NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

September 7, 2022

Dr. Ashish K. Jha
COVID-19 Response Coordinator
The White House
1600 Pennsylvania Avenue, N.W.
Washington, DC 20502

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dr. Rochelle Walensky
Director
Centers for Disease Control and Prevention
1600 Clifton Rd, N.E.
Atlanta, GA 30333

The Honorable Robert M. Califf, MD, MACC
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244

Ms. Dawn O'Connell
Assistant Secretary for Preparedness and Response
Administration of Strategic Preparedness and Response
200 Independence Avenue, S.W.
Washington, DC 20201

The Honorable Carole Johnson
Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

*Sent via email*

**Re: Action Needed Now to Support Smooth Commercialization of COVID-19 Countermeasures**

Dear Dr. Jha, Secretary Becerra, Dr. Walensky, Dr. Califf, Administrator Brooks-LaSure, Assistant Secretary O'Connell, and Administrator Johnson:

The National Association of Chain Drug Stores (NACDS) appreciates your leadership in serving the American people throughout the COVID-19 pandemic. We are committed to supporting a seamless transition of the nation's COVID-19 vaccines and therapeutics from government-purchased product to a commercially available supply in 2023. Together, the nation's pharmacies in collaboration with federal, state, and local governments have supported widespread access points for the public to obtain important pandemic vaccinations, testing, and therapeutics.

Through the Federal Retail Pharmacy Program for COVID- 19 Vaccination (FRPP), pharmacies have provided more than 260 million vaccination doses – or two out of every three shots in America – including millions for the uninsured and underinsured. The data support the narrative that pharmacies are the nation's answer to health equity – we extended the reach across all populations, including ethnic and racial groups, with such scale that may have seemed unimaginable prior to the pandemic. Pharmacies continue serving all populations as the CDC announced on June 18 its approval of vaccines for children as young as six months of age, and as the ACIP

recommended use of bivalent Pfizer and Moderna booster shots for those 12 years and older. Every step of the way, the nation's pharmacies have elevated their commitment to serving the American people to meet dynamic public health needs during this challenging time.

In fact, pharmacy flexibilities through the PREP Act Declaration and Amendments have supported widespread, comprehensive and reliable access for the public to receive needed countermeasures during the pandemic, and offer solutions to maintain better access to equitable care moving forward. For example, as a result of these flexibilities:

- Pharmacies have administered more than 260 million COVID-19 vaccinations to date.[1]
- About 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]
- 40% 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[6]
- 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[7]
- Pharmacies have provided access to millions of courses of COVID-19 antivirals at thousands of locations nationwide with emphasis in vulnerable communities

NACDS appreciated the opportunity to actively participate in the HHS COVID-19 Medical Countermeasures Commercialization Meeting held on August 30. We look forward to future stakeholder engagements. Building on our prior comment letter from June 24, our evolving understanding of the planned transitions based on the August 30 meeting, and HHS' recent report on coverage considerations for COVID-19 vaccines and therapeutics, we provide the following key recommendations to allow for a more seamless transition:

1. **NACDS Recommendation**: Now is the time for the Administration to lead this country toward a smooth transition of government-purchased to commercially available product. At a minimum, the Administration must establish specific dates for a regular cadence of meetings with stakeholders, including pharmacy. Moreover, the Administration must immediately develop and release a transparent transition plan that identifies specific roles for all stakeholders, including government agency participants. This level of planning and detail is necessary so that industry stakeholders can begin to assign roles and responsibilities within their organizations to ensure that, together, we continue to provide optimal levels of care to the American people during this transition.

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[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.

[6] *Id.*

[7] 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/.

2. **NACDS Recommendation:** The Administration should act to issue a new amendment to the existing PREP Act Declaration to ensure that the relevant pharmacy-provided countermeasures granted in various amendments to the Secretary's existing declaration extend through October 1, 2024 in order to immediately remove current ambiguities to help secure reliable patient access to COVID-19 countermeasures to support effective response and recovery efforts that prioritize the Administration's goals on access and equity.

