



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES



COMMUNITY RETAIL PHARMACIES' EXPERIENCE DURING THE COVID-19 RESPONSE:

Successes and Lessons Learned to Date

NOVEMBER 2021

Table of Contents

Executive Summary 1

Section 1. Introduction 4

Section 2. Key Findings 13

Section 3. Looking Forward: Issues on the Horizon 40

Section 4. Policy Recommendations..... 44

Section 5. Conclusion 52

Section 6. Glossary..... 55

Section 7. End Notes 56

Executive Summary

Community pharmacies play an important role during public health emergencies, and pharmacists are accessible providers of care and recognized health educators, immunizers, and healthcare professionals. As part of the COVID-19 pandemic response, the Centers for Disease Control and Prevention (CDC) issued specific guidance to state and local jurisdictions advising them to include pharmacies as early COVID-19 vaccination providers. The ability for pharmacies to provide comprehensive access to COVID-19 vaccinations and testing was heavily reliant on the Department of Health and Human Services' (HHS') issuance of the Public Readiness and Emergency Preparedness (PREP) Act declaration, subsequent amendments and policy guidance that removed many barriers related to state pharmacy scope of practice restrictions, and alterations in reimbursement and payment policies.

Since December 2020, pharmacies have administered more than 163 million doses of the COVID-19 vaccine, and as of mid-July 2021, 92 percent of all vaccine was being distributed through the Federal Retail Pharmacy Program.¹ As the pandemic progressed, pharmacies made major changes to their hours of operation, staffing, processes, workflows, and practices to accommodate the new tasks of COVID-19 vaccination and testing for millions of people. To understand these experiences and the interim “lessons learned” from community pharmacies providing COVID-19 vaccinations and testing, the National Association of Chain Drug Stores (NACDS) queried its members, in collaboration with Health Preparedness Partners, using a web-based survey and conducted a 90-minute virtual discussion. Overall, pharmacies had many successes in their role as key COVID-19 vaccinators and testing providers. Survey respondents indicated continuing to serve the public during and after the COVID-19 pandemic as a top priority, and almost all ranked preservation of the current scope of practice flexibilities and policies as critical to do so.

For up-to-date data about vaccines administered through the Federal Retail Pharmacy Program for COVID-19 Vaccination visit <https://tinyurl.com/CDC-FRPP>.

There were several key lessons learned as well. From these findings, important policy recommendations include:

- HHS should permanently expand pharmacy scope of practice across all states to improve access to key care interventions, at a minimum, vaccinations, point of care testing, and access to therapeutics, for patients of all ages.
- The Centers for Medicare and Medicaid Services (CMS) should permanently implement a payment pathway in Medicare Part B for clinical care delivered by pharmacists to support more seamless public access to care, rather than the implementation of ad-hoc workarounds, as observed during the pandemic, which often led to inadequacies and inefficiencies.
- CDC should develop a centralized data reporting mechanism for vaccine administration during a public health emergency to reduce reporting burden during a long-duration outbreak like COVID-19.
- CDC and states/jurisdictions should harmonize vaccine eligibility so pharmacies can apply the same eligibility protocols nationwide.
- HHS should utilize a centralized system so vaccine providers can easily determine patient insurance status.

Further based upon these findings, pharmacies may have their own considerations to explore, such as:

- Contemplate conducting an “after-action” review to explore their experiences, assess outcomes, and discuss with leadership internally how to fold COVID-19 lessons learned and successes into short and long-term planning for the next public health response;

- Contemplate maintaining communications and partnerships with public health officials after the COVID-19 response subsides to review “lessons learned” and collaborate on future responses and enhance community-level outcomes; and
- Contemplate stockpiling some personal protective equipment (PPE) for staff to enable continuity of function in the early days of a pandemic.

The successes from these efforts demonstrate that pharmacies and their staff can play a vital healthcare delivery role during a public health crisis and could be further leveraged in normal times to improve healthcare access and strengthen community healthcare infrastructure nationwide. It is important for communities to maintain their access to pharmacy care that they have come to expect and depend on during the pandemic. Therefore, it is critical to ensure that the public policy adjustments that increased the provision of pharmacy services during the pandemic remain in place and can be expanded upon to enhance access to care and improve health outcomes after the pandemic subsides.

Section 1. Introduction

During the ongoing COVID-19 pandemic, frontline pharmacy staff have attended to Americans every day by keeping pharmacies open to offer COVID-19 vaccinations and testing, dispense critical medications, and provide patient education and referrals. Community pharmacies play an important role during public health emergencies, and pharmacists are accessible providers of care and recognized health educators, immunizers, and healthcare professionals.² As part of ongoing pandemic planning, the CDC indicated that pharmacies play an especially vital role in vaccination of the public during a pandemic. Further, the CDC has conducted exercises with pharmacies to test their ability to provide vaccines and other countermeasures during a pandemic³, and recommended that state and local public health authorities⁴ actively collaborate with pharmacies to ensure they are able to rapidly vaccinate their populations.^{6, 7}

Although during the 2009 H1N1 influenza pandemic pharmacies were provided vaccine late in the outbreak⁸, they administered millions of doses of pandemic vaccine.⁹ Even though pharmacies were ultimately underutilized as pandemic vaccinators in 2009¹⁰, this effort demonstrated a valuable proof-of-concept and effectiveness, leading to more robust modelling and planning efforts that have paved the way for the central role of pharmacies in today's COVID-19 response. In fact, public health officials continue to increasingly recognize the valuable contributions¹¹ of pharmacies in advancing population health and emergency preparedness and response efforts.

The Pharmacy Model Has Been Tested in a Prior Pandemic

For a brief 3-month period during the 2009 H1N1 pandemic response, the federal government leveraged the strength of 10 of the largest chain pharmacies in America to distribute 5.5 million doses of federally purchased pandemic vaccine to more than 10,700 retail stores nationwide.⁹

This initiative accounted for 23% of all vaccine distributed during the same time period.

Building on Pharmacies' H1N1 Experience, Pandemic Modelling Data Emphasized the Key Impact of Pharmacies Long Before COVID-19

- For more than a decade, the federal government has been convening states and pharmacies to prepare for the next pandemic, leverage lessons learned, and build on this existing infrastructure for distributing and administering federally purchased pandemic vaccine.
- The federal government and other stakeholders have conducted extensive pandemic vaccine modeling and have quantified the value of pharmacies' contributions.^{12, 13, 14, 15, 16}
- One pivotal modelling study indicated that by including community pharmacies that provided vaccinations (using extended hours) during a severe pandemic, 16.5 million symptomatic influenza cases could be prevented, 145,278 deaths averted and \$1.9 billion direct costs, \$4.1 billion in productivity loss, and \$69.5 billion in overall costs could be avoided.¹⁷
- Another study conducted by CDC demonstrated that time to achieve 80% vaccination coverage nationally during a pandemic was reduced by seven weeks when community pharmacies were included in vaccination distribution and administration, assuming high public demand for vaccination.⁷

Table 1. Timeline of Key Events: Pharmacies' Role in Advancing Access to COVID-19 Countermeasures, Including Vaccine & Testing

Date	Key Event
March 2020	<ul style="list-style-type: none"> • HHS Secretary's PREP Act Declaration that provides "liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving "willful misconduct" as defined in the PREP Act."
April 2020	<ul style="list-style-type: none"> • HHS Guidance issued for licensed pharmacists to order and administer Food and Drug Administration (FDA)-authorized COVID-19 tests.
May 2020	<ul style="list-style-type: none"> • HHS initiated public-private partnerships with pharmacies and Community-Based Testing Sites (CBTS) for COVID-19 Testing, which included 362 live sites across 45 states and District of Columbia (DC).
June 2020	<ul style="list-style-type: none"> • CBTS pharmacy testing sites increased to 623 sites in 48 states, DC, and Puerto Rico. Since the initiation of the program, over 700,000 samples had been processed.
August 2020	<ul style="list-style-type: none"> • PREP Act – Third Amendment is issued which authorizes State-licensed pharmacists to order and administer, and pharmacy interns (who are licensed or registered by their State board of pharmacy and acting under the supervision of a State-licensed pharmacist) to administer, any vaccine that the ACIP recommends to persons ages three through 18 according to ACIP's standard immunization schedule.
September 2020	<ul style="list-style-type: none"> • HHS Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act is issued which authorizes State-licensed pharmacists to order and administer, and State-licensed or registered pharmacy interns acting under the supervision of the qualified pharmacist to administer, to persons ages three or older COVID-19 vaccinations that have been authorized or licensed by the FDA. Such pharmacists and pharmacy interns will qualify as "covered persons" under the PREP Act, subject to other applicable requirements of the Act and the requirements discussed below. They may also receive immunity under the PREP Act with respect to all claims for loss caused by, arising out of, relating to, or resulting from, the administration or use of FDA-authorized or FDA-licensed COVID-19 vaccines. 42 U.S.C. § 247d-6d(a)(1).

Date	Key Event
October 2020	<ul style="list-style-type: none"> • 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 is issued which authorizes qualified pharmacy technicians and State-authorized interns acting under the supervision of a qualified pharmacist to administer both childhood vaccines and COVID-19 vaccines and administer COVID-19 tests, including serology tests, that the FDA has approved, cleared, or authorized. Such qualified pharmacy technicians and State-authorized pharmacy interns will qualify as “covered persons” under the PREP Act, subject to other applicable requirements of the Act and the requirements discussed below. They may also receive immunity under the PREP Act with respect to all claims for loss caused by, arising out of, relating to, or resulting from, the administration or use of such vaccines. 42 U.S.C. § 247d-6d(a)(1). • HHS Guidance that clarifies PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures is issued. This guidance specifies that pharmacies are also qualified persons under 42 U.S.C. 247d-6d(i)(8)(B) when their staff pharmacists order and administer, or their pharmacy interns and pharmacy technicians administer, these covered countermeasures consistent with the terms and conditions of the Secretary’s Declaration and guidance, as of the date that these staff pharmacists, pharmacy interns, and pharmacy technicians were authorized to order or administer these covered countermeasures. Preempts state or local restrictions that that prohibits or effectively prohibits those pharmacies that satisfy these requirements from distributing or administering COVID-19 vaccines, ACIP-recommended routine childhood vaccines, or COVID-19 tests. • CDC issued specific guidance to state and local jurisdictions advising them to include pharmacies as early COVID-19 vaccination providers. • State/Jurisdiction-Level Program(s)/Partnership(s) for COVID-19 Vaccination: Pharmacies had the option to enroll directly in a jurisdiction’s immunization program as a vaccine provider to offer COVID-19 vaccination in their communities. • Federal Pharmacy Partnership for Long-Term Care (LTC) Program: In October 2020, CDC collaborated with several pharmacy organizations to establish the program. Prior to October, CDC also exclusively recruited several pharmacy organizations to provide COVID-19 vaccinations to some of the highest priority populations (LTC residents).
November 2020	<ul style="list-style-type: none"> • HHS released a list of participating pharmacy companies in what would come to be known as the Federal Retail Pharmacy Program for COVID-19 Vaccination.

