

December 10, 2020

Bill McBride
Executive Director
National Governors Association
444 North Capitol Street
Suite 267
Washington, D.C. 20001

Submitted via email: BMcBride@nga.org

RE: Critical Refinements to Address the COVID-19 Pandemic Across States

Dear Mr. McBride,

The National Association of Chain Drug Stores (NACDS) appreciates our ongoing collaborative work to ensure safe and effective COVID-19 vaccine development, distribution, allocation, and administration for all Americans. Governors have taken extraordinary steps toward reopening America and defeating the pandemic, contributing greatly toward our nation's unprecedented pandemic response. NACDS and the National Governors Association (NGA) share the recognition that to fully re-open America and beat the COVID-19 pandemic, our nation needs widespread, convenient access to COVID-19 vaccinations. To do so, state strategies can be augmented by leveraging the private sector, including retail community pharmacies, to accelerate the administration of COVID-19 testing and vaccines. Community pharmacies have and continue to serve as critical healthcare destinations throughout the pandemic response. NACDS has shared multiple recommendations with national and state leaders, urging actions to benefit patients and support our nation's response to COVID-19. At this critical time as COVID-19 cases are surging and some state leadership transitions may occur in January, NACDS asks NGA to share these recommendations with its membership. We urge governors to engage their state executive teams in addressing the following recommendations:

Recommendation 1: Medicaid Program Coverage of COVID-19 Vaccine Administration Fees

Last week the Centers for Medicare and Medicaid Services (CMS) published its Toolkit on Coverage and Reimbursement of COVID-19 Vaccines, Vaccine Administration, and Cost Sharing under Medicaid, the Children's Health Insurance Program, and Basic Health Program.¹ As summarized (***See Attachment A: Toolkit Summary***), the Toolkit provides several clarifications and recommendations for state Medicaid programs regarding coverage of COVID-19 vaccine administration fees. NACDS urges governors to engage State Medicaid Directors/State Medicaid program leaders about this Toolkit and consider the clarifications and recommendations made therein alongside the additional recommendations from NACDS:

1a. Coverage & Billing – State Medicaid programs should cover the COVID-19 vaccine administration fees for pharmacies under the prescription drug benefit. Further, state Medicaid programs should clarify whether this coverage will be done under a state's Medicaid fee-for-service program or by the state's Medicaid managed care

¹ CMS, Coverage and Reimbursement of COVID-19 Vaccines, Vaccine Administration, and Cost Sharing under Medicaid, the Children's Health Insurance Program, and Basic Health Plan Program, Nov. 23, 2020, *available at* <https://www.medicare.gov/state-resource-center/downloads/covid-19-vaccine-toolkit.pdf>.

plan(s). States should clearly communicate benefit and program coverage to private actors, including retail community pharmacies, via public notice posted in a central and accessible location. Regardless of how the vaccine administration fee is covered, state Medicaid programs should utilize the Medicare rates for COVID-19 vaccine administration as a reimbursement floor and that reimbursement should not be reduced in any way due to administrative, network, or other fees. Pursuant to the Toolkit, should state's cover the administration fee under Medicaid fee-for-service, the state should immediately seek an expedited change to its State Plan Amendment (SPA) to accommodate the Medicare reimbursement rate floor. Finally, NACDS encourages states to work with the Medicaid fee-for-service claims administrators and Medicaid managed care plans to make necessary systems adjustments to recognize administration fees once adjudicated by a pharmacy.

1b. Enrollment – Medicaid enrollment is different in each state and is an especially complex process for multi-state pharmacy chains. Given the variation in enrollment process, we urge state Medicaid programs to permit pharmacies who are enrolled in Medicare to be sufficient for the state Medicaid enrollment process as well, and not require enrollment of the pharmacists. Second, a state Medicaid programs must recognize, pursuant to the aforementioned CMS Toolkit, that various federal Medicaid and CHIP statutes and regulations that reference state scope of practice are effectively preempted by the recent PREP Act declaration and guidances made thereunder. In doing so, state Medicaid programs should streamline certain state requirements that are based on such federal statutes or regulations. For example, the Affordable Care Act requires ordering and referring (ORP) providers to be enrolled in Medicaid. Yet, many states do not recognize pharmacists as a provider and therefore states prevent a pharmacist from enrolling as an ORP. For those Medicaid programs that may permit a pharmacist to enroll as an ORP for the COVID-19 pandemic, NACDS is concerned that states do not have enough time or resources complete that enrollment process for all pharmacists. Therefore, we urge state Medicaid programs to waive ordering and referring provider enrollment requirements for the prescribing/administering pharmacists who is ordering the COVID-19 vaccines and instead leverage the NCPDP claims processing guidance to trigger the exception rules.²