3. **NACDS Recommendation:** Leaning on the VFC program to ensure access after commercialization of COVID-19 vaccines ignores pandemic lessons that have proven pharmacies are essential to providing vaccination access and fostering equity. Given the extensive barriers to pharmacy participation in the VFC program, NACDS recommends CMS maintain the essential ability for pharmacies to bill Medicaid for VFC-eligible children beyond the commercialization of COVID-19 vaccines and the PHE until the VFC program is revamped. Should CMS end the temporary billing authority that supported vaccination access for millions of children during the pandemic before VFC modernization occurs, it is likely to force vaccination access for vulnerable children to plummet.

4. **NACDS Recommendation:** For COVID-19 vaccines, CMS should reconsider its proposal to align COVID-19 vaccine administration fees down to the same rate as routine vaccines because the operational costs associated with administration of the COVID-19 vaccine remain higher than for other Part B preventive vaccines, and this will not change immediately following the end of the PHE. For oral antivirals, the Administration should already be planning strategies to address gaps in Part D coverage for products not yet approved by the FDA. For COVID-19 tests, CMS should continue to allow pharmacies to bill COVID-19 tests as laboratories, a current pandemic flexibility.

5. **NACDS Recommendation**: The Administration should already be encouraging state Medicaid programs to cover COVID-19 vaccines with no cost-sharing and to reimburse providers on a cost-based reimbursement basis. For oral antivirals, the Administration should already be working on efforts to mitigate gaps and educate the affected patients so that they are aware of their coverage options post-PHE.

6. **NACDS Recommendation:** The Administration must begin planning education efforts to ensure that patients with commercial health insurance coverage are fully versed in the coverage details for COVID-19 vaccines and therapeutics.

7. **NACDS Recommendation**: Given the essential role of pharmacies in the nation's response, NACDS urges the Administration to immediately begin working closely with us and other stakeholders to promote feasibility for pharmacies to participate in the potential VFA program. It is critical that we ensure that barriers within the current VFC program that forcibly exclude pharmacies are not transposed onto the future VFA program. The government should address the uninsured funding stoppage and should make pharmacies whole for covering this government expense for the last 5 months, and still ongoing.

## I. The Biden Administration Must Immediately Commit to a Clear Transition Timeline & Plan

NACDS remains deeply concerned about the likely negative impacts to public health without a clear plan to transition vaccines and therapeutics to the commercial market. The success of this transition will depend on the transparency of the planning process and the engagement of all impacted stakeholders in a comprehensive manner. HHS' August 30 meeting was a first step in the right direction, yet to our knowledge, specific next steps and follow up conversations have yet to be fully clarified. With the transition of some vaccines potentially five months away, a coordinated planning strategy is urgently needed now. As a first step, the Administration must establish a regular cadence of meetings to ensure that numerous facets of planning are addressed to mitigate adverse impacts to the public's access to care.

Further, because the success of this broad sweeping transition depends on the synergistic activities of so many across the healthcare continuum, the Administration must immediately develop and release a streamlined transition plan that clearly outlines the recommended deadlines and activities of each stakeholder across the continuum to support a seamless transition for the public. Major stakeholders include pharmacies, manufacturers, wholesalers and distributors, health plans/payers, including Medicare and Medicaid plans, commercial payers, the National Council for Prescription Drug Programs (NCPDP), and patient groups, in coordination with the federal government including the White House, Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response (ASPR), Centers for Disease Control and Prevention (CDC), Centers for Medicare and Medicaid Services (CMS), and Biomedical Advanced Research and Development Authority (BARDA), among others. The transition plan should aim to streamline the transition process where possible given that each product will be transitioned separately, and in some cases, different age groups for one product could have different transition timelines. For example, providing specific target transition dates and major activities specific to each stakeholder that should be undertaken by a certain deadline, as part of the planning assumptions, will be critical.