Date	Key Event
December 2020	<ul style="list-style-type: none"> • FDA issues emergency use authorizations (EUA) for both the Pfizer-BioNTech COVID-19 vaccine and Moderna COVID-19 vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) for administration in individuals 16 and 18 years of age and older, respectively. • PREP Act – Fourth Amendment is issued which modifies and clarifies the training requirements (immunization and cardiopulmonary resuscitation (CPR) training) for licensed pharmacists and pharmacy interns to administer certain routine childhood or COVID-19 vaccinations. Specifies that certain pharmacists, pharmacy interns, and pharmacy technicians are Covered Persons who are Qualified Persons, because they are authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures • CDC’s ACIP recommended that the first vaccines should be targeted to both healthcare personnel and residents of long-term care facilities as part of the initial phase of the vaccination program. • After that recommendation was released, NACDS called for the federal government to “turn on the Federal Pharmacy Partnership Program to enable vaccination of the millions of people in these target populations.” • The federal government provided most of the limited supply of vaccine doses to states and jurisdictions and began a vaccine distribution program to selected pharmacies targeting residents and staff in LTC facilities. • Federal Pharmacy Partnership for Long-Term Care (LTC) Program: began providing on-site vaccinations for LTC and assisted living facility residents and staff on December 21, 2020, as part of the earliest vaccination efforts.
January 2021	<ul style="list-style-type: none"> • CDC issued funding and guidance for all jurisdictions and included as its first recommendation to jurisdictions “Increase the number of vaccine provider sites, including through the use of pharmacies”. • CBTS pharmacy sites increased to 3,300 locations across all 50 states, DC, and Puerto Rico. Since the initiation of the program in May 2020, more than 5.6 million samples had been tested. Over 70% of pharmacy sites within the program located in communities with moderate-to-high social vulnerability.
February 2021	<ul style="list-style-type: none"> • FDA issued EUA for Janssen’s single-dose COVID-19 vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) for administration in individuals 18 years of age and older. • Federal Retail Pharmacy Program for COVID-19 Vaccination: Launched by CDC in February, 2021 as a “a key part of its COVID-19 vaccination strategy”, this public-private partnership with 21 national pharmacy partners and networks of independent pharmacies represents over 41,000 pharmacy locations nationwide. Then, in February 2021, it began three additional vaccine distribution programs focused on providing COVID-19 vaccine doses to pharmacies, federally supported health centers, and mass vaccination sites for administration. • Federal Transfer Program with Jurisdiction(s) for COVID-19 Vaccination: A program that allowed states to transfer their allocated vaccine doses to federal pharmacy partners to help vaccinate target populations in their communities.

Date	Key Event
March 2021	<ul style="list-style-type: none"> • PREP Act – Seventh Amendment is issued which authorizes pharmacists and pharmacy interns/student pharmacists who have licenses that are inactive, expired, or lapsed in the past 5 years to prescribe, dispense, and/or administer COVID-19 vaccines (based on previous PREP Act authority) provided the licensee was in good standing before inactivity, expiration, or lapse. • CBTS pharmacy sites increased to 6,211 locations across all 50 states, DC, and Puerto Rico. Since the initiation of the program in May 2020, over 9.8 million samples have been processed.
April 2021	<ul style="list-style-type: none"> • CDC issued further guidance and funding to jurisdictions urging them to “Improve access to COVID-19 vaccines” by “using multiple types of locations and with flexible hours that are accessible to and frequented by the identified communities of focus” including pharmacies. • CDC and FDA recommended a pause in the use of the Janssen vaccine so the agencies could review data involving six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving this vaccine. CDC and FDA lifted the pause on April 23, 2021, following a safety review, and revised the Janssen vaccine fact sheets for health care providers and recipients and caregivers to include information about the risk.
May 2021	<ul style="list-style-type: none"> • FDA expanded the EUA for the Pfizer-BioNTech COVID-19 Vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) to include adolescents 12 through 15 years of age.
August 2021	<ul style="list-style-type: none"> • PREP Act – Eight Amendment issued which clarifies that qualified pharmacy technicians are Qualified Persons covered by the Declaration, and to expand the scope of authority for qualified pharmacy technicians to administer seasonal influenza vaccines to adults within the state where they are authorized to practice and for interns to administer seasonal influenza vaccines to adults consistent with other terms and conditions of the Declaration. • FDA amended the EUAs for both the Pfizer-BioNTech COVID-19 Vaccine and the Moderna COVID-19 Vaccine to allow for the use of an additional dose in certain immunocompromised individuals. CDC endorsed the ACIP recommendation for use of an additional dose of COVID-19 vaccine for people with moderately to severely compromised immune systems after an initial two-dose vaccine series.
September 2021	<ul style="list-style-type: none"> • PREP Act – Ninth Amendment issued which provides liability immunity to and expands the scope of authority for licensed pharmacists to order and administer select COVID-19 therapeutics to populations authorized by the FDA and for pharmacy technicians and pharmacy interns to administer COVID-19 therapeutics to populations authorized by the FDA. • FDA amended the EUA for the Pfizer-BioNTech COVID-19 Vaccine to allow for use of a single booster dose, to be administered at least six months after completion of the primary series in selected populations and CDC endorsed the CDC ACIP recommendation for a booster shot of COVID-19 vaccines in certain populations. • President Biden’s COVID-19 Action Plan outlines plans to expand the HHS CBTS program to 10,000 pharmacies.

Date	Key Event
October 2021	<ul style="list-style-type: none"> • FDA authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 to include children 5 through 11 years of age. CDC endorsed the CDC ACIP recommendation that children 5 to 11 years old be vaccinated against COVID-19 with the Pfizer-BioNTech pediatric vaccine. • FDA expanded the use of a booster dose for COVID-19 vaccines and amended the emergency use authorizations for multiple COVID-19 vaccines to allow for the use of a single booster dose. CDC approved and expanded eligibility for COVID-19 vaccine boosters for all adults who received a Johnson & Johnson COVID-19 vaccine and certain high-risk adults who received the Moderna vaccine and approved using different vaccines than used in the primary series for a booster “mix-and-match”. • President Biden committed to doubling the number of pharmacies within the CBTS program from 10,000 to 20,000. These local pharmacies offer free COVID-19 testing through the federal program, and are in addition to the 10,000 other community-based free testing sites throughout the country.
November 2021	<ul style="list-style-type: none"> • FDA amended the emergency use authorizations for both the Moderna and Pfizer-BioNTech COVID-19 vaccines authorizing use of a single booster dose for all individuals 18 years of age and older after completion of primary vaccination with any FDA-authorized or approved COVID-19 vaccine. • CDC also endorsed the CDC ACIP’s expanded recommendations for booster shots to include all adults ages 18 years and older who received a Pfizer-BioNTech or Moderna vaccine at least six months after their second dose. • FDA’s Antimicrobial Drugs Advisory Committee Meeting was held to discuss an EUA submitted by Merck & Co. Inc., for emergency use of molnupiravir oral capsules for treatment of mild to moderate COVID-19 in adults. While the EUA has not yet been issued, the committee voted in favor of the product. The US government purchasing more than 3 million courses. • Pfizer requested FDA emergency use authorization for its COVID-19 antiviral pill, Paxlovid, on November 16, 2021. The US government purchasing 10 million courses of this product.

Since COVID-19 vaccines were made available in the U.S. starting in mid-December 2020^a, pharmacies have consistently played pivotal roles in vaccinating eligible populations through multiple programs, administering more than 163 million doses thus far.^{18, 19} In addition, thousands of pharmacies have also offered COVID-19 testing services throughout the pandemic, with the Biden Administration recently announcing plans to ramp up to 20,000 pharmacies within the federal Community-Based Testing Sites Program.²⁰

^a Pfizer BioNTech and Moderna COVID-19 vaccines were authorized in the U.S. under an Emergency Use Authorizations (EUA) in December, 2020, whereas the Janssen J&J vaccine was authorized for use under and EUA in February, 2021. (See Table 1. Timeline of Key Events: Pharmacies’ Role in Advancing Access to COVID-19 Countermeasures, Including Vaccine & Testing, Section 1, Pages 7-11).

Although most U.S. pharmacies have been engaged in providing these services, no efforts have yet captured the interim lessons learned to inform systematic improvements. The purpose of this report is to summarize and characterize the industry's successes and lessons learned while providing COVID-19 vaccinations and testing services, and to inform public policy and industry efforts to improve pandemic preparedness and response in the future. Specifically, these findings will inform public strategies for near-term increased demand for COVID-19 vaccinations/boosters and testing, help inform future policy decisions, and offer action steps for pandemic planning and preparedness.

As the pandemic progressed, pharmacies made major changes to their hours of operation, staffing, processes, workflows and practices to accommodate the new tasks of COVID-19 vaccination and testing for millions of patients. To understand these experiences and the interim lessons learned from community pharmacies providing COVID-19 vaccinations and testing, NACDS queried its members, consistent with its antitrust policy, using a 22-item web-based survey and conducted a 90-minute virtual discussion titled: "NACDS Virtual Forum: Pharmacy Experiences & Lessons Learned During the COVID-19 Response."

An email invitation was sent by NACDS to its retail pharmacy membership to request their participation in the online, anonymous survey and virtual discussion. The survey included questions about pharmacy successes and challenges providing COVID-19 vaccination and testing services, explored the relevance of COVID-19-related federal waivers and policies that affected pharmacies, and asked participants about their pharmacies' readiness for providing additional doses for immunocompromised patients, booster vaccination doses, vaccinations for children ages 5 to 11 years old, and providing seasonal influenza vaccinations.

Upon completion of the survey, each participant was invited to take part in the Virtual Forum (known as "Forum" hereafter in this report), that was held by videoconference on September 24, 2021. The Forum was designed to facilitate a series of conversations focused on the following areas, expanding upon survey items:

- Pharmacy COVID-19 Vaccination Programs:
 - o Successes
 - o Challenges
- Pharmacy COVID-19 Testing Programs:
 - o Successes
 - o Challenges
- Next Steps:
 - o Providing Additional Doses and Boosters
 - o Vaccinating Children
 - o Coadministration of COVID-19 and Influenza Vaccines
- Lessons Learned and Key Recommendations/Policy Changes

For each topic area, participants discussed successes and challenges that arose during these programs, identified issues that may arise with the near-future efforts, and made policy recommendations for improving systems and processes.

During the Forum, facilitators moderated discussions in three virtual “break-out rooms” to elicit responses from participants. After the breakout sessions, all participants joined a group discussion to summarize and discuss the key issues. Notetakers in each breakout session recorded key issues and statements (without attribution). These notes were then collated and coded. The codes that were mentioned consistently across participants were clustered and identified as themes, and similar themes were combined. Frequency of mention and the importance of the issue as stated by the participants were factors in the identification of themes in this report.

Key findings are presented to highlight and summarize the results from the survey and Forum discussions to identify key successes and lessons learned. This report also offers policy recommendations that highlight opportunities and areas for further work to help improve future pharmacy-based public health efforts, including emergency vaccination and testing programs.

Section 2. Key Findings

The online survey was sent to 32 NACDS member companies and 26 responded, for a response rate of 81%. All survey recipients were invited to join in the Forum, with opportunity for up to two representatives per company. A total of 29 participants representing 22 companies participated. For a few companies, more than one person participated, however they served in different roles and provided perspectives from their vantage point.

Most of the survey respondents had a pharmacy or clinical role, managed pharmacy operations or were responsible for government affairs and policy issues. Respondents represented both national and regional chain pharmacies, with a majority of respondents representing pharmacies in grocery store locations, about a third representing traditional drug stores, and a few representing mass merchants.

Most survey respondents reported that their company participated in more than one type of COVID-19 vaccination program. Almost all respondents took part in the Federal Retail Pharmacy Program for COVID-19 Vaccination, over three-fourths took part in a state/ jurisdiction-level program for COVID-19 vaccination, about a third participated in the Federal Transfer Program, and a fifth of responders participated in the Federal Long-Term Care Facility program. Almost all of the respondents that participated in state or jurisdictional-level programs reported they focused on providing vaccinations to the community at large and underserved populations. About a third of pharmacy responders also provided vaccinations to schools and teachers and about a fifth reported providing vaccinations to those in long-term care facilities (not affiliated with the federal program).

Forum participants were enthusiastic about sharing their experiences providing services during the pandemic and selected quotes of their statements are used in this report to highlight their voices about the successes and challenges faced during this unprecedented pandemic.

