























September 4, 2020

Dr. William H. Foege, Co-Chair
Dr. Helene D. Gayle, Co-Chair
Committee on Equitable Allocation of Vaccine for the Novel Coronavirus
National Academies of Science, Engineering and Medicine (NASEM)
500 Fifth St., N.W.
Washington, D.C. 20001

Re: Public Listening Session: Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine

Dear Co-Chairs Drs. Foege and Gayle:

Our organizations are pleased to submit these comments on the "<u>Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine</u>," (Framework) to optimize the utilization of pharmacists and pharmacies in order to not only prepare, but meet the needs for equitable mass distribution and immunization administration of the COVID-19 vaccine(s).

Pharmacies and pharmacists in all practice settings are essential front-line health care providers and have been providing COVID-19 and related patient care since the coronavirus first appeared in the United States. We are proud of the tremendous critical efforts that our members have undertaken to help our nation respond to the pandemic. Collectively, our pharmacist members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities.

Given the clear accessibility and success to date of pharmacists administering all types of vaccines to vulnerable and underserved populations, serving as knowledgeable and accessible immunization providers within their communities, as well as their collaboration with public health and other providers, a successful vaccination distribution plan for the equitable allocation of COVID-19 vaccine(s) *must involve all licensed pharmacists and pharmacies*. An all-hands-on-deck approach will be needed.

As the Committee considers the Framework, we urge you to include the following recommendations for allocation and distribution of the COVID-19 vaccine:

- 1) Allocation prioritization must include pharmacists in all practice settings in Tier 1 since they are front-line health care providers and essential to community protection and continuity of care,
- 2) Allocation and distribution must include ALL pharmacies, as they are highly accessible immunization points in the community and serve individuals and populations at risk of COVID-19, and
- 3) Recommend funding to pharmacies and pharmacists for community-based education and outreach programs supporting recommended vaccines.
- 1. First tier of vaccine recipients: Allocation prioritization must include pharmacists in all practice settings in Tier 1 since they are front-line health care providers and are essential to community protection and continuity of care.
 - During the COVID-19 pandemic, pharmacists have continued to fight on the frontlines to meet patients' medication and health care needs. Pharmacists have been:
 - ensuring medication access and availability to support continuous adherence to therapeutic regimens,
 - > expanding the availability of COVID-19 tests, and administering vaccines to protect adolescents and adults from vaccine preventable diseases, including the flu.
 - > providing evidence-based information to other health care providers and patients on medications for COVID-19 treatment and symptomatic support,
 - delivering in-person and telehealth services to patients with chronic conditions in collaboration with other providers, and
 - > compounding drugs to mitigate and prevent shortages.
 - These essential public health protection efforts provided by pharmacists are critical to advancing the overall health of our nation and ensuring those who support critical infrastructure remain healthy to do their jobs and keep the country open and productive.
 - Pharmacists provide direct patient care on a daily basis as health care providers and will be key immunizers for persons at high risk of transmission in patient care settings and in the community.
 - The Framework identifies "clinicians," and "other workers in health care settings who meet the Phase 1a risk criteria." Pharmacists meet 3 of the 4 risk criteria, including: Criterion 1: Risk of Acquiring Infection; Criterion 3: Risk of Negative Societal Impact; and Criterion 4: Risk of Transmitting Infection to Others. Therefore, pharmacists fall in Tier 1, not Tier 2.
 - The Committee asked how to identify "occupations at higher risk (e.g., health care workers)," in determining the first wave of vaccine recipients. The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) COVID-19 Vaccine Work Group recommends that four groups of

people get first access to a COVID-19 vaccine: health care personnel, essential workers, people with medical conditions or diseases that make them high risk for contracting the virus, and people older than 65 years old and specifically lists "pharmacies" in its definition of health care personnel.¹

- Community pharmacists serve as direct points of health care access for their patients. For many underserved Americans (including priority recipients and minority groups at higher risk), 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 and administering life-saving vaccines or referring patients for further follow-up. This supports the key role community pharmacists and pharmacies should have in ensuring patients' access under an equitable allocation of the COVID-19 vaccine(s).
- Pharmacists are also stepping up to tackle some of the most daunting challenges of this pandemic, including shortages of health care staff and burnout of health care professionals.
- HHS recognizes the important role that pharmacists play in maintaining the country's economic, educational, and health and safety efforts by authorizing pharmacists to order and administer COVID-19 tests² and childhood vaccines,³ and recognizes pharmacies as points of care for tests,⁴ which has enhanced the position of community pharmacies as primary access points for high priority patients to receive COVID-19 preventive services.