Without a clear transition plan and specific planning dates, this vague, piecemeal approach has the potential to cause unnecessary, widespread confusion among providers, payors, and consumers. For example, we have not heard that there will be a consistent approach to maintain the scope and reimbursement pandemic flexibilities for pharmacies who have been instrumental in achieving access and fostering equity throughout the pandemic response. In particular, no guidance or realistic planning has been offered to continue pharmacy scope of practice flexibilities and reimbursement flexibilities that have supported widespread access to care for the nation, especially the most vulnerable populations, including the uninsured and VFC-eligible children. The lapse or removal of such flexibilities – especially at the time of a transition that has the potential to cause public confusion – would lead to the unraveling of years of work and progress in leveraging the skills, expertise, and experience of our nation's pharmacies and pharmacy personnel in serving as a key healthcare destination that allows vaccination, testing, and treatment to flourish at an unprecedented scale. This Administration's inaction has great potential to leave many patient populations, especially underserved communities, without a reliable healthcare destination for these services and countermeasures.

We are particularly concerned that the Administration is unraveling the underpinnings that have led to a successful pandemic response, especially the vital pharmacy personnel flexibilities, at a time when they are needed the most – a time of transition. Although the transition may start in early/mid 2023, it will not end there. As such, pharmacy personnel flexibilities will continue to be critical to meeting patient needs throughout the transition period, and continuation through 2024 may allow states time needed to modernize their laws to make such flexibilities permanent. From our experience in stepping up and serving as key health care providers of COVID-19 countermeasures for our nation's most vulnerable populations, along with the numerous challenges we have faced and successfully overcome, we sincerely urge the Administration to pay heed to and

mitigate the potential and likely pitfalls we foresee in the coming months and years in order to prevent undue gaps and interruptions in care for the American people.

**NACDS Recommendation**: Now is the time for the Administration to lead this country toward a smooth transition of government-purchased to commercially available product. At a minimum, the Administration must establish specific dates for a regular cadence of meetings with stakeholders, including pharmacy. Moreover, the Administration must immediately develop and release a transparent transition plan that identifies specific roles for all stakeholders, including government agency participants. This level of planning and detail is necessary so that industry stakeholders can begin to assign roles and responsibilities within their organizations to ensure that, together, we continue to provide optimal levels of care to the American people during this transition.

## II. The Administration's Approach to Winding Down Pandemic Flexibilities Has Been Ineffective for Meeting Future Public Health Needs

We are concerned that despite numerous letters and conversations with the Administration – at all levels – for years and months now, the Administration has not addressed the need to clarify the extension of the PREP Act pharmacy flexibilities to October 1, 2024. Specifically, the Administration should amend the existing PREP Act Declaration for pharmacy personnel (i.e., pharmacists, technicians, and interns) to ensure the following countermeasures extend through October 1, 2024:

- Ordering and administration of COVID-19, flu, and pediatric vaccines, and
- Ordering and administration of COVID-19 testing and therapeutics;
- As well as for pharmacists and interns with respect to reciprocity across state lines.

Pharmacies need formal confirmation to eliminate uncertainty and allow them to continue providing the critical COVID-19-related services of testing, vaccinations, and therapeutics. As you are aware, the flexibilities granted to pharmacy personnel have been instrumental in achieving the Administration's equitable access, response, and recovery priorities. A poll conducted by Morning Consult and commissioned by NACDS shows that 70% of Americans support extending these policies and 68% support making them permanent. Those who received a COVID-19 vaccination from a pharmacy are even more supportive: 85% support extending these policies and 84% support making them permanent.

The current ambiguities leave pharmacy personnel and the patients they serve in an untenable position. Without the certainty of the October 1, 2024 deadline, pharmacies and their patients will be subject to a patchwork of federal and state agreements, all of which have ambiguous and uncertain timeframes for winding down. Especially for pharmacies that serve patients on a nationwide basis, it will be nearly impossible for them to develop and implement enterprise-wide policies and procedures for smooth and successful transitions to commercialization. A transition to commercialization without the certainty that pharmacy personnel flexibilities will extend further interjects unnecessary levels of potential chaos into a moment in time during the pandemic response and recovery that is already fraught with operational complexities, potential for consumer confusion, and potentially harmful gaps in patient care.