Vaccination Program Successes

All survey respondents and Forum participants mentioned a number of key achievements of their COVID-19 vaccination efforts both during the planning phase and during program implementation. The success of pharmacy COVID-19 vaccination efforts has also been recognized by the federal government. For example, HHS called out pharmacies' key role in providing COVID-19 vaccinations in an August 2021 report *Overview of Barriers and Facilitators in COVID-19 Vaccine Outreach*²¹ by recognizing that "Federal partnership programs with pharmacies have helped increase access points for vaccination around the country."

Pharmacy Planning for Vaccinations

In September 2020, HHS and CDC reached out to selected pharmacies to engage them in participating and planning for COVID-19 vaccination programs, and pharmacy planning began immediately after that notice.²² In January 2021, the White House released updated vaccination plans featuring community pharmacies as prominent venues for COVID-19 vaccinations.²³

When asked about this planning process, most survey respondents reported that they were given adequate information from federal entities such as the HHS and the CDC to aid their planning efforts, while over half reported adequate planning information was received from state and/or local entities. A majority of survey respondents reported being able to secure necessary resources as part of the planning process.

Pharmacy Vaccination Administration and Program Implementation

Survey respondents and participants in the Forum reported multiple successes as part of their participation providing COVID-19 vaccinations. The top successes that they identified in providing COVID-19 vaccinations included the following:


Key Successes Identified by Pharmacies in Providing COVID-19 Vaccinations

- Served existing and new patients, including high-risk and underserved populations
- Enhanced public health partnerships
- Expanded role of pharmacies and staff during a pandemic/emergency
- Increased visibility of the role of pharmacies and pharmacists
- Leveraged prior vaccination experience, contributing to success
- Promoted opportunities to make progress with needed innovations
- Reimbursement for vaccine administration helped to cover costs

Served Existing and New Patients During a Public Health Emergency, Including Underserved & Vulnerable Populations


Almost all survey and Forum respondents reported that a major success of their vaccination program was the ability to serve their existing patients and the wider community, including the ability to engage new patients.

“This has been a great opportunity for us to help people.”



“Understanding that new patients are individuals that may not have considered pharmacies as healthcare destinations and what all [they] can provide, this has opened up avenues for patients [and pharmacies] to build relationships going forward.”

Most survey respondents and Forum participants noted this as their top achievement for their vaccination program as it gave them the opportunity to provide a critical service when it was most needed. Forum participants specifically mentioned that vaccinating staff and residents as part of the Long-Term Care Facility (LTCF) program was very successful,^{24,25} in addition to their experiences vaccinating the broader public through the Federal Retail Pharmacy Program. Many also mentioned examples of how they reached underserved communities by collaborating with community and faith-based leaders, using mobile vaccination vans to travel to hard-to-reach areas to offer vaccines, and host or participate in “pop-up” clinics, in addition to offering vaccinations on-site at established and convenient pharmacy locations. Those that mentioned these efforts reported that their outreach to underserved and vulnerable populations was a key success factor, especially when vaccinating the elderly and those living in rural and other areas with few healthcare services available. NACDS and its members have prioritized health equity as a key goal for pharmacy-provided services during the COVID-19 response.²⁶



“Pharmacies are in medically underserved and rural areas – and pharmacies are reaching and providing care to those populations. Looking ahead, pharmacy needs to [continue to] leverage [its] impact in reaching those populations.”

Enhanced Partnerships with Federal, State, and Local Public Health Entities

Almost all survey respondents reported that they were able to create or enhance their relationships with public health entities throughout the pandemic by serving as vaccinators and thus assisting public health officials in their efforts to vaccinate the entire community. Although the value of pharmacy and public health partnerships for pandemic planning and response has been previously described,²⁷ in one national survey of pharmacists conducted in 2012, over two-thirds of pharmacists polled had no contact with a state or local public health official in the past year.²⁸ In stark contrast, Forum participants frequently mentioned that establishing and reinforcing partnerships with state and local public health was a major success factor that will yield benefits beyond the current pandemic. One Forum participant mentioned “this was really our first connection with our state Department of Health (DOH)”. Several Forum participants noted that it was the first time that public health officials “saw what we could do to improve public health. Public health folks are now advocating for what pharmacy used to have to solely advocate for.” Another commented that “this [partnership] gave pharmacy [better ability to collaborate with public health] to pinpoint where there are pockets of needs for vaccine services – this can be grown potentially for other clinical services in future.”

“Public health folks are now advocating for what pharmacy used to have to solely advocate for – so telling legislators they need to change local / state law to allow pharmacists to vaccinate.”

“States and public health entities heavily relied on pharmacies to help with mass clinics to broaden reach to various communities.”

In addition, it was also the first opportunity for many pharmacies to have direct communication with the CDC and HHS. One participant mentioned the value in their close relationship with CDC and HHS to identify and target vaccines for underserved populations. Several Forum participants noted that a high priority going forward would be to continue to build relationships with federal, state, and local public health officials.

Expanded Role of Pharmacies and Staff During a Pandemic/Emergency Including New Roles and Responsibilities for Pharmacy Technicians and Interns

As a target for pandemic planning, in 2019 CDC provided guidance to states and jurisdictions to plan to vaccinate at least 80% of their population with two doses of pandemic vaccine within 12 weeks of vaccine availability.²⁹ Currently, the U.S. government's goal is to have the capability and enough COVID-19 vaccine for all people in the U.S. who wish to be vaccinated. Recognizing that public health entities could not accomplish this goal alone, and to maximize the number of immunizers of COVID-19 vaccine, in fall 2020, CDC directly engaged with pharmacies and advised states to engage pharmacies as vaccinators.³⁰

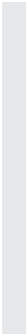
Additionally, on March 10, 2020, the Secretary of HHS issued a Declaration under the PREP Act. This declaration³¹ (along with subsequent amendments and specific HHS Guidance documents) authorized licensed pharmacists nationwide to order, and pharmacy interns and pharmacy technicians to administer CDC-recommended routine vaccinations for children 3-18 years old, and COVID-19 vaccinations for individuals 3 years and older (See Table 1. Timeline of Key Events: Pharmacies' Role in Advancing Access to COVID-19 Countermeasures, Including Vaccine & Testing, Section 1, Pages 7-11), in addition to granting authority for pharmacy technicians and interns to administer flu vaccinations for adults 18 years and older.

Forum participants mentioned that the expanded role of pharmacies (enabled by PREP Act declaration amendments) during the pandemic better matched the training and expertise of pharmacy staff and enhanced the care they provided by offering critical services consistently across the country. In particular, PREP Act amendments and HHS Guidance documents were

viewed by Forum participants as the most important and critical enablers to allow pharmacies to mount a comprehensive vaccination response. The ability of pharmacy technicians to provide COVID-19 vaccinations was reported by Forum participants as contributing to the success of their vaccination efforts and allowed pharmacies to serve more patients. Without such Amendments, pharmacies would have been restricted by state variations in vaccination scope of practice laws and pharmacist regulations, which would have significantly limited the number of pharmacists and technicians that could administer vaccine, severely constraining the provision of vaccinations across jurisdictions.




Expansion of pharmacy technicians' role in vaccination efforts was a “huge success.”




“Pharmacies understood very clearly, if they did not have [pharmacy technicians as vaccinators], they would’ve been overwhelmed. They valued enhanced technician support.”

Increased Visibility of the Role of Pharmacies and Pharmacists

Although recently there has been increased recognition of community pharmacies' role as a healthcare destination³² in the U.S., the multiple roles that pharmacies have played during the pandemic have brought greater visibility to the critical services pharmacies can provide every day, and especially during a public health emergency. CDC recognized that “Ensuring continuous function of pharmacies during the COVID-19 pandemic is important”³³ and provided guidance to pharmacies early in the pandemic outbreak to advise how to protect the workforce and preserve critical pharmacy services.



“There is now an incredible amount of data demonstrating the success of pharmacies and what they’ve been able to do to help with [the] pandemic response. Pharmacy has done so much with COVID-19, childhood & flu vaccines, and there is now more data to support this.”



“Government recognition of the value of pharmacy [has] resulted in key actions that helped advance scope of practice priorities, especially via the PREP Act, plus other federal waivers and guidance.”


Further, administering COVID-19 vaccines has significantly increased the visibility of community pharmacies to the public and policy makers and has demonstrated that pharmacies can be a key provider of care services during a pandemic emergency. Pharmacies have also received recognition by state and local public health officials for sending personnel to staff state and federally-run mass vaccination clinics.

Almost all survey and Forum respondents noted that increased visibility of pharmacies was a prominent success factor of their vaccination work. Community pharmacists have been recently recognized as having expertise offering healthcare services that serve to detect, control, and manage acute and chronic conditions, and during the pandemic have been recognized as playing an important role addressing COVID-19, especially among populations facing health disparities.^{34, 35}

Leveraged Prior Vaccination Experience, Contributing to Success

As previously mentioned, a number of pharmacies had provided pandemic vaccinations during the 2009-2010 pandemic.⁹ Since 2010, the proportion of adults receiving annual influenza vaccinations and other immunizations at community pharmacies has increased steadily. During the 2020-2021 flu season, about 39% of adults and 12% of children received an influenza vaccination at a retail pharmacy.³⁶ Patients cite that convenience, not having to make an appointment, shorter waiting times, and often, no out-of-pocket expenses as key reasons why they received their influenza immunizations at pharmacies.³⁷

Therefore, these years of community pharmacy experience in planning and administering influenza (and other) vaccines provided a “warm base” of expertise to draw upon when designing COVID-19 vaccination programs. Forum participants mentioned this experience as a positive enabler of providing COVID-19 vaccination services.



“The government knew what pharmacy could do and took steps to leverage pharmacy providers in the pandemic response.”

Promoted Opportunities to Make Progress with Needed Innovations

Many Forum participants mentioned that the urgency and complexity of the COVID-19 response caused their pharmacies to accelerate internal improvements in IT (Information Technology) systems and processes. One respondent mentioned that offering COVID-19 vaccinations “Forced the pharmacy to [move] things forward – that would have been caught in backlog and pulled some things forward that needed to be tackled.” Another mentioned “it made us take a long hard look at how we do everything; it was like starting from a blank slate to get things done. It really allowed more creativity on all processes across the board.” In

particular, some necessary IT improvements were sped up and addressed. “This was a nudge for us to adopt some better IT capabilities (schedules, interfaces built with registries, etc.) and to bring our game where we needed to be; [the pandemic] made it a priority for us.”

Reimbursement for COVID-19 Vaccine Administration Helped to Cover Costs

Over time, compensation for vaccine administration better covered the additional expenses that pharmacies incurred by offering vaccinations, including extended operating hours, additional staff, procurement of software, PPE, and other equipment. A number of Forum participants mentioned that reimbursement helped to enable their pharmacies to continue to provide vaccination services throughout the pandemic.

Vaccination Program Challenges

It is not unexpected that providing vaccinations during the COVID-19 pandemic to millions of patients yielded challenges for pharmacies (and other providers), as there has never before been such a large, intensive, and complex effort to vaccinate essentially the entire U.S. population during a public health emergency.

Insufficient Planning Information Provided to Pharmacies

During the vaccination planning phase (before vaccine was available), almost all survey respondents mentioned that uncertainty around the vaccine supply from Operation Warp Speed (OWS) and from CDC leadership limited planning efforts. At the time of this planning effort (August to December 2020), there were still many unknowns including which vaccines would receive authorization for use and the date which they may be distributed to pharmacies, the number of doses that might be available for distribution and the cadence of vaccine supplies, disposition of ancillary supplies, storage and handling considerations, eligible populations, and many other unanswered questions. This lack of information limited pharmacy planning efforts.

In August 2020, OWS released planning assumptions to state and local public health programs³⁸ to guide planning for COVID-19 vaccine distribution and administration. State and local public health officials were advised to “onboard” pharmacies as well as other healthcare entities in their jurisdiction as vaccine providers. Other planning documents released by OWS³⁹ in September 2020 mentioned pharmacies as critical vaccine distributors and administrators and alerted Federal Pharmacy Partners that their supply of vaccine would probably be made available during “Phase 2” after the initial distribution to a selected group of providers and the LTC Pharmacy program.