Recommendation 2: Medicaid Program Billing for COVID-19 Testing

Direct Pharmacy Billing – It is NACDS' understanding that pharmacies bill Medicaid for COVID-19 tests as CLIA-waived laboratories for any point-of-care testing conducted at retail pharmacies. However, like in Medicare, pharmacies should also be permitted to directly bill Medicaid for services provided by pharmacists that are conducted under other types of testing models, including the Swab-and-Send Model and the Drop-Off Model. Currently, these services in some states can only be billed to Medicaid "incident to" a physician. HHS has given clear and preemptive authority to pharmacists to autonomously order and administer COVID-19 tests under the current PREP Act declaration. Thus, it is illogical that some states are preventing pharmacies from directly billing Medicaid when a pharmacist administers a COVID-19 test to a Medicaid beneficiary. Pharmacies should be paid when pharmacists administer COVID-19 tests, and states should remove any requirements for pharmacists to bill "incident to a physician," which is an unnecessary requirement into this model.

² See NCPDP Emergency Preparedness Guidance Version 1.8, Section 10.3, P. 42, Sept. 2020, available at <https://www.ncpdp.org/Resources.aspx> (last accessed Nov. 18, 2020).



Recommendation 3: State Health Department COVID-19 Vaccine Plans

Operational Alignment – Secretaries of Health/Departments of Health should revise their state COVID-19 vaccine plans to be aligned with the federal/national strategy and refrain from creating state-specific provider enrollment, operational, or other requirements that could impede their state from efficiently and safely vaccinating their populations. Upon close review of the interim state COVID-19 vaccine plans, NACDS is concerned that significant deviations from the national/federal strategy at the state level, via the state COVID-19 vaccination plans, may lead to preventable inefficiencies. Such variations and inefficiencies could make it difficult for private sector partners, including chain pharmacies, to partner with states and support their initiatives to efficiently and safely vaccinate Americans. The most common and burdensome requirements noted across state plans (**See Attachment B: State-by-State Plan Analysis**) include: (a) use of enrollment portals, surveys, MOUs, and other prerequisites to enroll for appropriate allocation and distribution of the vaccine product; (b) non-alignment with recent PREP Act guidance and advisory opinions that preempt state law such as restrictive age administration requirements; and (c) state-specific efforts to recreate guidelines for equitable vaccine distribution or additional review of vaccines, conflicting with federal/national-established, trusted efforts to do so appropriately and safely.

Summary

As the nation continues to identify and implement the necessary measures to protect Americans and improve overall public health during this global pandemic, pharmacies stand ready to support states' efforts to ensure comprehensive, efficient, and equitable COVID-19 vaccine access. However, in order to do so sustainably, states should address COVID-19 vaccine coverage, billing, and enrollment challenges that have the potential to impede access to care. Further, distributing and administering COVID-19 vaccines to Americans in a timely, efficient, and safe manner is an unprecedented undertaking that requires strong public-private partnership and cooperation across stakeholders. In support of state and federal planning of this distribution, pharmacies are poised to leverage their existing systems and expertise to vaccinate priority populations swiftly and safely, including medically underserved and rural areas, throughout the nation. NACDS appreciates NGA's, governors, and their state executive team's consideration of our recommendations aimed to improve efficient, accessible, and safe access to COVID-19 countermeasures across states. To discuss this matter further, please contact NACDS' Kathleen Jaeger (kjaeger@nacds.org).