Moreover, as discussed in more detail below, the Administration has not expressed interest in maintaining the Medicare rate for COVID-19 vaccine administration, but instead points to the Physician Fee Schedule proposal to align administration fees down with routine vaccines. Further, CMS mentioned when vaccines transition, VFC-eligible populations would no longer be billed under Medicaid using pandemic flexibilities. Instead, payment will be redirected to the traditional VFC program pathway. Without modernization of the VFC program to support pharmacy participation, this transition will force significantly reduced access to vaccinations for VFC-

eligible children at pharmacies, despite the reality that pharmacies have administered more than 40% of COVID-19 vaccinations for the 5-11-year-old population. Additionally, a permanent solution is also imperative to address testing access for the public moving forward. While CMS has allowed pharmacies to bill as laboratories during the pandemic to support COVID-19 testing, permanent solutions that support pharmacy and pharmacist billing for testing services is essential to long term sustainability. For example, HR 7213 – *Equitable Community Access to Pharmacist Services Act* if enacted would establish a permanent payment pathway for certain pharmacist care services under Medicare Part B, including COVID-19 testing among others.

**A. PREP Act Flexibilities:** As we have discussed with Administration officials on a number of occasions, the uncertainty and potential variation of expirations for the PREP Act declaration authorizations for pharmacy personnel continue to leave pharmacies and the patients they serve in an untenable position. The unresolved uncertainties will undermine pharmacies' abilities to continue to provide uninterrupted equitable, comprehensive, nationwide care to our nation's most vulnerable communities. Without clear expiration timing, planning for an operational ramp down will be extremely challenging. Also, the subsequent confusion for the public about which authorities for which products expire at which timeframes will lead to patients not knowing which product or service is available from any given pharmacy at any given time. Ultimately, this will lead to care access gaps, especially for the most vulnerable, for interventions that remain essential to supporting the ongoing pandemic response and recovery, including vaccinations, testing, and treatment access. We urge the Administration to consider the consequential impacts to patient access and care to COVID-19 countermeasures that will result from the continued inaction on this matter; and to remove the ambiguities to help secure reliable patient access to COVID-19 countermeasures through October 1, 2024 by way of a new Amendment to the COVID-19 PREP Act Declaration.

**NACDS Recommendation:** The Administration should act to issue a new amendment to the existing PREP Act Declaration to ensure that the relevant pharmacy-provided countermeasures granted in various amendments to the Secretary's existing declaration extend through October 1, 2024 in order to immediately remove current ambiguities to help secure reliable patient access to COVID-19 countermeasures to support effective response and recovery efforts that prioritize the Administration's goals on access and equity.

Adding to our concerns about no clear plan for a smooth transition for pharmacy personnel authorizations, there appears to be no concerted effort by the Administration to help ensure that providers receive adequate reimbursement for countermeasure-related products and services, especially vaccines, therapeutics, and testing.

**B. Ensuring Access to Vaccinations for VFC-eligible Children:** With respect to VFC-eligible children, the current indication that the Administration will rely on the VFC program following the commercialization transition will be woefully inadequate to meet the needs of low-income children. To advance access and equity during the pandemic, CMS permitted pharmacies to bill Medicaid for COVID-19 vaccinations administered to VFC-eligible children.[8] This authority was desperately needed given the insurmountable barriers that exist for pharmacy VFC participation. In parallel with authorities granted under the PREP Act, the ability to bill Medicaid for VFC-eligible kids to receive pharmacy-based vaccinations resulted in pharmacies administering more than

[8] CMS billing clarification on coverage of vaccine administration for children through the Medicaid program in lieu of the Vaccines for Children Program: https://www.medicaid.gov/state-resource-center/downloads/covid-19-vaccine-toolkit.pdf

46% of doses to 5-11 year-olds, including almost 49% of doses in high SVI areas.[9] At the time of the study (January 2022), this equated to more than 6 million vaccinations, but would be much higher today.

The current VFC program has been unworkable for the vast majority of pharmacies since the inception of the program. This is exemplified in the fact that **fewer than 100 (less than 1%) of pharmacies across the country participate in the VFC program** because of the various operational and reimbursement barriers. Per Kaiser Family Foundation, as of October 2020, "Out of nearly 38,000 participating VFC providers, a CDC spokesperson said, about two-thirds work in private practices. Seventy-one are pharmacies."[10] For many years now, NACDS and other pharmacy and public health stakeholders have called for modernization of the VFC program that recognizes the importance of pharmacies as essential vaccination access points and supports pharmacy participation.[11] The barriers to pharmacy participation have been well documented.[12] NACDS welcomes the opportunity to collaborate with CDC and others to modernize the VFC program requirements in an accessible and equitable manner to better meet the needs of vulnerable children.