Although the messages from federal entities, augmented by NACDS staff communications, were ongoing during this planning process, there were many mentions by Forum participants about unclear, delayed, and often times, conflicting communications from federal entities and state and local health departments, when planning for the vaccination campaign. Most survey respondents also reported there was also a lack of clarity in information related to anticipated billing and reimbursement processes, which prevented pharmacies from being able to ready their systems in advance and likewise, hindered ability to ensure payers’ systems were prepared.

Strategies to Promote and Enhance Vaccination Uptake: Community pharmacies have systems and processes to market the availability and benefits of vaccination to patients and the public. Survey respondents reported that they used multiple outreach and promotion efforts including placing signage inside or outside the pharmacy, training pharmacy personnel to provide additional patient education, making available in-store patient education materials, having proactive conversations about vaccination with their patients and the broader public, helping patients book appointments, and holding pop-up clinics at various locations in the community, for example.

Challenges in Pharmacy Vaccination Administration/ Program Implementation

In mid-December 2020, the Pfizer-BioNTech COVID-19 Vaccine was authorized for use under an EUA for individuals 16 years of age and older^b, and a week later, the Moderna vaccine was authorized by EUA for use in individuals 18 years of age and older. Once these vaccines were authorized for use, HHS began distribution to selected state entities and pharmacies. As expected, there were challenges and “bumps in the road” as vaccine initially rolled out, and throughout the program, several challenges in distribution arose that are still impacting pharmacies at the time of this report.

^b On August 23, 2021, the FDA fully approved the Pfizer-BioNTech COVID-19 Vaccine.

Survey respondents were queried to identify the leading challenges that they faced implementing their vaccination program and then were asked to rank order the challenges from the most challenging to the least. The top challenges mentioned by most survey respondents and also noted by many Forum participants as key challenges are described on the next page:

Key Challenges Identified by Pharmacies in Providing COVID-19 Vaccinations

- Limited vaccine supply or issues with allocation
- Unclear/delayed communication/coordination with state and/or local health departments
- Burdensome data reporting requirements
- Challenges related to IT systems
- Billing and reimbursement challenges
- Difficulty enrolling as a COVID-19 vaccine provider in State or Federal vaccine programs
- Challenges with identifying eligibility of persons in priority groups given unclear guidance
- Staffing shortages

Limited Initial Vaccine Supply or Issues with Allocation

When vaccines were first released by the federal government through OWS, the supply was not as robust as expected and there were inconsistencies in the advance notice of the amount of vaccine that pharmacies would receive. In addition, adverse weather conditions in February 2021 hampered distribution of vaccine and closed vaccination sites in many locations across the country.⁴⁰ Initially the federal government distributed the majority of vaccine doses through states and jurisdictions, but this changed over time. The amount of vaccine doses distributed through CDC's retail pharmacy program increased from 29% to 92% from April to July 2021.⁴¹ The issues of insufficient and erratic vaccine supplies were noted by almost all of the survey respondents and ranked as the number one challenge in the first months after vaccine became authorized and available for use. Pharmacies had far more capacity to deliver vaccinations than the supply received.⁴² Several Forum participants mentioned the issues related to vaccine "trickling" out at first and some (short-term) supply

issues. Similar supply shortfall issues affecting pharmacies have been described in a recent Government Accountability Office (GAO) report.⁴³

Once the three vaccines had been authorized by FDA and were being distributed, several Forum participants that received vaccine through agreements with state or local health departments noted that some jurisdictions were slow in providing vaccine to their pharmacies. Lack of adequate and consistent allocation at both the federal and jurisdiction levels, as well as limited communications from public health authorities, often made it difficult for pharmacies to plan vaccination clinics and other activities, market availability of vaccine to the public, schedule appointments more than 1-2 weeks at a time, and provide a satisfactory explanation to patients that the vaccine they sought was not available.

Unclear/Delayed Communication/Coordination with State and/or Local Health Departments

Although the development of new partnerships and strengthening of existing partnerships between pharmacies and state and local public health officials was mentioned frequently as a success, unclear or delayed communications between pharmacies and state and local health departments was ranked by survey participants as the second highest challenge they faced. Forum participants explained that these communication issues largely stemmed from delays in vaccine supplies, and logistics issues. Survey respondents also identified that inconsistent communications and conflicting and changing messages between jurisdictions and CDC, at times led to confusing guidance to pharmacies about vaccine storage and administration practices. Differing guidance about how long vaccines could be out of the freezer, whether to hold back stock for a second dose, if vaccines could be pre-drawn before administration were among the multiple, complex issues that arose.

Burdensome Data Reporting Requirements

As part of participation in federal and state/local vaccination programs, pharmacies are obligated to report an array of vaccination data in a timely way to multiple entities. Specifically,

COVID-19 vaccination providers are required to report information on vaccine inventory and waste, in addition to vaccine administration information, such as general recipient information, vaccine product information, vaccinator information, etc. The CDC's COVID-19 Vaccination Reporting Specification (CVRS) includes more than 40 data fields, however not all fields are required. These files are extracted and sent to the CDC Data Clearinghouse (DCH). Similar data fields are separately required by state vaccine registries, yet vaccine providers must report these data through disparate systems, and nuances in data reporting requirements vary from state to state. Further, if the Vaccine Administration Management System (VAMS) is used in the jurisdiction, similar information may also need to be reported there, and further, vaccine providers must report information related to inventory, waste, and ordering into additional systems such as VaccineFinder and Tiberius.⁴⁴

One of the biggest burdens for pharmacies participating in COVID-19 vaccination efforts is reporting the same or similar data to multiple federal, state, and local jurisdictions. All survey respondents indicated that reporting data to multiple entities was arduous, and almost all said that manual reporting was especially cumbersome. Specifically, both survey respondents and Forum participants identified that duplicative and multiple reporting requirements across various systems took additional staff time and effort. They described that these data systems were not interoperable, therefore data had to be reported to each system separately. Several Forum participants explained that they had to hire additional staff and/or external entities to manage data reporting, as it was so complex and demanded so many resources.

One Forum participant explained “This put undue pressure on vendors, stores and support staff to report the right data to 65+ different states and/or local authorities. It would have been better to just report to the state instead of local jurisdictions – or better yet, one national system. It also would have been better if everyone had consistent reporting requirements that aligned with what the feds wanted.”

Challenges Related to Information Technology (IT) Systems

About two-thirds of survey respondents reported challenges with IT systems and technical changes. Because of varying reporting obligations, Forum participants described having to install different software programs and create multiple automated systems to comply with changing and updated reporting requirements.

Because states have different immunization registry systems and different mandatory variables to report, which also differed from the federal data reporting requirements, and these systems included new data fields that pharmacies had not collected or reported on before, pharmacies had to set up different software and create a number of internal systems to adhere to these reporting requirements.⁴⁵

Almost all survey respondents reported challenges integrating various systems into existing pharmacy workflows, and a majority mentioned problems with modifications and updates that were needed to the pharmacy dispensing system, and challenges with appointment schedulers. Since there was no standard template or software used for scheduling vaccination appointments, each pharmacy had to develop their own software to manage vaccination appointment schedules. Also, when vaccine was first made available, schedulers needed updates on an ongoing basis to reflect changing vaccine eligibility, as has also been required recently with boosters and pediatric COVID-19 vaccinations. When advisory committees such as The Vaccines and Related Biological Products Advisory Committee (VRBPAC) and CDC's Advisory Committee on Immunization Practices (ACIP) recommend changes in groups that are eligible for vaccine, pharmacies often have very little time after issuance of their recommendations and related CDC guidance to get their systems updated, because as soon as such decisions are made, the public quickly begins seeking vaccine at pharmacies and other vaccine providers.

Billing and Reimbursement Challenges

Participation in COVID-19 vaccination programs increased expenditures for pharmacies including extending hours of operations, hiring new staff, procuring supplies and personal

protective equipment for staff, adding software or systems to handle appointment scheduling, additional billing and data reporting procedures, and rearranging or remodelling stores to accommodate higher volumes of vaccination patients. Therefore, timely billing and reimbursement for vaccination administration is a critical element of the process, especially in sustaining a long emergency vaccination response.

HHS designed the COVID-19 vaccination program so that anyone seeking vaccination would incur zero costs, as required by the Coronavirus Aid, Relief, and Economic Security (CARES) Act and Families First Coronavirus Response Act (FFCRA).⁴⁶ To date, the federal government has purchased and supplied the vaccination product and vaccine providers including pharmacies, can bill private and public insurance for the vaccine administration fee. Beneficiaries with Medicare, Medicaid, or private health plans do not pay for COVID-19 vaccines or their administration, and there is no applicable copayment, coinsurance or deductible.⁴⁷

Additionally, vaccine providers may submit claims for reimbursement for administering the COVID-19 vaccine to underinsured individuals (or for those whose health plan denies or only partially pays the administration fee) through the [COVID-19 Coverage Assistance Fund](#), administered by the Health Resources and Services Administration (HRSA).⁴⁸ Pharmacies can also submit administration fees for uninsured people to a separate program, the [HRSA COVID-19 Uninsured Program](#).⁴⁹

However, pharmacies need to know the insurance status of the vaccine recipient so they can bill the administrative fee correctly through the right program/system and must also be able to identify the relevant insurer (if applicable). Many Forum participants identified this process as a key challenge that delayed provision of services because of the extended time it took to investigate insurance status since there was no centralized way for pharmacies to look up this information. Several Forum participants mentioned the burden of doing this “look-up” process and mentioned the impact on workflow. Because the vaccines were marketed as “free” to the public, pharmacies encountered tremendous difficulty eliciting insurance information from

individuals. Because the public understood the vaccines to be without cost, some insured individuals would indicate they did not have insurance, which further complicated this “look-up” process.

“There were challenges with identifying the uninsured, and then ensuring those patients who said they were really were uninsured. Pharmacy was on the hook to handle all of the checking and validating, pulling in insurance, and then billing insurance for individuals who actually had insurance. Also, some international patients came into pharmacies without a U.S. ID and billing for those individuals was problematic.”

Furthermore, while a very valuable resource, a number of challenges were encountered with the HRSA programs especially time lags and delays, manual submission requirements, and the requirement for vaccine providers to ask for information such as social security numbers or other identification, which may have led to hesitation from individuals who do not have such identification.

In addition to challenges with billing, three-fourths of survey respondents mentioned reimbursement issues as a top challenge. Initially, Forum participants reported, the early Medicare reimbursement rate for administering vaccine did not fully cover the costs of providing this expanded service, although the rate was increased on March 15, 2021. While many states have ensured that their Medicaid programs pay the same as Medicare, several states have reimbursement rates that are lower than the Medicare rate. And private insurers often were not required to meet any specific government payment rates.

Furthermore, for the Medicare population, COVID-19 vaccine administration and testing are being covered under Part B, while state Medicaid programs can choose to pay under either the medical or pharmacy benefit. According to NACDS' internal review, at least 10 state Medicaid programs determined to cover COVID-19 vaccines under the medical benefit. Unfortunately, pharmacy systems do not often seamlessly bill the medical benefit, including Medicare Part B, because systems and processes are not set up to bill in real-time as with a prescription drug benefit. For vaccinations, pharmacies can bill Medicare Part B as mass immunizers via an "administrative fee" for suppliers. However, Part B supplier codes can be less convenient and result in delays in payment. Further, for Medicaid programs, billing to the medical benefit also incurs challenges related to credentialing as pharmacies and pharmacists may not be eligible "providers" in the state's Medicaid program.

Difficulty Enrolling as a COVID-19 Vaccine Provider in State or Federal Vaccine Programs


The process of enrolling as a vaccine provider varied highly by jurisdiction. In some areas, it was accomplished by submitting an online request form and for other jurisdictions, a phone call and manual process was needed. This variable process was especially difficult for pharmacies operating across multiple jurisdictions given that they had to perform enrollments into many systems across the nation. In certain cases, jurisdictions required pharmacies enroll in the state's Vaccines for Children (VFC) program, which has historically low pharmacy enrollment due to administrative and logistical hurdles for pharmacies.