Sincerely,

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

cc:

NGA Chair Gov Andrew Cuomo (NY) – gov.cuomo@chamber.state.ny.us
NGA Vice Chair Asa Hutchinson (AR) – info@governor.arkansas.gov

Opportunities for Enhanced Pharmacy Engagement within State COVID-19 Vaccine Allocation Plans

- ❖ **Enrollment Forms, Surveys & Portals-** *Extraneous requirements for healthcare professionals to be recognized as COVID-19 vaccine providers are administratively burdensome and delay the delivery of quality patient care.*

State Action:

- Utilize the CDC COVID-19 Provider Agreement as the sole requirement to onboard pharmacies as providers.
- Eliminate additional requirements outside of those stated within the federal agreement form.

- ❖ **Prerequisite: Vaccines for Children (VFC) Program-** *Prerequisites requiring COVID-19 vaccine providers to be existing VFC Program providers limits provider enrollment.*

State Action:

- Utilize the CDC COVID-19 Provider Agreement as the sole requirement to onboard pharmacies as providers.
- Eliminate additional requirements outside of those stated within the federal agreement form.

- ❖ **Extraneous Freezer/Storage Specifications-** *Additional cold chain and storage and handling provisions, such as requiring additional documentation (i.e. specific make/model of storage units, certification, photographs) outside of the CDC toolkit, are unnecessary and burdensome.*

State Action:

- Adhere to CDC's Vaccine Storage and Handling Toolkit.
- Utilize the CDC COVID-19 Provider Agreement as the sole requirement to onboard pharmacies.
- Remove state-specific storage and handling requirements not mandated within the CDC Toolkit or the COVID-19 Provider Agreement.

- ❖ **Inventory Reporting Requirements-** *Providers reporting inventory to various platforms proves to be administratively burdensome and duplicative, especially for multi-jurisdictional vaccine providers, like pharmacies.*

State Action:

- Follow CDC-published guidance detailing the necessary requirements for vaccine providers to accurately and efficiently report COVID-19 vaccine inventory.
- Eliminate additional requirements requiring vaccine providers to report to various entities and platforms

- ❖ **Indirect Shipment of Vaccine-** *Redistribution of the COVID-19 vaccine outside of the federal-mandated process could potentially impact vaccine integrity, effectiveness, and the delivery of quality vaccination services.*

State Action:

- Utilize the CDC COVID-19 Provider Agreement as the sole requirement. The provider agreement sets up pharmacies to receive direct allocation of COVID-19 vaccines from the private sector channel.
- Complete the additional CDC form that relates to redistribution of vaccine, if needed.
- Refrain from redistributing vaccine directly to pharmacy store locations and adhere to federal processes.

- ❖ **QR Code to access EUA and VIS fact sheets-** *QR codes require certain tools that not all healthcare settings currently utilize. States requiring additional tools/ devices outside of the provider agreement is costly and unnecessary.*

State Action:

- Comply with the requirements detailed within the CDC COVID-19 provider agreement regarding patient safety and sharing vaccine information.
- Limit the inclusion of additional requirements beyond those already set in the provider agreement.

- ❖ **Education requirements-** *Additional education requirements such as trainings/ certifications external to the requirements put forth by the federal government delays the provider enrollment process.*

State Action:

- Adhere to federal guidance which adequately details sufficient training requirements to safely and effectively administer COVID-19 vaccine.
- Remove additional education training requirements (i.e. trainings and certifications) outside of educational requirements issued by the federal government.

- ❖ **Vaccination of children:** *Existing age restrictions for COVID-19 vaccine administration, especially in light of the recent the Department of Health and Human Services (HHS) advisory guidance for pharmacist immunization authority, limits convenient access to vaccine services for a large portion of the population.*

State Action:

- Adopt national strategies for equitable vaccine prioritization and vaccine administration authority as determined by the federal government.
- Fully leverage all qualified healthcare vaccination providers with the ability to administer the forthcoming COVID-19, such as pharmacists, to safely and effectively vaccinate all populations.

