is essential to promoting access and administration of immunizations and may be an especially important factor in addressing disparities and improving health equity.

NACDS urges OIDP to prioritize actions and strategies related to this issue and designate lead groups if not already stated in the draft VFIP. Specifically, we suggest CMS be a lead across strategies and actions on this topic.

NACDS Recommendation 3:
Coordinate with pharmacy stakeholders to mitigate undue barriers limiting the ability for pharmacies to participate in the Vaccines for Children (VFC) program *(In alignment with Strategy 4.1.3 to expand the number of VFC sites and reduce barriers to provider enrollment and corresponding action to assess barriers in pharmacy enrollment in VFC and explore options to reduce barriers while maintaining sufficient quality assurance oversight and requirements).*

NACDS strongly appreciates the inclusion of an assessment and exploration of options to mitigate pharmacy barriers within the VFC program as outlined in the VFIP. As recognized, pharmacies continue to experience longstanding barriers

[16] https://www.ajpb.com/journals/ajpb/2016/AJPB_JulyAugust2016/factors-associated-with-zostavax-abandonment#sthash.85nSmz1P.dpuf
[17] https://www.thecommunityguide.org/sites/default/files/assets/Vaccination-Reducing-Out-of-Pocket-Costs.pdf
[18] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6313857/
[19] "These services are free only when delivered by a doctor or other provider in your plan's network" https://www.healthcare.gov/coverage/preventive-care-benefits/
[20] "Copays vary by plan" https://www.medscape.org/viewarticle/830835_3
[21] http://newsroom.ucla.edu/releases/requiring-insurers-to-cover-retail-pharmacy-vaccinations-for-adult-californians-could-save-lives-study-finds
[22] http://healthpolicy.ucla.edu/publications/Documents/PDF/2018/immunizationbarriers-brief-aug2018.pdf
[23] Ibid.

in VFC program participation.[24] These challenges include for example, inventory segregation, the need for multiple refrigerators, separate ordering and inventory processes, billing challenges, layered on state-by-state nuances, including enrollment barriers, and more.

Unfortunately, barriers preventing pharmacy participation undermine goals to improve health equity and vaccination access. Especially considering that more than 30% of children ages 5 to 11 who received a COVID-19 vaccination did so at a pharmacy, there is tremendous opportunity to meaningfully improve vaccination access for vulnerable children and their families by mitigating barriers to pharmacy participation in VFC. Importantly, during the COVID-19 pandemic, for example, coverage of COVID-19 vaccinations was required across health plans without cost-sharing and state Medicaid programs implemented flexibility for pharmacies to bill Medicaid rather than seek reimbursement through the VFC program, which would have been particularly challenging for pharmacies. In fact, out of nearly 38,000 participating VFC providers, a CDC spokesperson said, only 71 are pharmacies.[25]

Unfortunately, even as flexibilities are in place to foster COVID-19 vaccination access at pharmacies for individuals 18 and under, pharmacies are still subject to VFC requirements for non-COVID-19 vaccinations, limiting the ability for pharmacies to provide access to routine and catch-up vaccinations. Smoothing the patchwork of inconsistencies across health plan coverage to improve access to vaccinations and other care at pharmacies is critical, including mitigation of pharmacy-related barriers within the VFC program to improve community access. NACDS greatly appreciates and applauds consideration of such barriers within the VFIP, and we would strongly urge for collaboration with pharmacy stakeholders in working to mitigate these challenges, together with CDC, state immunization managers, and other stakeholders.

NACDS Recommendation 4:
Support the direct participation of pharmacies and pharmacists in value-based payment models given their accessibility and expertise in promotion of public access to care, including for vaccination uptake and their ability to support vaccine-related quality measures in such models *(in alignment with Strategy 4.4.4 Promote the use of vaccination as a quality measure in value-based payment models).*

As outlined by the VFIP, despite some inclusion of vaccine-related measures in a subset of value-based payment models, there is opportunity to strengthen the use of vaccine-related quality measures within alternative payment models. Further, as described above, pharmacies play a meaningful role in expanding vaccination access and uptake, along with other facets of high priority clinical care. However, unfortunately, pharmacies have not had the opportunity to directly participate in the Center for Medicare and Medicaid Innovation's models to date. NACDS supports the VFIP's strategy to promote use of vaccination as a quality measure in value-based payment models, as outlined, and in tandem, would recommend the VFIP support direct participation of pharmacies and pharmacies in value-based care models to help effectively act on such measures.