Without expedited changes to the VFC program that support pharmacy participation, NACDS is highly concerned that millions of children may be facing loss of vaccination access unless CMS maintains the temporary billing authority that helped to facilitate COVID-19 vaccination access for children at pharmacies during the pandemic. It is well documented that pharmacies are the most accessible vaccination setting. For example, CDC published in July 2022 that most U.S. counties had a pharmacy (69.1%) or public health clinic (61.3%) offering COVID-19 vaccines to children aged 5–11 years; fewer counties had a pediatric clinic (29.7%), family medicine clinic (29.0%), or federally qualified health center (22.8%). Beyond geography, pharmacies are often open extended hours, including nights and weekends, compared to other care settings and offer accessible options for VFC-eligible children and their families. However, this access option will be forced out of existence without a long-term commitment to modernize the VFC program, and in the meantime, taking steps to maintain the current flexibility to bill Medicaid for this population.

**NACDS Recommendation:** Leaning on the VFC program to ensure access after commercialization of COVID-19 vaccines ignores pandemic lessons that have proven pharmacies are essential to providing vaccination access and fostering equity. Given the extensive barriers to pharmacy participation in the VFC program, NACDS recommends CMS maintain the essential ability for pharmacies to bill Medicaid for VFC-eligible children beyond the commercialization of COVID-19 vaccines and the PHE until the VFC program is revamped. Should CMS end the temporary billing authority that supported vaccination access for millions of children during the pandemic before VFC modernization occurs, it is likely to force vaccination access for vulnerable children to plummet.

**C. Ensuring Access for Medicare Patients:** With respect to the Medicare population, CMS has indicated its desire to align COVID-19 vaccine administration fees down to the same rate as routine vaccines. In the Physician Fee Schedule proposed rule, CMS acknowledges that the current costs for administering the COVID-19

[9] Kim C, Yee R, Bhatkoti R, Carranza D, Henderson D, Kuwabara SA, Trinidad JP, Radesky S, Cohen A, Vogt TM, Smith Z, Duggar C, Chatham-Stephens K, Ottis C, Rand K, Lim T, Jackson AF, Richardson D, Jaffe A, Lubitz R, Hayes R, Zouela A, Kotulich DL, Kelleher PN, Guo A, Pillai SK, Patel A. COVID-19 Vaccine Provider Access and Vaccination Coverage Among Children Aged 5-11 Years - United States, November 2021-January 2022. MMWR Morb Mortal Wkly Rep. 2022 Mar 11;71(10):378-383. doi: 10.15585/mmwr.mm7110a4. PMID: 35271559; PMCID: PMC8911999.

[10] https://khn.org/news/pharmacist-federal-training-program-perform-vaccinations-to-boost-childhood-immunization-rates/

[11] https://www.nashp.org/increasing-access-to-routine-child-immunizations-state-approaches-for-increasing-pharmacy-enrollment-in-the-vfc-program/#toggle-id-1

[12] ASTHO. KEY CONSIDERATIONS FOR PHARMACIES AND THE VACCINES FOR CHILDREN (VFC) PROGRAM: SUMMARY OF INTERVIEW AND SURVEY FINDINGS https://www.mysocietysource.org/sites/HPV/ResourcesandEducation/Lists/Clearinghouse/Attachments/516/ASTHO%20VFC%20Pharmacy%20Report_Executive%20Summary.pdf

vaccine may be higher and necessitate a higher administration rate during the PHE. However, they state effective January 1 of the year following the year in which the PHE ends, the $40 payment rate for administration of the COVID–19 vaccines will be adjusted to align with the payment rate for the administration of other Part B preventive vaccines. NACDS strongly urges CMS to reconsider this proposal as the operational costs associated with administration of the COVID-19 vaccine remain higher than for other Part B preventive vaccines, and this will not change immediately following the end of the PHE.

This proposal to lower the payment rate for COVID-19 vaccines is illogical, as the administration costs are unmoved by the end of the PHE. Again, this policy falls short of fully planning for and meeting the actual needs of patients and their caregivers as we transition away from the PHE and toward full commercialization.