CDC helped to alleviate some of those barriers by encouraging states to adopt federal enrollment requirements without additional burdens, and also through programs like the Federal Transfer Program, where pharmacy partners enrolled federally, rather than at the jurisdiction-level, but received "transferred" vaccine from the jurisdiction's allocation. CDC advises "To become a COVID-19 vaccination provider, you must be licensed to administer vaccines in the jurisdiction where you will be practicing. Your health system or you, as an independent provider, are required to sign and abide by the terms of the CDC COVID-19

Vaccination Program Provider Agreement.” Although some jurisdictions reduced the burden on pharmacy companies that had multiple stores in their jurisdiction, enrollment both at the federal and at the jurisdiction levels often proved challenging for pharmacies.⁵⁰ Survey respondents ranked the challenge of enrolling as a vaccine provider in the top 5 of challenges identified with implementing their COVID-19 vaccine program.

Challenges with Identifying Eligibility of Persons in Priority Groups Given Unclear Guidance

Some Forum participants stated that lack of clarity regarding the initial priority groups to receive the first doses of vaccine created confusion among pharmacy staff and patients. Many mentioned that the difference in eligibility criteria between states, localities, and CDC was also confusing and difficult to implement (e.g., priority groups sometimes were different between federal and state guidance, or different between state and local public health guidance). One Forum participant mentioned that several health departments were initially “overwhelmed” when vaccine first came out and couldn’t provide clear direction for determining eligibility or answer questions regarding vaccination protocols. Another eligibility issue that arose after the Pfizer-BioNTech received full FDA approval was the challenge of prescribers writing prescriptions for off-label use of the vaccine, outside of recommended eligibility groups. CDC provided guidance to pharmacy partners that off-label use was not supported based on their Provider Agreements, which was critical to guiding pharmacies on how to handle such situations.



“Working with the different jurisdictions to determine who was eligible made it difficult; (there were) mixed messages.”

Staffing Shortages

Survey respondents and Forum participants noted that their pharmacies experienced staff shortages at times, but that amendments to the PREP Act allowing fuller utilization of pharmacy team members, including pharmacy technicians, helped. After the initial rollout of vaccine, subsequent amendments to the PREP Act allowed fuller utilization of the pharmacy staff team members, including pharmacy technicians, which helped.

In addition to the top challenges described above, some survey respondents also mentioned the following challenges as they provided COVID-19 vaccinations to their patients:

Workflow Challenges: Vaccinating a large number of patients caused challenging disruptions in dispensing workflow. Adapting the workflow to accommodate vaccination provision as well as maintaining other pharmacy functions required ongoing modifications and additional staff training.

Addressing Vaccine Hesitancy: Several times during the pandemic, public interest in vaccine waned considerably and pharmacies had to redouble their efforts to reach unvaccinated populations. Forum participants mentioned the challenges related to the public receiving mixed and inaccurate messages about the safety and efficacy of the vaccines from a variety of sources. Some Forum participants said they had to constantly provide patient education to “combat vaccine hesitancy and helping to inform that the vaccine is safe. That was a big challenge.”

COVID-19 Testing Considerations

In the Spring, 2020, as the need to rapidly expand COVID-19 testing across the country accelerated, HHS took several actions under the PREP Act^{c, 51} which authorized licensed pharmacists to order and administer FDA-authorized COVID-19 tests, allowed pharmacy technicians and interns to administer COVID-19 tests, if they met certain requirements including the pharmacy must first obtain a Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver and a separate CLIA license from their respective state agency⁵².

These key actions under the PREP Act lifted various state restrictions that previously limited the ability of pharmacists to order and perform point of care tests⁵³. Lifting these restrictions was the key enabler for pharmacies to offer testing across the country during the pandemic emergency, as in many states, scope of practice would not have allowed pharmacies to independently provide testing, and most payers, including Medicare, would not have reimbursed pharmacies for testing services. To address this, CMS took action to allow pharmacies to bill as laboratories for purposes of billing for COVID-19 tests, and legislative action helped to ensure tests could be provided at no-cost to patients.^{54, 46}

^c HHS PREP Act guidance stated “authorizing qualified pharmacy technicians and State-authorized pharmacy interns to administer COVID-19 tests, including serology tests, that the FDA has approved, cleared, or authorized. By doing so, such qualified pharmacy technicians and State authorized pharmacy interns will qualify as “covered persons” under the PREP Act. And they may receive immunity under the PREP Act with respect to all claims for loss caused by, arising out of, relating to, or resulting from, the administration or use of FDA-authorized COVID-19 tests. 42 U.S.C. § 247d-6d(a)(1).” <https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf>

About three-fourths of survey respondents reported that their company has participated in a COVID-19 testing program, which was either a federal or state/jurisdictional testing program. The federal testing program for pharmacies kicked off in May 2020 and was ultimately built on The Federal Emergency Management Agency’s (FEMA’s) Community-Based Testing Sites (CBTS) model by integrating retail pharmacies and named CBTS 2.0 or “community-based sites public-private partnership.” HHS reported that the private sector partners were responsible for coordinating the full testing process, including registration, scheduling, provider order, patient notifications, medical supplies, equipment, and lab testing.⁵⁵ Additional milestones of this program are included in Table 1. Also, pharmacies partnered with clinical laboratories or businesses that contracted with their company to conduct testing of their employees.

Testing Program Successes

Similar to the vaccination program, most survey respondents reported that COVID-19 testing, while logistically complex, afforded multiple successes.

Key Successes Identified by Pharmacies in Providing COVID-19 Testing

- Served existing and new patients, including high-risk and underserved populations
- Enhanced public health and laboratory partnerships
- Expanded role of pharmacies and staff during a pandemic/emergency
- Enhanced visibility of the role of pharmacy as a healthcare provider

Served Existing and New Patients During a Public Health Emergency, Including Underserved and Vulnerable Populations

As with providing vaccinations, almost all survey respondents and Forum participants reported that the most prominent success of their testing program was the ability to serve their existing patients and the wider community, including the ability to engage new patients. Testing services in some areas of the country were scarce during much of the pandemic. Several mentioned that by offering convenient testing services, they were helping meet the needs of their community, especially to underserved populations.

Enhanced Public Health and Laboratory Partnerships

Most survey respondents reported that, by offering testing, they were able to enhance their relationships with public health entities at state and local levels. In addition, it was also the first opportunity for many to have direct communication with laboratories and create partnerships with these entities. Several Forum participants mentioned that by adding COVID-19 testing services, pharmacies could establish enduring partnerships with laboratories for other conditions and testing opportunities.


Expanded Role of Pharmacies and Staff During a Pandemic/Emergency Including New Roles and Responsibilities for Pharmacy Technicians and Interns

The PREP Act declaration amendments and related actions enabled pharmacy technicians to test patients, which expanded the staff's ability to manage the large influx of patients


seeking testing at different times during the pandemic. This was especially important as most pharmacies conducted testing outside the store, which meant a dedicated staff had to operate the testing processes and therefore were unavailable for other pharmacy tasks.

Enhanced Visibility of Pharmacy as a Healthcare Provider

Most survey respondents noted that pharmacies were getting increased recognition for providing testing services during the pandemic. Similar to the comments made by Forum respondents about offering vaccinations, most noted that offering testing increased the visibility of their pharmacies and the pharmacy profession and was a prominent success factor of their program.



“Pharmacists are now recognized as being on the same tier as other healthcare professionals in fighting the pandemic.”



“The entire nation now sees pharmacy as part of the healthcare system and that pharmacy can help.”

Testing Program Challenges

Despite the successes outline above, as would be expected, there were a number of challenges mentioned by survey respondents and Forum participants.

Key Challenges Identified by Pharmacies in Providing COVID-19 Testing

- Billing and reimbursement challenges
- Shortage of testing supplies
- Workflow and scheduling issues
- Scope of practice issues
- Staffing shortages/issues
- Staff concerns about exposure to disease

Billing and Reimbursement/Payment for Testing

Payment/reimbursement difficulties were mentioned as the leading challenge with offering testing services by survey respondents; most had issues with billing and payment/reimbursement for the testing supplies and almost half of respondents encountered challenges with payment/reimbursement for ordering and/or administering the tests. While action taken by CMS was helpful to create a method for pharmacies to bill as laboratories, this pathway only offered billing ability for the testing supplies and not for the administration of the test. Just like for vaccinations, coverage by Medicaid and private payers for COVID-19 tests varied from state to state. The other pathway for pharmacies to sustain testing is through the Federal Community-Based Testing Site program whereby the federal government covered the administration of tests at a flat fee.²⁶

Shortage of Testing Supplies

Almost all survey respondents who participated in testing programs reported that the lack of testing supplies (particularly the swabs needed to obtain nasopharyngeal specimens) hampered their ability to offer testing services, especially in Spring and Summer 2020.

Shortages of personal protective equipment also impacted and limited offering of testing services. In more recent months, low supplies of Over-the-Counter (“at-home”) testing kits has been reported across testing providers, however at the time of this report, the federal government continues to invest in efforts to ramp up supply of at-home tests and access to free testing including via pharmacies.⁵⁶

Staff Concerns About Exposure to Disease During Testing

One of the key challenges noted by survey respondents was staff reluctance to provide testing because of exposure concerns. Pharmacy staff had to receive training and don full personal protective equipment to conduct testing, which at times was difficult to procure and uncomfortable to wear, particularly in hot weather conditions. Also, to mitigate COVID-19 exposure risk to staff and other patients, most pharmacies did not allow individuals seeking testing to come into their stores. Rather, testing was conducted in a separate setting (e.g., kiosks or tents in parking lots) or through drive-through lines. Some pharmacies had difficulty identifying physical space to perform testing while mitigating exposure risks.

Workflow and Scheduling Challenges

Most survey participants noted that providing testing services caused challenging disruptions to dispensing and other pharmacy workflow. Pharmacies often conducted testing via drive-through or outdoor operations, which usually required dedicated staff that would be unavailable for other pharmacy functions. Because there were limited number of staff to administer tests and the time that it took for the testing process, at times, the wait for testing was longer than anticipated. In addition, it was not uncommon for more than one person to request testing in a drive-through setting even though they had booked only one appointment, which further slowed down the process and increased wait times.



“One car might have 1 appointment slot, but come with a car full of 5 people who all want COVID-19 tests in that single timeslot.”

Scope of Practice Issues

Despite the vital actions taken under the PREP Act to authorize pharmacy staff to perform COVID-19 testing across the country, irrespective of state or local scope of practice restrictions, some states challenged the pre-emptive nature of the PREP Act authorities. In some cases, state authorities continue to question pharmacies’ ability to perform testing, despite the PREP Act provisions, that pharmacies were safely and effectively performing testing and that the services continue to be critically necessary in the public health emergency response. Still today, some states refuse to acknowledge the pre-emptive nature of the PREP Act, which hampers the ability for pharmacies to provide critical pandemic-related care services for communities in need by introducing unnecessary friction and, in some cases, implementation delays.

Section 3. Looking Forward: Several Issues on the Horizon

In addition to survey questions and Forum discussions about pharmacies' experiences with COVID-19 vaccination and testing, questions about their public plans to provide additional doses to immunocompromised persons, booster doses, vaccinate children, and coadministration of flu and COVID-19 vaccines were included in the survey questions and the Forum discussions.