- ❖ **Vaccine Prioritization:** *State-specific workgroups/ advisory boards implementing additional recommendations delays distribution of COVID-19 vaccine supply and limits states from leveraging qualified state vaccine providers to expand access to a vital healthcare service.*

State Action:

- Eliminate existing, or the creation of, state-specific workgroups and advisory boards regarding the determination of vaccine prioritization and administration.
- Adopt national strategies for equitable vaccine prioritization and vaccine administration authority as determined by the federal government.
- Fully leverage all qualified healthcare vaccination providers with the ability to administer the forthcoming COVID-19, such as pharmacists, to safely and effectively vaccinate all populations.



NACDS' Summary of CMS' COVID-19 Vaccinations and Medicaid Toolkit

Updated 11-24-2020

On Monday, Nov. 23rd CMS released its [Toolkit](#) on Coverage and Reimbursement of COVID-19 Vaccines, Vaccine Administration, and Cost Sharing under Medicaid, the Children's Health Insurance Program, and Basic Health Program. NACDS has prepared this high-level summary of the toolkit. NACDS continues to evaluate this toolkit and will update this summary as appropriate.

COVID-19 Vaccinations:

- Provider Enrollment:
 - P. 27-28: "Some states enroll pharmacies as Medicaid or CHIP providers, but do not provide a pathway to enrollment for individual pharmacists, pharmacy interns, or pharmacy technicians. These states need not begin to enroll pharmacists, pharmacy interns, or pharmacy technicians in order to provide Medicaid or CHIP coverage and reimbursement for COVID-19 vaccinations ordered or administered by these individuals consistently with the HHS COVID-19 PREP Act declaration and authorizations. ***Instead, such a state may reimburse the enrolled pharmacy as the furnishing provider.***"
- Coverage:
 - P. 22: "***States must ensure that all services covered under the Medicaid and CHIP state plans are available and accessible to enrollees of managed care plans in a timely manner, including the administration of covered vaccines in accordance with section 6008(b)(4) of the FFCRA*** (see 42 CFR §§ 438.206(a) and 457.1230(a)). Therefore, states that utilize a managed care delivery system may elect to include vaccine administration coverage in their managed care plan contracts and capitation rates."
 - P. 22: "Alternatively, states may also elect to provide vaccine administration coverage and payment under their Medicaid and CHIP fee-for-service programs, and carve the vaccine benefit out of the managed care program and contracts."
- Preemption of Certain State/Federal Requirements:
 - P. 28: "Various federal Medicaid and CHIP statutes and regulations expressly refer to state licensure or scope of practice laws. In particular, several CMS regulations governing Medicaid and CHIP benefits that states could use to cover COVID-19 vaccinations require that services be prescribed, furnished, recommended, or provided by practitioners acting within the scope of their practice as defined by state law. See 42 C.F.R. §§ 440.60 and 440.130(c), and 42 C.F.R. § 457.402(x). CMS interprets references to state law in federal Medicaid and CHIP laws and regulations as incorporating the PREP Act preemption of state law."
 - P. 29: "***Accordingly, CMS expects all state Medicaid programs subject to FFCRA section 6008(b)(4), including in states where a state law governing pharmacy, pharmacist, pharmacy intern, or pharmacy technician scope of practice is preempted by the HHS COVID PREP Act declaration and authorizations, to identify a pathway to reimbursing pharmacies and/or pharmacists for COVID-19 vaccinations ordered and administered by pharmacists, or administered by pharmacy interns and pharmacy technicians, in a manner that is consistent***"

with the HHS COVID-19 PREP Act declaration and authorizations issued pursuant to the declaration.”

- P. 29: “The same expectations do not apply, however, to separate CHIPs...” but “**states operating separate CHIPs may not deny CHIP reimbursement for a covered COVID-19 vaccination to a pharmacy or pharmacist** on the basis that the pharmacy, pharmacist, pharmacy intern, or pharmacy technician is not licensed or authorized under state law to provide a COVID-19 vaccination.”

- Billing Pathways:

- P. 11: “States are strongly encouraged to use a uniform billing standard for vaccine claims (e.g., **the National Council for Prescription Drug Programs (NCPDP) standard for pharmacy billings**).”
- P. 12: “States should also consider whether their billing manuals appropriately reflect policies to streamline and facilitate vaccine administration (e.g., through roster billing).”