For oral antivirals in the Medicare program, CMS has stated that current law prevents the government from requiring coverage of EUA products under Part D.[13] This issue was temporarily addressed during the pandemic. However, should commercialization occur before oral antivirals are FDA approved, which is likely as currently presented, Part D beneficiaries will experience coverage and access gaps. The Administration must plan for these anticipated gaps, mitigate them wherever possible, and help beneficiaries understand their options. Specifically, to help ensure access for Medicare beneficiaries, CMS should implement a reimbursement pathway for pharmacists to conduct patient assessments. This can be implemented by leveraging pharmacies that are enrolled in Part B as mass immunizers, for example, through CMS demonstration authority, as was successfully done to cover OTC COVID-19 tests at pharmacies. Additionally, CMS should recognize pharmacists as eligible prescribers of oral antivirals, such as Paxlovid.

Turning COVID-19 testing, the Administration has not yet commented on how it will address flexibilities related to pharmacy billing of COVID-19 tests. During the pandemic, a flexibility was implemented that allowed pharmacies to bill COVID-19 tests as laboratories. We urge the Administration to continue this vital flexibility to allow Americans to continue receiving this vital service at pharmacies especially during a time of transition.

**NACDS Recommendation:** For COVID-19 vaccines, CMS should reconsider its proposal to align COVID-19 vaccine administration fees down to the same rate as routine vaccines because the operational costs associated with administration of the COVID-19 vaccine remain higher than for other Part B preventive vaccines, and this will not change immediately following the end of the PHE. For oral antivirals, the Administration should already be planning strategies to address gaps in Part D coverage for products not yet approved by the FDA. For COVID-19 tests, CMS should continue to allow pharmacies to bill COVID-19 tests as laboratories, a current pandemic flexibility.

**D. Ensuring Access for Medicaid Populations:** While the highly flawed and unworkable VFC program has been mentioned as a solution for providing COVID-19 vaccines to Medicaid-eligible children after the end of the PHE, for most adults it appears that individual state Medicaid programs will determine coverage, reimbursement, and cost-sharing. Here, the Administration and CMS should already be communicating to state Medicaid programs to encourage coverage and reimbursement with no cost-sharing and for cost-based provider reimbursement practices. For uninsured individuals, there will likely be gaps in care following the temporary period after the PHE ends. Presumably, patients that would otherwise have had access during the PHE through the HRSA COVID-19 Uninsured Program, for example, would find coverage through the yet-to-be authorized Vaccines for Adults program, discussed in Section 3, below, of this letter.

[13] ASPE. Understanding Coverage Considerations for COVID-19 Vaccines and Treatments: https://aspe.hhs.gov/sites/default/files/documents/1072f5093254224ac902ca395387085c/coverage-considerations-covid-19.pdf

Oral antivirals present a particularly challenging issue here, as we understand that the Medicaid Drug Rebate Program does not apply to EUA medications.[14] As such, there will likely be gaps in care following the temporary period after the PHE ends. Presumably, patients that would otherwise have Medicaid coverage would then find coverage through the VFA program. Here again, the Administration should already be working on efforts to mitigate access gaps and educate the affected patients so that they are aware of their coverage options post-PHE.

**NACDS Recommendation**: The Administration should already be encouraging state Medicaid programs to cover COVID-19 vaccines with no cost-sharing and to reimburse providers on a cost-based reimbursement basis. For oral antivirals, the Administration should already be working on efforts to mitigate gaps and educate the affected patients so that they are aware of their coverage options post-PHE.

**E. Commercial Market Concerns:** With respect to the COVID-19 vaccines in commercial health insurance market, we are pleased that for plans subject to the Affordable Care Act requirements, coverage without cost sharing will be preserved.[15] However, many patients may not have the necessary information to know whether their specific plan will provide coverage without cost sharing. Here, it will be critical for the Administration to engage in education efforts to help ensure that patients know what to expect when they go to receive their vaccine after the transition to commercialization.

For therapeutics, such as the oral antivirals, we understand that each plan will determine coverage, reimbursement, and cost-sharing. Here, the Administration should already be engaging with the commercial health plans to encourage broad access to the life-saving medications, and at minimal- to no-cost-sharing. Moreover, planning for education efforts should already be underway to help patients understand their health plan coverage details and options.