Additional Doses for Immunocompromised Persons and Booster Doses

On August 13, 2021, CDC endorsed their independent ACIP recommendation that certain immunocompromised persons may benefit from an additional dose of vaccine (as part of their primary series) and on October 21, 2021, CDC endorsed ACIP's recommendation for a booster shot of COVID-19 vaccines in certain populations.⁵⁷ All survey respondents reported that their pharmacy planned to offer COVID-19 vaccine going forward including provision of additional doses to those who are immunocompromised and booster doses. There was considerable discussion during the Forum about the logistics of providing these vaccines. Although survey respondents and Forum participants were committed to providing these services, they outlined some challenges that would likely arise including:

- **Concern about how to assess eligibility** of additional doses for immunocompromised persons and those who need boosters as the FDA and CDC guidance initially only authorized additional doses of vaccines and boosters for certain population groups.⁵⁸ Further, concerns were raised that jurisdictions may determine different booster dose eligibility criteria than what was recommended by the ACIP. Also, some Forum participants reported that verifying and documenting patient eligibility may be challenging and will add an extra step to the vaccination process.
- **Additional staffing may be needed** to provide COVID-19 vaccinations to those who are unvaccinated and those seeking additional doses and boosters. In almost every

jurisdiction, mass vaccination and public health clinics that were opened in the Spring of 2021 by federal, state, and local entities have stopped their operations, so pharmacies will be a major provider for further vaccinations. As of mid-November 2021, CDC accepted ACIP's recommendation for providing boosters for all adults going forward, requiring a large workforce to administer these vaccinations.⁵⁹

- **Determining the correct schedule, vaccine type and dosage** will be essential to provide the right vaccine to the right person at the right time. Currently there are different recommendations for administering an additional vaccine dose for those who are immunocompromised compared with those seeking a booster dose. In addition, one vaccine that will be used as a booster dose is given as half of the dose administered for the primary series. Forum participants anticipated that training pharmacy staff with the new protocols would be needed to address these variations. In addition, Forum participants mentioned that, giving the booster at the appropriate time will be important. A lack of centralized reporting could make it harder to validate the timing and specific vaccine a patient had received for their primary series, especially if the patient was first vaccinated in another state.
- **Educating patients** will be necessary so patients have realistic expectations and seek boosters at the right time. If the public is confused or uncertain about when and how to get additional doses or booster vaccinations, Forum participants were concerned that there would be excessive calls to the pharmacies seeking that information. They also noted the need for providing increased on-site patient counseling and education, to reduce vaccine hesitancy and inequities that arise from complicated recommendations, as has been observed in the pandemic thus far.



“To have help in educating the general public on who is ready/eligible for boosters would be helpful.”

Vaccinating Children

By November 2, 2021, FDA and CDC had approved and recommended, respectively, Pfizer-BioNTech’s pediatric COVID-19 vaccination for children ages 5 to 11 years. Guidance for planning to immunize children and pre-ordering vaccine doses began in mid-October 2021.⁶⁰ Most survey respondents reported that their pharmacy planned to offer pediatric COVID-19 vaccinations. While many children may get vaccinated at their pediatrician’s or primary care provider’s office, pharmacies will likely be vaccinating children as well. At the time of this report, pharmacies have been provided an allocation of pediatric COVID-19 vaccine and given their convenient locations in communities, are expected to help provide meaningful access for children and their families.

Administration of Influenza Vaccine

As the influenza season is now underway, pharmacies have been preparing to administer seasonal influenza vaccinations, but doing so during the COVID-19 pandemic will be an ongoing challenge. There are two concerns related to influenza vaccinations, first that there will not be adequate uptake in this vaccine as people will be more concerned with getting the COVID-19 vaccine, and the opposite issue, that there will be a large demand for influenza vaccine. As of the end of October, 2021, CDC reported that manufacturers have projected they will provide as many as 200 million doses of influenza vaccine in the U.S.⁶¹ However, CDC is reporting that early uptake in influenza vaccine this season is lower than in previous seasons compared with the same time period.⁶² Although there has been low flu activity in early Fall, 2021, it is very important to protect against influenza, particularly for those at higher risk for complications.

Regarding the potential for a later demand for influenza vaccinations, pharmacies are preparing to prevent crowding and are scheduling appointments to prevent long waits given potential surge of patients seeking flu vaccinations at the same time that there is a demand for COVID-19 vaccinations, including additional doses, boosters and pediatric COVID-19 vaccine. Almost all survey respondents reported that their pharmacy planned to offer influenza vaccinations.

However, in addition to the staffing needs mentioned above, Forum participants expressed concerns that patients may feel they have to choose between receiving COVID-19 vaccination or influenza vaccination and not feel confident that both can be administered in the same visit. Forum participants suggested that patient educational materials about coadministration of COVID-19 and influenza vaccines be made available to pharmacies. Research to help uncover specific patient concerns about coadministration may also help tailor messages that will resonate on this important topic. At the time of this report, a number of resources have been made available on coadministration, yet early available information show that some patients remain hesitant.⁶³ Most survey respondents said they would continue to offer an array of ACIP-recommended vaccines as well as influenza vaccine.

Expanding Access to COVID-19 Oral Therapies

At the time of this report, pharmacies are also looking ahead to playing a central role in expanding community access to COVID-19 oral therapies, once authorized and recommended. As authorized by the Ninth declaration amendment to the Public Readiness and Emergency Preparedness (PREP) Act, pharmacists are authorized to independently order, and pharmacy technicians and interns are authorized to administer, COVID-19 therapeutics.⁶⁴ At the time of this report, FDA discussions are ongoing on the potential authorization of at least one oral COVID-19 therapeutic, with more products expected for consideration in the coming weeks to months.

Section 4. Policy Recommendations

The ability for pharmacies to provide comprehensive access to COVID-19 vaccinations and testing was heavily reliant on HHS' issuance of the PREP Act declaration, subsequent amendments and policy guidance that removed many barriers related to state pharmacy scope of practice restrictions, and alterations in reimbursement and payment policies. Survey respondents were asked to comment as to whether several categories of existing policy/regulatory changes identified in existing NACDS policy positions were the most critical and impactful to pharmacies' ability to support their communities during the COVID-19 pandemic. These categories included "scope-related policy/regulatory changes" and "payment-related policy/regulatory changes." They were also asked if there was any other policy item that their company would add or remove from this listing of most critical actions.

Almost all survey respondents agreed that the following were the most critical enabling policies related to vaccination and testing:

Scope-Related Policy/Regulatory Changes:

Vaccinations

- PREP Act authorities allowing pharmacists to order and administer, and pharmacy interns and technicians to administer, COVID-19 vaccines for 3 years and up, all ACIP-recommended vaccines for 3-18 year olds, and technicians and interns to administer flu shots to adults.
- HHS General Counsel Advisory Opinions and other confirmatory agency documents clarifying the preemptive nature of the PREP Act declaration, amendments, and guidances to help alleviate state/local barriers.
- PREP Act authorities for pharmacist license reciprocity in other states/expired license/certificates to administer COVID-19 vaccines.
- State action(s) to support/recognize authorities for pharmacy staff granted under the PREP Act, in addition to implementing permanent state scope of practice expansions for pharmacists to order and administer, and for technicians and interns to administer, vaccines.

Testing

- PREP Act authorities allowing pharmacists to order and administer, and pharmacy technicians and interns to administer, COVID-19 testing for individuals 3 years and up.
- HHS General Counsel Advisory Opinions and other confirmatory agency documents clarifying the preemptive nature of the PREP Act declaration, amendments, and guidances to help alleviate state/local barriers.
- State action(s) to support/recognize authorities for pharmacy granted under the PREP Act, in addition to implementing permanent state scope of practice expansions for pharmacists to order and administer, and for technicians and interns to administer, tests.

Payment-Related Policy/Regulatory Changes:

Vaccinations

- CMS' Toolkits and Interim Final Rules on coverage and billing clarifications for federal programs and commercial payers, including clarification on coverage of vaccine administration for children through the Medicaid program in lieu of the Vaccines for Children Program.
- Mandatory coverage of COVID-19 vaccinations within commercial, Medicare, and Medicaid plans, as required by the CARES Act and FFCRA.
- Emergency billing guidance from the National Council for Prescription Drug Programs (NCPDP).
- Implementation of the [HRSA Uninsured Program](#).
- Implementation of the [HRSA Coverage Assistance Fund \(CAF\) Program](#) for the Underinsured.
- Several state Medicaid agencies' adoption or recognition of NCPDP emergency guidance for billing standards for administration of vaccine.
- Several state Medicaid agencies' promulgation or announcement of coverage and reimbursement requirements for administration of vaccine.

Testing

- CMS' Toolkits and Interim Final Rules on coverage and billing clarifications for federal programs and commercial payers.
- Emergency billing guidance from the National Council for Prescription Drug Programs, (NCPDP).
- Mandatory coverage of COVID-19 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).
- Waiver of regulatory requirements to permit pharmacies to bill Medicare Part B as laboratories.
- Implementation of the HRSA Uninsured Program.
- State Medicaid agencies' promulgation or announcement of coverage and reimbursement requirements for performing COVID-19 tests as a laboratory.

During Forum discussions, participants emphasized the importance of the PREP Act Amendments and other policy allowances that authorized pharmacy staff to provide vaccinations and testing services. Without these policies, far fewer people in the U.S. would be vaccinated against the virus causing COVID-19, and far fewer tests would have been administered.

Public Policy Recommendations for Improvement and More

Based on the extensive information gathered through the survey and Forum discussions, participants suggested multiple policy recommendations to continue to support the critical roles of pharmacies during a public health emergency. These are not an exhaustive list but include:

- **HHS should permanently expand pharmacy scope of practice across all states to improve access to key care interventions, at a minimum, vaccinations, point of care testing, and access to therapeutics, for patients of all ages.** Throughout the COVID-19 response, the additional services that pharmacies have provided has contributed to protecting the health of millions of people during the pandemic. Therefore, making the flexibilities granted for pharmacies under the PREP Act (See Table 1) permanent is critical for improving access to preventive and acute care going forward. Additionally, while implemented shortly before the Forum, HHS took additional action under the PREP Act that expands the scope of practice for pharmacy personnel by authorizing licensed pharmacists to order and administer, and pharmacy technicians to administer, COVID-19 therapeutics.⁶⁵ Pharmacies are likely to play an important role in expanding access to new therapies as they emerge and are suitable for outpatient initiation.

Whereas the actions taken under the PREP Act were tremendously helpful in expanding pharmacy services to communities during the public health emergency because many states had previously restricted such activities, there were delays

in the uptake of these services caused by lack of public awareness that these interventions were available at pharmacies. In addition, some states' lack of recognition of the PREP Act as preemptive in nature caused delays and challenges in pharmacies getting up and running with these interventions. Permanent expansion of state scope of practice to allow pharmacy staff to practice at the top of their expertise would allow for much more seamless access to care for the public at pharmacies during an emergency, and for the routine and everyday care that improves health. For example, a number of interventions that are well within pharmacy staff's capabilities and have high health impact for the public include: ordering and administering all recommended vaccinations across ages, ordering and administering point-of-care tests, initiating treatment guided by test results, and other key pandemic-related services or other care that advances population health.