- Reimbursement:

- P. 11: “States have significant discretion in determining vaccine administration reimbursement rates that are paid to qualified providers that have a provider agreement with the Medicaid agency.”
- P. 11: “States should review their payment policies for vaccine administration reimbursement to determine if the rates are sufficient and if they are accurately reflected in the Medicaid state plan, provider materials and published fee schedules.”
- P. 22: “If states utilize a managed care delivery system, as with all covered benefits in a managed care plan contract, **Medicaid capitation rates must be developed to include all reasonable, appropriate, and attainable costs that are required under the terms of the contract, as specified in 42 CFR § 438.4(a)**.”

- Other Re Medicaid Managed Care:

- P. 22: “To ensure that beneficiaries enrolled in managed care plans have easy and prompt access to a COVID-19 vaccine, states are strongly encouraged to consider whether any contractual requirements under § 438.214(b)(1) on their managed care plans for credentialing and network contracting should be amended.”
- P. 22: Further managed care entities are encouraged to “suspend limits on out-of-network coverage for managed care enrollees to specifically improve access to COVID-19 vaccines.”

Vaccines for Children: P. 15 “[W]hen a pediatric COVID-19 vaccine becomes available, CDC will determine whether to distribute COVID-19 vaccine(s) outside of the VFC program.”

State Plans for COVID-19 Vaccine Allocation: Pharmacy Engagement Opportunities

Chain pharmacies strongly value their strong partnership with jurisdictions, especially as the nation works together to distribute and administer COVID-19 vaccines to priority populations and the public. In reviewing the interim draft state plans for COVID-19 vaccine allocation,¹ many acknowledge that chain pharmacies must be leveraged to improve vaccine access, such as Michigan noting pharmacies are “strong vaccination partners.” However, the extent to which pharmacies are currently folded into existing plans varies. States are continuously updating their plans as new information becomes available, and as such, NACDS has identified opportunities to realign portions of state plans to support improved engagement, participation, and partnership among jurisdictions and chain pharmacies. NACDS welcomes the opportunity to seek resolution directly with jurisdictions, public health associations, and the Centers for Disease Control and Prevention.

Barriers to Enroll as COVID-19 Pharmacy Vaccine Providers **Issue identified in state through means other than state plan.*

Issue	States	Explanation and Proposed Solution
Enrollment Forms, Surveys & Portals	GA, ID, IL, LA, MD, ME, MN, MT, NC*, ND, NV, NY, OH, OK, SC, SD, TN, TX ² , UT, VA, WA, WY Example: Utah’s state plan says, “All facilities are required to enroll satellite locations individually.” <i>*Issue identified in state through means other than state plan.</i>	<ul style="list-style-type: none"> The CDC COVID-19 provider agreement is the tool states should be using to enroll any COVID providers, including pharmacies. No amendments, additions, or other modifications should be made to this CDC agreement. However, some state plans refer to other mandatory, new MOUs, surveys, or other tools beyond this CDC agreement. Such requirements are duplicative and may not be feasible for companies with multiple locations to complete.
Prerequisite: Vaccines for Children (VFC) Program	NE Example: Nebraska’s state plan requires Phase 1 Providers to be current VFC Program providers who meet VFC requirements such as training, storage / temperature requirements, site visits, and inventory management.	<ul style="list-style-type: none"> The CDC COVID-19 provider agreement should be the sole requirement to onboard pharmacies as providers. VFC Program enrollment is separate and distinct from COVID-19 enrollment, and as such, should not be used as a prerequisite for COVID-19 provider enrollment.

¹ 46 of the 50 state plans are publicly available online either in full-text or executive summary.