**NACDS Recommendation**: The Administration must begin planning education efforts to ensure that patients with commercial health insurance coverage are fully versed in the coverage details for COVID-19 vaccines and therapeutics.

## III. The Administration Must Address the Needs of the Uninsured

Despite Secretary Becerra's August 30 remarks centered around "not leaving anyone in the community behind," the Administration has made no mention or interest to address the funding stoppages related to the uninsured or how to help ensure that pharmacies and other providers can be properly reimbursed. It is worth noting that since April when the HRSA uninsured and underinsured programs became defunct, the government has turned a blind eye toward the funding stoppage, and America's vaccinators – mostly pharmacies – have covered this expense due to a misguided application of a requirement within a government agreement. It appears that the Administration plans to rely on a yet-to-be-authorized by Congress $2.1 billion "Vaccines for Adults" (VFA) program, the details of which have yet to be determined.

[14] ASPE. Understanding Coverage Considerations for COVID-19 Vaccines and Treatments: https://aspe.hhs.gov/sites/default/files/documents/1072f5093254224ac902ca395387085c/coverage-considerations-covid-19.pdf
[15] ASPE. Understanding Coverage Considerations for COVID-19 Vaccines and Treatments: https://aspe.hhs.gov/sites/default/files/documents/1072f5093254224ac902ca395387085c/coverage-considerations-covid-19.pdf

NACDS remains intrigued by the concept of a VFA program to support improved vaccination access for uninsured individuals in the long-term. As we have highlighted in the past, with the PHE eventually ending, fewer people will be eligible for Medicaid coverage because of reenrollment requirements. There will be a larger population of uninsured people as a result, thus reinforcing the importance for a VFA or similar type of program. As pharmacies have demonstrated they are a cornerstone of vaccination access for the American people, it is essential that any potential VFA program be designed and implemented with pharmacies in mind to promote patient access and foster equity. In particular, NACDS continues to advocate that the design of the prospective VFA program intentionally learn from the flaws currently established in the VFC program that effectively hinder pharmacy participation. NACDS has developed several recommendations to inform the development of a potential VFA program – please see Appendix. NACDS is highly concerned by the rhetoric during the August 30 meeting that held the VFC program up as a gold standard government program.

**NACDS Recommendation:** Given the essential role of pharmacies in the nation's response, NACDS urges the Administration to immediately begin working closely with us and other stakeholders to promote feasibility for pharmacies to participate in the potential VFA program. It is critical that we ensure that barriers within the current VFC program that forcibly exclude pharmacies are not transposed onto the future VFA program. The government should address the uninsured funding stoppage and should make pharmacies whole for covering this government expense for the last 5 months, and still ongoing.

## IV. Conclusion

We look forward to further conversations with the Administration to address and resolve these concerns in the coming weeks and months. NACDS strongly urges the Administration to immediately schedule a regular cadence of meetings with all relevant stakeholders and set specific target dates for the transition of all COVID-19 products becoming commercially available. For questions or further discussion, please contact NACDS' Sara Roszak, Senior Vice President, Health and Wellness Strategy and Policy at sroszak@nacds.org or 703- 837-4251.

Sincerely,

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

Cc: Lisa Barclay; The White House
Tom Tsai; The White House
Sean Christiansen; The White House
Meg Sullivan; ASPR
Stephen Cha; HHS
Jon Blum; CMS
William Harris; CMS
Jason Roos; H-CORE
Georgina Peacock; CDC
Andrew Leboeuf; FDA
Dave McAdams; CDC

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

**APPENDIX: NACDS Key Recommendations for the Creation of Any Vaccines For Adults Program**

**Background:** In recent months, the idea of creating a Vaccines For Adults (VFA) program to provide uninsured adults with coverage and access to ACIP-recommended vaccines has surfaced in the President's Budget, at MACPAC, and in the CDC FY 2023 Justification of Estimates for Appropriation Committees for Congress. There is momentum toward permanently standing up such a program within CDC. At this point, it is NACDS' understanding that any VFA program is still in the concept stage and would first need to be authorized by Congress ahead of an appropriations process before implementation.