- **CMS should permanently implement a payment pathway in Medicare Part B for clinical care delivered by pharmacists.** Payment and reimbursement barriers for pharmacies during the pandemic often stemmed from the lack of a permanent payment infrastructure for pharmacy-based clinical care covered in Medicare Part B. Importantly, this issue applies across Medicaid and commercial payers as well, given that other payers often look to Medicare for guidance on payment. A permanent payment pathway in Medicare Part B for pharmacist-provided clinical care would support more seamless public access to care, rather than the implementation of ad-hoc workarounds, as observed during the pandemic, which often led to inadequacies and inefficiencies. Federal legislative efforts to recognize pharmacists as providers of patient care within Medicare Part B are needed, especially to help ensure the nation has permanent and seamless access to pandemic and related services including, but not limited to, vaccinations, testing and initiation of treatment, in addition to key routine and everyday care. Further, state Medicaid Directors together with State Legislators also should help to ensure the development and

implementation of viable pathways for pharmacies to sustain the delivery of clinical care within state Medicaid programs, especially for CLIA-waived testing, vaccinations, and other pandemic-related services. As an example, this can be accomplished by designating pharmacists as Other Licensed Providers (OLPs) in state Medicaid programs.⁶⁶

- **CDC should develop a centralized data reporting system for vaccine administration during a public health emergency for use by all vaccine providers.** Although almost every state has its own Immunization Information System (IIS), there needs to be a consolidated repository of vaccination information that can be made available to public health authorities and vaccine providers during an emergency. Although similar challenges were faced by pharmacies administering vaccine during the H1N1 pandemic in 2009, now, over a decade later, almost no progress has been made to create streamlined and unified vaccination reporting during a pandemic.⁶⁷ Reducing reporting burden is especially important during a long-duration emergency like COVID-19.
- **CDC should endeavour to harmonize vaccine eligibility between CDC and the states so pharmacies can apply the same eligibility protocols nationwide.** To reduce confusion and maximize adherence to vaccination policies, eligibility criteria must be consistent between jurisdictions.
- **HHS should develop and utilize a centralized system so vaccine providers can easily determine patient insurance status.** During the next public health emergency where a medical countermeasure or vaccine is needed, it would be helpful for pharmacies (and other providers) if there could be a user-friendly portal for information about patients' insurance status. The Emergency Prescription Assistance Program (EPAP)⁶⁸, or an EPAP-like program could be activated at some level. This program, designed for limited area natural disasters, leverages real-time pharmacy claims processing systems that adhere to multiple national standards and can identify

whether a patient has current health insurance coverage by using a specially developed database. Most pharmacies in the U.S. are enrolled in this program. Activation of the EPAP “look-up” features during a pandemic will allow for rapid identification of health insurance status and for those who are uninsured, provide pharmacies with a link to the HRSA Coverage Assistance Funds.

Further, based on information gathered via the Forum, pharmacies may have their own considerations to explore, such as:

- **Contemplate conducting an “after-action” review.** When the COVID-19 pandemic finally resolves or reduces its impact, community pharmacies may want to consider conducting an “after-action” review to explore their experiences, assess outcomes, and discuss with leadership internally how to fold COVID-19 lessons learned and successes into short and long-term planning for the next public health response. Although it is not possible to predict future public health emergency scenarios, it might benefit pharmacies to use the lessons learned from this pandemic to be even more prepared for a future event.
- **Contemplate maintaining communications and partnerships with public health.** The new partnerships that were built and the existing partnerships that were both tested and strengthened during the pandemic between public health officials and pharmacies should be maintained going forward. These affiliations are important because response to public health emergencies and prevention as well as control of chronic health conditions require collaboration and coordination across multiple sectors in communities. Creating ongoing communication with local and state-level public health entities to review “lessons learned” and collaborate on future public health emergency planning may help to benefit pharmacy readiness for future responses and enhance community-level outcomes.

- Contemplate stockpiling some personal protective equipment (PPE) for staff.

Although it is not possible to stockpile all the PPE that may be needed in a future pandemic, it may be worth exploring the ability to acquire some stocks of respiratory protective equipment to help prepare for an infectious disease outbreak. Challenges faced during the COVID-19 pandemic included a shortage of PPE and staff reluctance to provide testing absent the PPE. A ready supply of PPE may enable continuity of function in the early days of a future pandemic.

Section 5. Conclusion

The COVID-19 pandemic is ongoing at the time of this report, and the trajectory is uncertain, as cases are increasing in many parts of the country and a new variant of concern (Omicron) has recently been detected in several countries.⁶⁹ Despite the dynamic pandemic scenario, COVID-19 vaccine will remain a key countermeasure and pharmacies will continue to be responsible for vaccinating the majority of Americans. This significant role has already reduced disease transmission, saved lives (especially for older people), and reduced healthcare costs.⁷⁰ Although a high proportion of people have been vaccinated, millions need booster shots and a sizable proportion of people in most communities are still unvaccinated and therefore, at high risk for disease. Significant efforts (largely by community pharmacies) will be needed to reduce the number of people who are unvaccinated, administer vaccine to children, provide booster doses to tens of millions of people and immunize against seasonal influenza in the coming months.

Pharmacies have also provided millions of COVID-19 tests. Expansion of testing in pharmacies was recently identified as part of President Biden's six-part plan to combat the COVID-19 pandemic⁷¹, and pharmacies will be central to disease control testing strategies going forward.

However, the challenges faced by community pharmacies during the COVID-19 pandemic must be addressed by policy and law makers, as the demands for care services from pharmacies will likely continue for months or longer. Most of these challenges are highly preventable and lessons learned from the experience during the pandemic must be addressed through public policy solutions implemented across the healthcare continuum to refine and improve future public health emergency responses. It is also critical to make necessary policy improvements to our healthcare systems and infrastructure to support better health and address health disparities in normal times, which in turn, will strengthen our ability to respond and provide care during emergencies. Some challenges may be amenable to shorter term solutions, while others may take longer to remediate.

The successes from these efforts demonstrate that pharmacies and their staff can play a vital healthcare delivery role during a public health crisis and could be further leveraged in normal times to improve healthcare access and strengthen community healthcare infrastructure nationwide. Approximately 90% of all U.S. residents live within five miles of a community pharmacy, therefore pharmacies are accessible healthcare destinations to offer needed countermeasures during a public health emergency and more broadly. The successes and challenges outlined in this report, while not exhaustive, can inform future pandemic planning and can also be leveraged for use after the emergency diminishes to continue to provide essential health services, particularly to underserved populations. It is important for communities to maintain their access to pharmacy care that they have come to expect and depend on during the pandemic. Therefore, it is critical to help to ensure that the adjustments that increased the provision of pharmacy services during the pandemic remain in place and can be expanded upon to enhance access to care and improve health outcomes after the pandemic subsides.

About NACDS

NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' 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.

About Health Preparedness Partners, LLC (HPP)

HPP helps organizations in their response to the COVID-19 pandemic, including providing practical and detailed guidance about determining when and how to return to the workplace, strategies for protecting employees and managing ongoing risk mitigation, and preparing for future waves of COVID-19, as well as other threats. Dr. Lisa Koonin, DrPH, MN, MPH founded Health Preparedness Partners after her 30+ year career with the Centers for Disease Control and Prevention (CDC). During that time, she led the development of national pandemic preparedness plans and policies, conducted large-format exercises, and consulted with businesses (including pharmacies), state and local governments, healthcare facilities, non-governmental organizations, academic institutions, and ministries of health around the world, to improve emergency preparedness. While she served at CDC, Dr. Koonin was responsible for leading the CDC Pharmacy H1N1 Vaccine Initiative, which provided pandemic vaccine directly to 10 large pharmacy companies during the 2009-2010 H1N1 pandemic. Please visit healthpreparednesspartners.com.

Section 6. Glossary

ACIP: Advisory Committee on Immunization Practices

CAF: Coverage Assistance Fund

CARES: Coronavirus Aid, Relief, and Economic Security

CBTS: Community-Based Testing Sites

CDC: Centers for Disease Control and Prevention

CLIA: Clinical Laboratory Improvement Amendment

CMS: Centers for Medicare and Medicaid Services

CPR: Cardiopulmonary Resuscitation

CVRS: COVID-19 Vaccination Reporting Specification

DCH: Data Clearinghouse

DOH: Department of Health

EPAP: Emergency Prescription Assistance Program

EUA: Emergency Use Authorization

FDA: Food and Drug Administration

FEMA: Federal Emergency Management Agency

FFCRA: Families First Coronavirus Response Act

GAO: Government Accountability Office

HHS: Department of Health and Human Services

HRSA: Health Resources and Services Administration

IIS: Immunization Information Systems

IT: Information Technology

LTC: Long-Term Care

LTCF: Long-Term Care Facility

NCPDP: National Council for Prescription Drug Programs

OLP: Other Licensed Provider

OWS: Operation Warp Speed

PPE: Personal Protective Equipment

PREP: Public Readiness and Emergency Preparedness

VAMS: Vaccine Administration Management System

VFC: Vaccines for Children

VRBPAC: Vaccines and Related Biological Products Advisory Committee

Section 7. End Notes

- ¹ CDC. The Federal Retail Pharmacy Program for COVID-19 Vaccination. <https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/faqs.html>
- ² GAO. COVID-19: HHS Agencies' Planned Reviews of Vaccine Distribution and Communication Efforts Should Include Stakeholder Perspectives. November 2021. <https://www.gao.gov/products/gao-22-104457>
- ³ Avalere Health LLC. Exploring Pharmacists' Role in a Changing Healthcare Environment. 2014. <https://www.nacds.org/pdfs/comm/2014/pharmacist-role.pdf>
- ⁴ Sokolow LZ, et al. Scripted Surge Pharmacy Pandemic Exercise: Testing Vaccine Administration and Antiviral Dispensing. Health Security. July/August 2018. <https://pubmed.ncbi.nlm.nih.gov/30133375>
- ⁵ Graitcer SB. Being Ready for the Next Pandemic: Expanded Access to Pandemic Vaccines <https://www.astho.org/Preparedness/Being-Ready-for-the-Next-Pandemic--Expanded-Access-to-Pandemic-Vaccines>
- ⁶ CDC. Public Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Public Health. October 2018. Updated January 2019. https://www.cdc.gov/cpr/readiness/00_docs/CDC_PreparednesResponseCapabilities_October2018_Final_508.pdf
- ⁷ Schwerzmann J, et al. Evaluating the Impact of Pharmacies on Pandemic Influenza Vaccine Administration. Disaster Med Public Health Prep. October 2017. <https://pubmed.ncbi.nlm.nih.gov/28219461>
- ⁸ Institute of Medicine. The 2009 H1N1 Influenza Vaccination Campaign: Summary of a Workshop Series. Washington, DC: The National Academies Press. <https://doi.org/10.17226/12992>
- ⁹ Koonin LM, et al. CDC's 2009 H1N1 vaccine pharmacy initiative in the United States: implications for future public health and pharmacy collaborations for emergency response. Disaster Med Public Health Prep. December 2011. <https://pubmed.ncbi.nlm.nih.gov/22146661>
- ¹⁰ Koonin LM, et al. CDC's 2009 H1N1 vaccine pharmacy initiative in the United States: implications for future public health and pharmacy collaborations for emergency response. Disaster Med Public Health Prep. December 2011. <https://pubmed.ncbi.nlm.nih.gov/22146661>
- ¹¹ CDC. Pharmacy Contributions to Improved Population Health: Expanding the Public Health Roundtable. September 2020 https://www.cdc.gov/pcd/issues/2020/20_0350.htm
- ¹² Schwerzmann J, et al. Evaluating the Impact of Pharmacies on Pandemic Influenza Vaccine Administration. Disaster Med Public Health Prep. October 2017. <https://pubmed.ncbi.nlm.nih.gov/28219461>
- ¹³ Bartsch SM, et al. Epidemiologic and economic impact of pharmacies as vaccination locations during an influenza epidemic. Vaccine. November 2018. <https://www.ncbi.nlm.nih.gov/pubmed/30340884>
- ¹⁴ del Rio C, Malani PN. COVID-19—New Insights on a Rapidly Changing Epidemic. JAMA. February 2020 <https://www.astho.org/Infectious-Disease/Pandemic-Influenza/Public-Health-and-Pharmacy-Collaboration-in-an-Influenza-Pandemic/>
- ¹⁵ Sanche S, et al. High Contagiousness and Rapid Spread of Severe Acute Respiratory Syndrome Coronavirus 2. Emerging Infectious Diseases. July 2020. <https://publichealth.jhu.edu/2018/during-a-flu-epidemic-dispensing-flu-vaccines-at-pharmacies-could-save-lives-and-costs>
- ¹⁶ Ying Liu, et al. Journal of Travel Medicine. March 2020. <https://www.cdc.gov/flu/pandemic-resources/pdf/pan-flu-report-2017v2.pdf>
- ¹⁷ Bartsch SM, et al. Epidemiologic and economic impact of pharmacies as vaccination locations during an influenza epidemic. Vaccine. November 2018. <https://www.ncbi.nlm.nih.gov/pubmed/30340884>
- ¹⁸ Oliver S. Evidence to Recommendation Framework: Pfizer-BioNTech COVID-19 Booster Dose. September 2021. <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-9-23/03-COVID-Oliver.pdf>
- ¹⁹ CDC. The Federal Retail Pharmacy Program for COVID-19 Vaccination. <https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html>

