



June 29, 2020

Robert P. Charrow
General Counsel
Office of the General Counsel
U.S. Department of Health and Human Services
200 Independence Ave., S.W., Room 713-F
Washington, D.C. 20201

Re: Authorization for Licensed Pharmacists to Order and Administer COVID-19 Vaccines under the PREP Act

Dear Mr. Charrow:

As organizations representing pharmacists and pharmacies, we are proud of the crucial efforts that our members have undertaken to help our nation respond to the COVID-19 pandemic by providing patients access to tests for the COVID-19 virus. The Department of Health and Human Services (“HHS”) helped expand the availability of COVID-19 tests on April 8, 2020, when HHS issued official guidance declaring that licensed pharmacists are authorized under the Public Readiness and Emergency Preparedness (“PREP”) Act to order and administer FDA-authorized COVID-19 tests.¹ HHS further clarified the ability of pharmacists to respond to the current public health emergency on May 19, 2020, when the HHS Office of the General Counsel issued an Advisory Opinion explaining that the PREP Act preempts any state or local requirement that prohibits or effectively prohibits a pharmacist from ordering and administering FDA-authorized tests for COVID-19.²

To further help America rapidly recover from the pandemic, we ask HHS to issue a similar PREP Act declaration authorizing pharmacists to provide COVID-19 vaccines to their patients.

¹ Office of the Assistant Secretary, “Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act,” (April 8, 2020), available at: <https://www.hhs.gov/sites/default/files/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf>

² Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary’s Declaration under the Act. May 19, 2020, available at: <https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf>

Specifically, we ask HHS to declare under the PREP Act that licensed pharmacists are authorized to order and administer all COVID-19 vaccines that the Food and Drug Administration (“FDA”) authorize or approve to prevent the COVID-19 virus. To avoid confusion and assure rapid patient access to COVID-19 vaccines, we ask HHS to specify that the requested PREP Act declaration preempts state and local requirements that prohibit or effectively prohibit pharmacists from ordering and administering FDA-authorized or approved COVID-19 vaccines to meet the needs of their communities.

More than 360,000 pharmacists have been trained to administer vaccines and are integral members of the “immunization neighborhood.” To successfully achieve our nation’s COVID-19 and routine vaccination goals, providing protection against vaccine preventable diseases will take collaboration, coordination, and communication among all stakeholders. As demonstrated during the 2009 H1N1 pandemic, and even more broadly over the last decade, removing barriers to pharmacy-based immunization meaningfully improves vaccine uptake.³ Therefore, we urge HHS to leverage the clinical expertise, knowledge, and accessibility of pharmacists by proactively removing state barriers to patient access, across the lifespan, to COVID-19 vaccines. Given the success to date of pharmacists administering vaccines, serving as knowledgeable and accessible immunization providers within their communities and their collaboration with public health and other providers, a successful vaccination plan must actively involve pharmacists. An all-hands-on-deck approach will be needed. With the right resources, pharmacists will dramatically expand access to COVID-19 vaccinations and rapidly advance our nation’s immunization program.

During this pandemic, pharmacists have been on the front lines every day serving our patients as healthcare professionals deemed critical to societal continuity. Pharmacists are the most accessible health care providers with close to 90% of the U.S. population living within 5 miles of a pharmacy,⁴ and patients do not usually require an appointment to see their pharmacist. In fact, for many underserved Americans, pharmacists are the only health professional they can readily access. Many pharmacists offer immediate care that is close and convenient to home and are a bridge between our communities and other providers, triaging medication and health needs, recommending needed vaccinations, and both administering those vaccines or referring patients for further follow-up. Additionally, with stay at home directives causing regular vaccinations to lapse during the height of the pandemic, pharmacists can and will play a key role in the catch-up effort.

On May 28, 2020 the Centers for Disease Control and Prevention (“CDC”) issued updated guidance stating “[a]s a vital part of the healthcare system, pharmacies play an important role in

³ Drozd EM, Miller L, et al. Impact of Pharmacist Immunization Authority on Seasonal Influenza Immunization Rates across States. Aug 2017. Clinical Therapeutics. doi: 10.1016/j.clinthera.2017.07.004

Patel AR, et al. The impact of pharmacy-based immunization services on the likelihood of immunization in the United States. Journal of the American Pharmacists Association. 2018. [https://www.japha.org/article/S1544-3191\(18\)30231-0/pdf](https://www.japha.org/article/S1544-3191(18)30231-0/pdf)

Goad JA, Taitel MS, Fensterheim LE, Cannon AE. Vaccinations administered during off-clinic hours at a national community pharmacy: implications for increasing patient access and convenience. Ann Fam Med. 2013;11(5):429-436. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3767711/>

Isenor JE, et al, "Impact of pharmacists as immunizers on vaccination rates: A systematic review and meta-analysis." Vaccine 34(47), 5708-5723 10/11/16, available at: <https://doi.org/10.1016/j.vaccine.2016.08.085>

⁴ NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.

providing medicines, therapeutics, vaccines, and critical health services to the public.”⁵ Pharmacists administer influenza and other vaccines in accordance with the CDC’s Advisory Committee on Immunization Practices (“ACIP”) recommendations, as authorized by state laws and regulations.