NACDS has developed key recommendations to inform the creation of any VFA program. These recommendations have been developed for use in conversations with CDC and members of Congress to advocate for a well-designed program that fully leverages pharmacy immunizers and is workable for the chain pharmacy community to ultimately support improved public access to vaccinations for this vulnerable population.

**Recommendations:**

1. **Broad coverage to support vaccine services for adults**
   - Program should include coverage of all ACIP-recommended vaccines for adults
   - Program should provide vaccines to both uninsured and underinsured individuals.

2. **Ensure program supports adequate reimbursement to providers**
   - Administration fees that cover costs pharmacies incur when administering vaccines to the uninsured population
   - Administration fees adjusted every 2 years to cover providers' rising costs of providing vaccine services
   - Establish a process to support adequate reimbursement to providers if/when a patient refuses to pay any applicable copay

3. **Establish workable billing practices**
   - Billing of claims through pharmacy billing system as if a pharmacy benefit. *Note: ok if claims are then billed to the medical benefit on the switch side (like 837 claims).*
   - The government should contract with one entity (akin to a TrOOP facilitator) to verify a patient's insurance status when assessing patient eligibility for vaccines under the VFA program in advance of the pharmacy visit – this information (along with patient eligibility) can then be provided to pharmacies by patients at the time when the patient presents at the pharmacy to receive a covered vaccine. *Note: this is tied to the recommendation below for determining patient eligibility in advance of the vaccine visit.*
   - Apply lessons learned from HRSA billing portal for COVID vaccines. Need to avoid back-end difficulties where patients may falsely attest that they have no insurance, which led to pharmacies having to go back and pursue reimbursement from the insurance provider post point-of-sale.

4. **Establish a clear, simple process to determine patient eligibility**
   - As above, the government should contract with one entity to conduct patient eligibility determinations in advance of the pharmacy visit – this information (along with patient insurance information) can then be provided to pharmacies by patients at the time when the patient presents at the pharmacy to receive a covered vaccine.

- To support this process, patients could first apply online for the program and if the patient meets eligibility requirements, the program administrator could provide the patient with a temporary card to provide at the pharmacy to identify that they are an eligible patient.

5. **Develop efficient enrollment processes modeled after the Federal Retail Pharmacy Program agreements**
   - Allow for batch enrollment for chain pharmacies with generalized practice site enrollment (and not down to NPI level of pharmacy).
   - One agreement per corporation.
   - Avoid duplicative enrollment process for pharmacies already enrolled in other federal programs (e.g., mass immunizers in the Medicare program) by pulling information over from other federal programs to support a pharmacy's enrollment in the VFA program.

6. **Ensure that enrollment process allows for and does not hinder the use of the full pharmacy team in administering vaccines under the program**
   - Maintain pharmacy providers' ability to utilize the full pharmacy team, including pharmacy technicians, for vaccine administration to eligible Vaccines for Adult individuals (i.e., as allowed per PREP Act authorities and successor policies)

7. **Allow participating pharmacies to "buy and bill" for vaccine stock administered to Vaccines for Adult program beneficiaries**
   - A "buy and bill" model would allow pharmacies to use standard, existing vaccine stock purchased through pharmacies' wholesalers and then bill the government for vaccines administered to patients under the program.
   - In such a model, the government could then seek any applicable rebates directly from manufacturers for vaccines administered to patients under the program.
   - For context, in the Vaccines For Children (VFC) program, the government purchases vaccines stock that goes to states to distribute to VFC program providers. This model is problematic for pharmacy providers, as it requires the use of dedicated and segregated vaccine stock. Moreover, it sets up potential patient access issues where states don't provide enough inventory to meet pharmacy demand, and inventory is not easily replenished. This must be avoided.

8. **Utilize existing pharmacy distribution and ordering systems for covered vaccine stock**
   - This program shouldn't reinvent the wheel by requiring pharmacies to order special vaccine stock from different places or add complications to existing ordering processes.

9. **Any vaccine reporting should be submitted to a single entity**
   - Avoid duplicative, overly burdensome reporting structures. Do not require pharmacies to report to both federal and state entities.