- ²⁰ HHS. Community-Based Testing Sites for COVID-19. <https://www.hhs.gov/coronavirus/community-based-testing-sites/index.html>
White House. Press Briefing by White House COVID-19 Response Team and Public Health Officials. October 2021. <https://www.whitehouse.gov/briefing-room/press-briefings/2021/10/06/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-60/>
- ²¹ ASPE. Overview of Barriers and Facilitators in COVID-19 Vaccine Outreach. August 2021.
<https://aspe.hhs.gov/sites/default/files/2021-08/Vaccine%20Outreach%20Research%20Report%208-27-2021%20FINAL.pdf>
- ²² DOD. Trump Administration Partners with CVS and Walgreens to Provide COVID-19 Vaccine to Protect Vulnerable Americans in Long-Term Care Facilities Nationwide. October 2020.
<https://www.defense.gov/News/Releases/Release/Article/2384541/trump-administration-partners-with-cvs-and-walgreens-to-provide-covid-19-vaccin>
- ²³ Biden, JR. National Strategy for the COVID-19 Response and Pandemic Preparedness. January 2021
<https://www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-COVID-19-Response-and-Pandemic-Preparedness.pdf>
- ²⁴ Gharpure, R, et al. Early COVID-19 First-Dose Vaccination Coverage Among Residents and Staff Members of Skilled Nursing Facilities Participating in the Pharmacy Partnership for Long-Term Care Program - United States, December 2020-January 2021. February 2021.
<https://pubmed.ncbi.nlm.nih.gov/33539332>
- ²⁵ Gharpure R, et al. COVID-19 Vaccine Uptake Among Residents and Staff Members of Assisted Living and Residential Care Communities-Pharmacy Partnership for Long-Term Care Program, December 2020-April 2021. August 2021. <https://pubmed.ncbi.nlm.nih.gov/34508695>
- ²⁶ NACDS. Striving Toward Health Equity in COVID-19: The Role of Pharmacies in a National Response. <https://www.nacds.org/pdfs/HealthEquity.pdf>.
- ²⁷ Rubin, SE, et al. Leveraging Partnerships Among Community Pharmacists, Pharmacies, and Health Departments to Improve Pandemic Influenza Response. April 2014.
https://www.liebertpub.com/doi/abs/10.1089/bsp.2013.0082?rfr_dat=cr_pub%3Dpubmed&url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&journalCode=bsp
- ²⁸ SteelFisher GK, et al. Pharmacist Views on Alternative Methods for Antiviral Distribution and Dispensing During an Influenza Pandemic. Health Security. March/April 2018. <https://pubmed.ncbi.nlm.nih.gov/29570363>
- ²⁹ CDC. 2019-2024 Public Health Emergency Preparedness (PHEP) Notice of Funding Opportunity – Supplemental Guidance and Resources. Domain 4: Key Components of Pandemic Influenza Operational Readiness. March 2019. https://www.cdc.gov/cpr/readiness/00_docs/PHEP_SupplementalGuidance_Key_Components_for_Pandemic_Influenza_FINAL_3.4.19_updated.pdf
- ³⁰ CDC. COVID-19 Vaccination Program Jurisdiction Operations Interim Operational Guidance. October 2020.
https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf
- ³¹ DHHS. 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 2020. <https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf>
- ³² Goode, JV, et al. Community-Based Pharmacy Practice Innovation and the Role of the Community-Based Pharmacist Practitioner in the United States. August 2019. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6789634>
- ³³ Guidance for Pharmacists and Pharmacy Technicians in Community Pharmacies during the COVID-19 Response. February 2020. Last Updated November 2020. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/pharmacies.html>
- ³⁴ Strand, MA, et al. Community Pharmacists' Contributions to Disease Management During the COVID-19 Pandemic. July 2020.
https://www.cdc.gov/pcd/issues/2020/20_0317.htm
- ³⁵ Burbage, S, Levitt J. Pharmacist Role in Addressing Social Determinants of Health during COVID-19. June 2021.
<https://cmopp.web.unc.edu/2021/06/pharmacist-role-in-addressing-social-determinants-of-health-during-covid-19>
- ³⁶ CDC. Flu Vaccination Coverage, United States, 2020–21 Influenza Season. October 2021.
<https://www.cdc.gov/flu/fluview/coverage-2021estimates.htm>

- ³⁷ Bach AT, Goad JA. The role of community pharmacy-based vaccination in the USA: current practice and future directions. *Integr Pharm Res Pract*. July 2015. <https://pubmed.ncbi.nlm.nih.gov/29354521>
- ³⁸ DHHS. COVID-19 Pandemic Vaccination Planning: Update for State and Local Public Health Programs. August 2020. https://philadelphia.cbslocal.com/wp-content/uploads/sites/15116066/2020/09/CDC-COVID-19-Pandemic-Vaccination-Planning_08.04.20.pdf
- ³⁹ HHS. From the Factory to the Frontlines The Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine. <https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf>
- ⁴⁰ Naishadham, S, Noveck, J. Crippling weather hampers vaccine deliveries, distribution. February 2021. <https://abcnews.go.com/Health/wireStory/crippling-weather-hampers-vaccine-deliveries-distribution-75951466>
- ⁴¹ GAO. COVID-19: HHS Agencies' Planned Reviews of Vaccine Distribution and Communication Efforts Should Include Stakeholder Perspectives. November 2021. <https://www.gao.gov/products/gao-22-104457>
- ⁴² GAO. Sustained Federal Action Is Crucial as Pandemic Enters Its Second Year. March 2021. <https://www.gao.gov/assets/gao-21-387.pdf>
- ⁴³ Ibid.
- ⁴⁴ CDC. FAQs for Private and Public Healthcare Providers About Implementing the CDC COVID-19 Vaccination Program in Provider Practices. <https://www.cdc.gov/vaccines/covid-19/vaccine-providers-faq.html>
- ⁴⁵ CDC. COVID-19 Vaccine IT Overview. <https://www.cdc.gov/vaccines/covid-19/reporting/overview/IT-systems.html>
- ⁴⁶ H.R.6201: Families First Coronavirus Response Act. 116th U.S. Congress (2019-2020). <https://www.congress.gov/bill/116th-congress/house-bill/6201/text>
H.R.748: Coronavirus Aid, Relief and Economic Security Act. 116th U.S. Congress (2019-2020). <https://www.congress.gov/116/bills/hr/748/BILLS-116hr748enr.pdf>
- ⁴⁷ CDC. The Federal Retail Pharmacy Program for COVID-19 Vaccination. <https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/faqs.html>
- ⁴⁸ CMS. Biden Administration Continues Efforts to Increase Vaccinations By Bolstering Payments for At-Home COVID-19 Vaccinations for Medicare Beneficiaries. June 2021. <https://www.cms.gov/newsroom/press-releases/biden-administration-continues-efforts-increase-vaccinations-bolstering-payments-home-covid-19>
- ⁴⁹ HRSA. What Providers Need to Know About COVID-19 Vaccine Fees and Reimbursements. <https://www.hrsa.gov/sites/default/files/hrsa/coronavirus/provider-covid-vaccine-factsheet.pdf>
- ⁵⁰ GAO. HHS Agencies' Planned Reviews of Vaccine Distribution and Communication Efforts Should Include Stakeholder Perspectives. November 2021. <https://www.gao.gov/assets/gao-22-104457.pdf>
- ⁵¹ DHHS. Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act. April 2020. <https://www.hhs.gov/sites/default/files/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf>
- ⁵² CMS. Frequently Asked Questions (FAQs), CLIA Guidance During the COVID-19 Emergency. December 2020. <https://www.cms.gov/files/document/frequently-asked-questions-faqs-clia-guidance-during-covid-19-emergency-updated-12-17-2020.pdf>
- ⁵³ DHHS. Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act. April 2020. <https://www.hhs.gov/sites/default/files/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf>
<https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf>
- ⁵⁴ CMS. Medicare 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>
- ⁵⁵ CRS. COVID-19 Testing: Frequently Asked Questions. September 2021. <https://crsreports.congress.gov/product/pdf/R/R46481>

- ⁵⁶ White House. Press Briefing by White House COVID-19 Response Team and Public Health Officials. October 2021. <https://www.whitehouse.gov/briefing-room/press-briefings/2021/10/06/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-60/>
- ⁵⁷ CDC. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States. October 2021. <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-covid19-vax-immunocompromised>
- ⁵⁸ CDC. Covid-19 Vaccine Booster Shots. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html>
- ⁵⁹ CDC. CDC Expands Eligibility for COVID-19 Booster Shots to All Adults. Media Statement. November 19, 2021. <https://www.cdc.gov/media/releases/2021/s1119-booster-shots.html>
- ⁶⁰ CDC COVID-19 Vaccination for Children 5-11 Years Old Information for Jurisdictions, Pediatric Healthcare Providers, Pharmacists and Community Partners. October 2021. <https://www.cdc.gov/vaccines/covid-19/planning/children.html>
- ⁶¹ CDC. Seasonal Influenza Vaccine Supply & Distribution. <https://www.cdc.gov/flu/prevent/vaccine-supply-distribution.htm>
- ⁶² CDC. Early, Low Estimates for Flu Vaccination Coverage in Some Groups Raise Concerns at CDC. <https://www.cdc.gov/flu/spotlights/2021-2022/early-vacc-coverage.htm>
- ⁶³ NFID. 2021 National Survey: Attitudes about Influenza, Pneumococcal Disease, and COVID-19. <https://www.nfid.org/2021-national-survey-attitudes-about-influenza-pneumococcal-disease-and-covid-19/>
- ⁶⁴ HHS. PREP Act Declaration: 9th Amendment <https://www.phe.gov/Preparedness/legal/prepact/Pages/PREPact-NinethAmendment.aspx>
- ⁶⁵ ASPR. Expanding Access to COVID-19 Therapeutics HHS PREP Act Declaration: 9th Amendment. <https://www.phe.gov/Preparedness/legal/prepact/Documents/PrepAct-Declaration-Amendment-FactSheet-8sept2021.pdf>
- ⁶⁶ Pamela Schweitzer, PharmD, Mark Atalla, PharmD, MBA, Medicaid reimbursement for pharmacist services: A strategy for the pharmacy profession, American Journal of Health-System Pharmacy, Volume 78, Issue 5, 1 March 2021, Pages 408–415, <https://doi.org/10.1093/ajhp/zxaa390>
- ⁶⁷ Institute of Medicine. The 2009 H1N1 Influenza Vaccination Campaign: Summary of a Workshop Series. The National Academies Press. 2010. <https://doi.org/10.17226/12992>
- ⁶⁸ PHE. The Emergency Prescription Assistance Program. <https://www.phe.gov/Preparedness/planning/epap/Pages/default.aspx>
- ⁶⁹ CDC. CDC Statement on B.1.1.529 (Omicron variant). <https://www.cdc.gov/media/releases/2021/s1126-B11-529-omicron.html>
- ⁷⁰ Samson, LW, et al. Associations Between County-level Vaccination Rates and COVID-19 Outcomes Among Medicare Beneficiaries. October 2021. <https://aspe.hhs.gov/reports/covid-19-vaccination-rates-outcomes>
- ⁷¹ The White House. Path Out of the Pandemic: President Biden's Covid-19 Action Plan. <https://www.whitehouse.gov/covidplan>