NACDS released a report late last year which provides a blueprint to better leverage pharmacies in the next generation of innovative care delivery within government programs. The report is steeped in research outlining the proven ability for pharmacies and pharmacists to move the needle on better health for patients, including vulnerable and high-risk populations, with respect to vaccination uptake and access, among other important interventions. The report, "Accelerating the Center for Medicare and Medicaid Innovation's Mission - Integrating Community Pharmacy Care into Value-Based Programs Amid COVID-19 Pandemic Recovery & Beyond," was co-authored by CapView Strategies and can be accessed here.

NACDS Recommendation 5:
Support the development of vaccine access programs for the uninsured at accessible care settings, including pharmacies, levering the success and lessons learned from the HRSA Uninsured Program, for example, which supported

[24] www.mysocietysource.org/sites/HPV/ResourcesandEducation/Lists/Clearinghouse/Attachments/516/ASTHO%20VFC%20Pharmacy%20Report_Executive%20Summary.pdf
[25] https://khn.org/news/pharmacist-federal-training-program-perform-vaccinations-to-boost-childhood-immunization-rates/

COVID-19-related care access for the uninsured during the pandemic. *(In alignment with Strategy 4.5.3: to improve access to free vaccines for uninsured adults and corresponding action to implement activities that expand or develop systems that provide access to free vaccines for uninsured adults.)*

During the COVID-19 pandemic, coverage was established for certain pandemic care for uninsured and underinsured individuals through the Health Resources and Services Administration (HRSA). Through the Uninsured Program, for example, healthcare providers, including pharmacies, community clinics, and hospitals, have been able to help meaningfully improve and sustain access for uninsured populations to receive essential COVID-19-related care, including vaccination, testing, and treatment for vulnerable, uninsured Americans. For example, pharmacies have been able to provide more than 11 million COVID-19 vaccinations to uninsured individuals through this program.[26]

Unfortunately, recent announcements indicate that funding for such programs will soon expire, emphasizing the need to establish permanent programs to maintain critical access for uninsured populations. Therefore, NACDS strongly supports the outlined strategy within VFIP to improve access to vaccines for uninsured adults. Additionally, NACDS supports the development of a potential program aimed at improving access to vaccination for uninsured adults as outlined in President Biden's FY 2023 Budget.[27] As noted above, to promote better access for the public, it is imperative that such a program does not mirror existing VFC barriers that largely prevent pharmacy participation.

NACDS Recommendation 6:
Support bidirectional, interoperable Immunization Information Systems (IIS) with standardized requirements across states that foster visibility communication to and from all providers and settings of vaccine delivery, including pharmacies, to improve the ability of vaccine providers to identify vaccination gaps and act on them. *(In alignment with Strategies 4.1.1 and 4.3.1 to improve IIS reporting, interoperability across jurisdictions, and bidirectional communication with other health data systems, and the corresponding action to link vaccination records from pharmacies, specialty care practices, and non-health care settings with the patient's primary care physician)*

Pharmacies continue to be effective contributors in reporting vaccination information to IIS and the COVID-19 pandemic may have strengthened vaccine registry reporting among some vaccinators given that all COVID-19 vaccinations were required to be reported to state IIS, including those administered by pharmacies. Even prior to the pandemic, pharmacies were effective contributors to IIS, however, often pharmacies can report to IIS but cannot always query the information in a bidirectional manner. Based on findings from 240 articles and abstracts, the Community Guide found that IIS demonstrate ability to facilitate increasing vaccination rates.[28] Specifically, the studies described or evaluated IIS capabilities to: (1) create or support effective interventions to increase vaccination rates, such as client reminder and recall, provider assessment and feedback, and provider reminders; (2) determine client vaccination status to inform decisions by clinicians, health care systems, and schools; (3) guide public health responses to outbreaks of vaccine-preventable disease; (4) inform assessments of vaccination coverage, missed vaccination opportunities, invalid dose administration, and disparities; and (5) facilitate vaccine management and accountability.[29]

For IIS to be best utilized and leveraged as a valuable public health tool, all providers need to be actively engaged and committed to its use. Additionally, standardized requirements across IIS are important to foster consistent and effective use. Evidence shows that pharmacists can contribute in improving the vaccine delivery infrastructure by collecting and tracking important health-related information including connecting to and communicating with public health agencies, such as through state-based IIS. [30] For example, the 2016-2017 CDC-funded adult immunization initiative found that pharmacy-based demonstration projects had success with connecting to and reporting immunization data to state-based registries. However, the lack of consistent reporting and visibility into vaccination registries for patients across