Pharmacists are playing an increasingly critical role in increasing influenza-vaccination rates across the United States with more than 25% of annual influenza vaccinations administered within pharmacies and more than 50% of shingles vaccines administered by pharmacists. As a result, an additional 4.1 million additional adults were vaccinated in 2013 because states allowed pharmacists to administer the flu vaccine, which resulted in between 81,000-134,000 fewer influenza infections among adults in that year, depending on vaccine effectiveness. Additionally, the odds that an adult would receive the flu shot increased by 7.8 percent in states that allowed pharmacists to be immunizers.⁶ Importantly, another pivotal CDC pandemic influenza vaccine study showed that weekly national vaccine administration capacity increased to 25 million doses per week, and the time to achieve 80 percent vaccination coverage nationally was reduced by seven weeks, when retail pharmacist vaccination capacity was included in the response.⁷ Pharmacists can play a similarly critical role in accelerating the nation’s recovery. To do so, however, we need HHS’ help in removing state barriers to pharmacists’ provision of COVID-19 vaccines.

Every state allows pharmacists to administer vaccinations to their patients at varying degrees,⁸ which is indicative of states’ recognition that pharmacists are qualified to safely and effectively administer vaccines.⁹ However, many states impose barriers that impede the ability of pharmacists to defeat the pandemic by broadly and rapidly vaccinating their patients when a vaccine becomes available. Our national effort to stop the pandemic cannot wait while states go through the lengthy process of amending their laws or rules to list new COVID-19 vaccines. Some states prevent pharmacists (but not other providers) from vaccinating certain age groups, even when vaccines have been included in ACIP vaccine recommendations and schedule, or are FDA approved or authorized. While every state allows pharmacists to administer flu, pneumococcal, and herpes zoster vaccines to adults, most states have age or other restrictions in place. Only a handful of states with modernized policies allow pharmacists to independently administer (no prescription or protocol needed) any type of vaccine to people of all ages. Additionally, the restrictions in place in other states follow no pattern. For example,

⁵ CDC. Guidance for Pharmacies. Guidance for Pharmacists and Pharmacy Technicians in Community Pharmacies during the COVID-19 Response. May 28, 2020, available at: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/pharmacies.html>

⁶ Drozd EM, Miller L, Johnsrud M. Impact of Pharmacist Immunization Authority on Seasonal Influenza Immunization Rates Across States. Clin Ther. 2017 Aug 3. pii: S0149-2918(17)30771-3, available at: <https://www.ncbi.nlm.nih.gov/pubmed/28781217>

⁷ Schwerzmann J, Graitcer SB, Jester B, Krahl D, Jernigan D, Bridges CB, Miller J. Evaluating the Impact of Pharmacies on Pandemic Influenza Vaccine Administration. Disaster Med Public Health Prep. 2017 Oct;11(5):587-593, available at: <https://www.ncbi.nlm.nih.gov/pubmed/28219461>

⁸ Cason D., Schmit, JD, et al., Expanding State Laws and a Growing Role for Pharmacists in Vaccination Services, (published online Aug. 12, 2017), available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5704925/>.

⁹ The federal government agrees. For years, pharmacists have served as Medicare “mass immunizers,” administering vaccines to millions of Medicare patients. See Medicare Learning Network, Roster Billing for Mass Immunizers (2019), available at: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Mass_Immunize_Roster_Bill_factsheet_ICN907275.pdf

pharmacists in Virginia can independently administer influenza vaccinations for individuals six months and older, whereas pharmacists in Montana are authorized to immunize those at least 12 years of age for the same vaccine. Utah and the District of Columbia have a very similar regulatory process for approving a list of vaccines pharmacists can administer, but pharmacists in Utah are allowed to administer a much broader range of vaccines than pharmacists in DC – even though their training is the same. And, in Wisconsin, pharmacists can independently order and administer any ACIP-recommended vaccine to patients at least 6 years of age, but a prescription order is required for immunization of children under 6 years old, while in New Mexico, there is no age limit.