² <https://www.dshs.texas.gov/coronavirus/immunize/provider-information.aspx>

<p>Extraneous Freezer/Storage Specifications</p>	<p>AR, CA, GA, ID, IA, MO, MT, OH, OK, OR, SC, TX*, UT, VT, WA, WV</p> <p>Example: “All COVID-19 vaccination provider sites will be required to complete a Vaccine Storage Agreement as part of the COVID-19 Vaccination Provider enrollment process. (WV)”</p> <p>On-the-Ground Example: Texas suspended COVID-19 pharmacy enrollment for pharmacies citing specific requirements for refrigeration control data loggers. Further, Texas and Georgia have used VFC Program refrigerator calibration certification requirements, which is inefficient and unnecessary.</p> <p><i>*Issue identified in state through means other than state plan.</i></p>	<ul style="list-style-type: none"> • The CDC COVID-19 provider agreement includes provisions for maintaining cold chain and adhering to CDC’s Vaccine Storage and Handling Toolkit. Jurisdictions should use the CDC agreement as the sole requirement to onboard pharmacies. • Any extraneous storage specifications, such as a specific make or model of storage unit or additional paperwork/administrative burdens related to storage, such as surveys, are unnecessary and will impede provider enrollment, including pharmacies. • COVID-19 vaccines undoubtedly pose unique storage considerations, and pharmacies will carefully implement and monitor proper vaccine storage using high quality equipment to ensure viability of vaccines provided to the public.
<p>Inventory Reporting Requirements</p>	<p>ME, PA*, VA*, VT</p> <p>Example: Vermont’s state plan requires, “Sites managing COVID-19 vaccines will run inventory management reports each morning and before each vaccine order to avoid waste and ensure the vaccine supply remains viable.”</p> <p><i>*Issue identified in state through means other than state plan.</i></p>	<ul style="list-style-type: none"> • CDC has published standardized guidance detailing the necessary requirements for vaccine providers to accurately and efficiently report COVID-19 vaccine inventory. • Requiring COVID-19 vaccine providers to report vaccine inventory to various entities is administratively burdensome and state strategy should be in alignment with federal guidance.
<p>Indirect Shipment of Vaccine</p>	<p>MI, ND</p> <p>Example: Michigan’s plan states that, “local health departments will distribute to pharmacies who have not received direct distribution from CDC.”</p>	<ul style="list-style-type: none"> • The CDC COVID-19 provider agreement sets up pharmacies to receive direct allocation of COVID-19 vaccines from the private sector channel. • Separately, there is an additional CDC form that relates to redistribution of vaccine. • Especially given the cold chain concerns for COVID-19 vaccines, state/local jurisdictions should not redistribute vaccine to pharmacy store locations and instead should use federal agreements/forms for guidance on this issue.

QR Code to access EUA and VIS fact sheets	MO, WV Example: West Virginia’s plan states that QR codes must be used to access EUA fact sheets for vaccine recipients.	<ul style="list-style-type: none"> The CDC COVID-19 provider agreement includes ample requirements for patient safety and sharing vaccine information. States should not create additional or different requirements beyond those already set in the provider agreement.
---	--	--

Incongruence with Intent of PREP Act Amendments and/or Guidance

Issue	States	Pharmacy Barrier to Vaccination Participation
Education requirements	AK, KS, KY Example: Alaska’s plan states that COVID-19 providers, “will be required to complete an Emergency Use Authorization (EUA) fact sheet/VIS training.”	<ul style="list-style-type: none"> States should not specify or require extraneous education requirements. The U.S. Department of Health and Human Services (HHS) has issued guidance that authorizes pharmacists, pharmacy interns, and pharmacy technicians to provide COVID-19 vaccines to people 3 years and older. Training requirements are a component of this guidance.
Vaccination of children	OK, VT Example: Oklahoma plan states, if vaccinating children, will utilize providers already enrolled in VFC Program. Vermont states, pharmacies in Phase 2 will focus on 18 years and older.	<ul style="list-style-type: none"> States should utilize the expanded authority of pharmacists, pharmacy interns, and pharmacy technicians to vaccinate children age 3+ under the PREP Act. Further, states should not bar pharmacy participation by requiring enrollment in the VFC Program.

Vaccine Prioritization Misaligned with National Strategy

Issue	States	Pharmacy Barrier to Vaccination Participation
Vaccine Prioritization	KY, MO, OK, TX, UT, VT, WV, WY Example: Wyoming’s plan states their Medical Ethics Committee is compiling recommendations for prioritization of subgroups within each critical population.	<ul style="list-style-type: none"> States should adopt the national strategy for equitable vaccine prioritization, to be put forth by ACIP. States may apply the national strategy to meet their local needs; however, any divergence from national guidelines will create operational challenges for vaccinators, especially those operating across multiple states.