[26] HRSA data as of January 2022
[27] https://www.whitehouse.gov/wp-content/uploads/2022/03/budget_fy2023.pdf
[28] https://journals.lww.com/jphmp/Fulltext/2015/05000/Immunization_Information_Systems_to_Increase.2.aspx
[29] Ibid.
[30] Isenor, J., Edwards, N., Alia, T. (2016). Impact of pharmacists as immunizers on vaccination rates: A systematic review and meta-analysis. Vaccine, 34(47) 5708–5723.

states, providers, and settings hinders the value of IIS to improve vaccination rates and other benefits as listed above.[31] **Pharmacists and their pharmacy teams in particular often lack bidirectional access – the ability to both see and contribute information.**[32] Based on an analysis[33] published in 2015,

- 31 (58.5%) jurisdictions mandated at least 1 type of provider or entity to report immunizations and 22 (41.5%) had no mandate to report immunizations
- 21 of the 31 (67.7%) mandated all immunization providers to report, 27 (87.1%) mandated public health providers to report, 23 (74.2%) mandated VFC providers to report, 21 (67.7%) mandated private providers to report, and 22 (71%) mandated pharmacies/pharmacists to report
- 12 of the 31 (38.7%) mandated that immunizations for all age groups be reported and 17 (54.8%) mandated that immunizations for children/adolescents/young adults (with upper age limits ranging from 18 to 26 years of age) be reported but not immunizations for adults
- 2 (6.3%) programs mandated reporting of immunizations for only young children (with upper age limits of 6 or 7 years of age)
- 26 of the 31 (83.9%) mandated that the report be to the IIS, 3 (9.7%) mandated that the report be to local public health, and 2 (6.3%) mandated that the report be to both local public health and the IIS

Therefore, in addition to the strategies outlined to improve interoperability, communication, and IIS, NACDS recommends the VFIP support bidirectional IIS and vaccine-related data sharing across states and vaccinators, including pharmacies, to improve the ability of vaccine providers to identify vaccination gaps and act on them.

Conclusion

NACDS greatly appreciates and applauds OIDP's work in developing the VFIP. We thank you for recognizing the importance of pharmacies and pharmacists in expanding vaccination access and equity as outlined through various strategies and actions within the VFIP. We support the finalization of such activities and appreciate the opportunity to provide additional thoughts and considerations as outlined above to advance vaccination access and strengthen vaccine infrastructure in the U.S., especially for vulnerable individuals facing disproportionate barriers to care. We look forward to working together to advance vaccination uptake and foster better health across the communities we serve in alignment with the forthcoming, final VFIP and the existing 2021-2025 VNSP. Please contact NACDS' Sara Roszak, Senior Vice President, Health and Wellness Strategy and Policy, at sroszak@nacds.org or 703-837-251.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

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NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' over 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit NACDS.org.

[31] https://www.healio.com/infectious-disease/news/print/infectious-disease-news/%7B5aa0df49-3774-45f1-bda2-dc2f89bb1633%7D/progress-on-the-horizon-to-implement-lifelong-immunization-registries
[32] https://www.pharmacytoday.org/article/S1042-0991(16)30702-2/fulltext
[33] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4671281/

Appendix A

Key Federal Actions Granted Critical Flexibilities for Expanded Access to COVID-19 Testing, Vaccinations, & Therapeutics at Community Pharmacies (Scope of Practice Changes via PREP Act)

- **April 2020: Guidance – Authorizes Pharmacists to Order and Administer COVID-19 Testing**
  - Under the PREP Act, HHS authorized pharmacists and pharmacy interns to order and administer COVID-19 tests.

- **May 2020: HHS Office of General Counsel Advisory Opinion**
  - HHS issued an advisory opinion emphasizing that action under the PREP Act preempts any state or local restrictions. Several confirmations, including this slip opinion from the Department of Justice, of this fact have been issued by the federal government over the past two years.

- **August 2020: PREP Amendment 3 – Authorizes Pharmacists and Pharmacy Interns To Do Childhood Vaccinations** and **September 2020: Guidance – Authorizes Pharmacists and Pharmacy Interns To Do COVID-19 Vaccinations**
  - Under the PREP Act, HHS authorized pharmacists to order and administer, and pharmacy interns to administer, ACIP-recommended vaccinations for children and adolescents 3-18 years of age and COVID-19 vaccinations.