Widespread vaccination of the populace will be key to defeating the pandemic, so pharmacists should be authorized to vaccinate all age groups with vaccines approved or authorized by the FDA for COVID-19 consistent with the FDA labeling or other instructions for use for such vaccines. In addition, several states do not allow pharmacists to order a clinically appropriate vaccination, but instead require a prescription from another healthcare provider or other permissive authority by the state.¹⁰ No diagnosis is needed for a vaccination, so this barrier to pharmacist vaccinations needlessly requires many patients across the country to work with multiple healthcare providers to obtain clinically appropriate vaccinations. Pharmacists are trained and able to follow and implement CDC immunization guidelines, and associated activities including patient vaccine assessment, recommendation, administration, referral and documentation.

In the HHS guidance and Advisory Opinion on testing, HHS appropriately determined that pharmacists qualify as “covered persons” (and thus, “qualified persons”) under the PREP Act.¹¹ This qualification is significant because the PREP Act’s liability immunity applies to covered persons with respect to administration or use of a “covered countermeasure.”¹² Importantly, HHS has determined that covered countermeasures include “any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.”¹³ Therefore, vaccines for COVID-19 clearly qualify as covered countermeasures under the PREP Act. We ask HHS to issue a new declaration stating that under the PREP Act licensed pharmacists are covered persons who are authorized to order and administer covered countermeasures beyond COVID-19 tests, including COVID-19 vaccines, when available.

Furthermore, as HHS recognized in Advisory Opinion, the PREP Act (and subsequent federal declarations made thereunder) preempt any state or local requirement that prohibits or effectively

¹⁰ Expanding State Laws and a Growing Role for Pharmacists in Vaccination Services, *available at* <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5704925/>.

¹¹ 42 U.S.C. § 247d-6d(a)(1).

¹² Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary’s Declaration under the Act. May 19, 2020, *available at*: <https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf>.

¹³ See 85 Fed. Reg. 15, 198, 15, 202; *see also* 42 U.S.C. § 247d-6d(i)(1) and (7).

prohibits a pharmacist from ordering and administering COVID-19 tests.¹⁴ It follows, therefore, that the PREP Act also preempts any state or local requirement that prohibits or effectively prohibits a pharmacist from ordering and administering COVID-19 vaccines. To help remove state barriers to COVID-19 vaccines, we ask HHS to specify that such barriers are preempted.

It is crucial that states have a full and complete understanding of the PREP Act's impact on state and local laws. While the Advisory Opinion regarding testing was meant to enable the expansion of pharmacists' ordering and administering FDA-authorized tests for COVID-19, we have received feedback that the Advisory Opinion alone has not been sufficient to force states to remove barriers (state laws, regulations, etc.). Accordingly, we encourage HHS to work directly with the states to ensure that pharmacists are able to order and administer COVID-19 tests and vaccines in accordance with the federal guidance and Advisory Opinion.

Pharmacists stand ready and able to help prevent the spread of COVID-19. We look forward to receiving specific clarification from HHS that pharmacists are authorized under the PREP Act to order and administer FDA authorized or approved COVID-19 vaccines. To avoid misunderstandings by state and local regulators and resulting delays, we ask HHS to specify that its declaration under the PREP Act preempts any state or local requirement that prohibits or effectively prohibits a pharmacist from ordering and administering a COVID-19 vaccine that the FDA has authorized or approved. If you have any questions, or if we can be of any assistance, please do not hesitate to contact us via Don L. Bell, II, JD, Senior Vice President, Health Policy & General Counsel, National Association of Chain Drug Stores (NACDS) at dbell@nacds.org or Ilisa BG Bernstein, PharmD, JD, FAPhA, Senior Vice President, Pharmacy Practice and Government Affairs, American Pharmacists Association (APhA) at ibernstein@aphanet.org.

Sincerely,

American Association of Colleges of Pharmacy (AACCP)
American College of Clinical Pharmacy (ACCP)
Accreditation Council for Pharmacy Education (ACPE)
Academy of Managed Care Pharmacists (AMCP)
American Pharmacists Association (APhA)
American Society of Consultant Pharmacists (ASCP)
American Society of Health-System Pharmacists (ASHP)
College of Psychiatric and Neurologic Pharmacists (CPNP)
Hematology/Oncology Pharmacy Association (HOPA)
National Association of Chain Drug Stores (NACDS)
National Alliance of State Pharmacy Associations (NASPA)
National Community Pharmacists Association (NCPA)
National Pharmaceutical Association (NPhA)

cc: William Chang, HHS Deputy General Counsel
ADM Brett P. Giroir, M.D., HHS Assistant Secretary for Health

¹⁴ 42 U.S.C. § 247d-6d(b)(8)(A); *see also* Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020, available at <https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf>.