- **October 2020: Guidance – Authorizes Pharmacy Technicians To Do Childhood and COVID-19 Vaccinations; Authorizes Pharmacy Technicians and Pharmacy Interns To Do COVID-19 Testing**
  - Under the PREP Act, HHS authorized pharmacy technicians to administer COVID-19 tests, COVID-19 vaccines, and recommended childhood vaccines.

- **December 2020: PREP Amendment 4 – Clarifies Training and Other Requirements for Pharmacists/Interns/Technicians COVID-19 and Childhood Vaccinations**

- **January 2021: PREP Amendment 5 – Permits Pharmacist License Reciprocity in Other States for Vaccinations**

- **August 2021: PREP Amendment 8 – Expands the Authorization for Qualified Pharmacy Technicians and Interns to Administer Seasonal Influenza Vaccines**
  - Under the PREP Act, HHS authorized pharmacy technicians and pharmacy interns to administer influenza vaccines to adults.

- **September 2021: PREP Amendment 9 – Expands the Authorization for Qualified Pharmacists to Order and Administer and for Pharmacy Technicians and Interns to Administer Select COVID-19 Therapeutics**
  - Under the PREP Act, HHS authorized pharmacists to order and administer and pharmacy technicians to administer COVID-19 therapeutics. In January 2022, pharmacists were authorized to administer flu shots across state lines. [34]

- **Note: PREP Amendment 1, PREP Amendment 2, PREP Amendment 6** (and technical corrections), and **PREP Amendment 7** do not include items specific to pharmacy.

[34] *PREP Act Amendment 10: https://www.federalregister.gov/documents/2022/01/07/2022-00151/tenth-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical*

Appendix B

Key Federal Actions Established Payment Pathways for Expanded Access to COVID-19 Testing & Vaccinations at Community Pharmacies (Flexibilities that Supported Payment/Reimbursement/ Sustainability)

- Mandatory coverage of COVID-19 vaccinations and testing within commercial, Medicare, and Medicaid plans, as required by the CARES Coronavirus Aid, Relief, and Economic Security) Act and FFCRA (Families First Coronavirus Response Act)[35]
- CMS' Toolkits and Interim Final Rules on coverage and billing clarifications for federal programs and commercial payers for COVID-19 vaccinations and testing[36]
- CMS billing clarification on coverage of vaccine administration for children through the Medicaid program in lieu of the Vaccines for Children Program[37]
- Emergency billing guidance from the National Council for Prescription Drug Programs (NCPDP) for COVID-19 vaccinations and testing[38]
- Waiver of regulatory requirements to permit pharmacies to bill Medicare Part B as laboratories for COVID-19 testing[39]
- Implementation of the HRSA Uninsured Program for COVID-19 Testing and Vaccinations and the HRSA Coverage Assistance Fund (CAF) Program for the Underinsured for COVID-19 Vaccinations[40]
- Several state Medicaid agencies' promulgation or announcement of coverage and reimbursement requirements for administration of COVID-19 vaccine
- Several state Medicaid agencies' adoption or recognition of NCPDP emergency guidance for billing standards for administration of COVID-19 vaccines
- State Medicaid agencies' promulgation or announcement of coverage and reimbursement requirements for performing COVID-19 tests as a laboratory

[35] *Coronavirus Aid, Relief and Economic Security Act: https://www.congress.gov/116/bills/hr748/BILLS-116hr748enr.pdf*
Families First Coronavirus Response Act: https://www.congress.gov/bill/116th-congress/house-bill/6201/text
[36] *CMS CLIA guidance: https://www.cms.gov/files/document/se20017.pdf*
CMS COVID-19 Toolkits: https://www.cms.gov/covidvax-provider
[37] *CMS Guidance on COVID-19 Vaccines outside of VFC: https://www.medicaid.gov/state-resource-center/downloads/covid-19-vaccine-toolkit.pdf*
[38] *NCPDP Guidance: https://www.ncpdp.org/NCPDP/media/pdf/NCPDPEmergencyPreparednessGuidance.pdf?ext=.pdf*
[39] *CMS May 8th Guidance: Pharmacies and Other Suppliers May Temporarily Enroll as Independent Clinical Diagnostic Laboratories to Help Address COVID-19 Testing: https://www.cms.gov/files/document/se20017.pdf*
[40] *HRSA: https://www.hrsa.gov/coviduninsuredclaim*