RECOMMENDATION: To ensure that pharmacists continue to provide critical care to patients, including administration of COVID-19 vaccine, the Framework must recognize pharmacists in all practice settings in Tier 1 as essential front-line health care providers for priority vaccine administration.

¹ Dooley, Kathleen. ACIP COVID-19 Vaccines Work Group. COVID-19 vaccine prioritization: Work Group considerations. August 26, 2020, available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-08/COVID-08-Dooling.pdf

² 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-licensedpharmacists-to-order-and-administer-covid-19-tests.pdf

³ HHS. Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19. August 19, 2020, available at: https://www.hhs.gov/sites/default/files/third-amendment-declaration.pdf

⁴ FDA. FAQs on Diagnostic Testing for SARS-CoV-2. Content current as of: 09/2/020, available at: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2

- 2. Equity in allocation of the vaccine: Allocation and distribution must include ALL pharmacies, as they are highly accessible immunization points in the community.
 - Pharmacists are the most accessible health care providers with close to 90% of the U.S. population living within 5 miles of a pharmacy,⁵ including many underserved areas. In addition, patients do not need an appointment to see their pharmacist and these practice sites have extended hours. As noted above, pharmacies are direct points of health care access for many patients across the country.
 - Every state authorizes pharmacists to administer vaccinations to their patients, ⁶ which is indicative of states' recognition that pharmacists are highly qualified to administer vaccines safely and effectively to all populations. ⁷
 - More than 25% of annual influenza vaccinations are administered within pharmacies, and more than 50% of shingles vaccines are 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.⁸
 - The odds that an adult would receive the flu shot increased by 7.8 percent in states that allowed pharmacists to be immunizers. 9
 - A 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 pharmacist vaccination capacity was included in the response. ¹⁰
 - Most recently, HHS has acknowledged the key role of pharmacists in administering vaccinations by authorizing state-licensed pharmacists (and pharmacy interns acting under their supervision to administer vaccines, if the pharmacy intern is licensed or

⁶ 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/

⁵ NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.

⁷ 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-NetworkMLN/MLNProducts/Downloads/Mass Immunize Roster Bill factsheet ICN907275.pdf

⁸ Drozd EM, Miller L, Johnsrud M. Impact of Pharmacist Immunization Authority on Seasonal Influenza Immunization Rates Across States. Clin Ther. Aug;39(8):1563-1580.e17. doi: 10.1016/j.clinthera.2017.07.004. Epub 2017 Aug 7, available at: https://pubmed.ncbi.nlm.nih.gov/28781217/ ⁹ Ibid.

¹⁰ 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):587593, available at: https://www.ncbi.nlm.nih.gov/pubmed/28219461

registered by his or her state board of pharmacy) to order and administer vaccines to individuals ages three through 18 years. ¹¹

- We believe broad access to pharmacists' immunization services for all patient
 populations is fundamental to achieving equitable accessibility to COVID-19
 vaccines to our nation's vulnerable populations as well as all clinically recommended
 vaccines to combat vaccination rates that have plummeted nationally since late March
 when COVID-19 cases started increasing and have continued to increase during the
 pandemic.
- It is also important to note that data shows there are approximately 21,767 independent pharmacies and 22,812 large national chains. ¹² Additional analysis shows that 20.5% of zip codes that have a pharmacy do not have a chain drug store, supporting the case for broad-based utilization of ALL community-based pharmacy practices under an equitable distribution of the COVID-19 vaccine(s).
- Dr. Julie Morito, Executive Vice President at the Robert Wood Johnson Foundation and former Commissioner of Chicago's Department of Health, who led the development of Healthy Chicago 2.0, which focused on achieving health equity by addressing social and structural determinants of health, recommended that this Committee leverage existing public health immunization infrastructure—including pharmacists and pharmacies. Dr. Morito noted that Chicago utilized pharmacists and pharmacies as part of 800 provider sites for distribution of the H1N1 vaccine in traditionally underserved areas as a model to improve health equity and build on public trust. ¹³

RECOMMENDATION: To ensure the equitable allocation of COVID-19 vaccines to priority and other populations, our organizations strongly urge the Committee's report include a primary recommendation that ALL licensed pharmacies are given a priority designation in Federal and State vaccine allocation, distribution, and immunization plans. This should include prioritization of ancillary supplies and access to personal protective equipment (PPE) in the delivery of care to patients and protection of our immunizing workforce.

¹¹ HHS. Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19. August 19, 2020, available at: https://www.hhs.gov/sites/default/files/third-amendment-declaration.pdf

¹² 2019 NCPA Digest, Changing the Pharmacy Payment Model

¹³ See, NASEM. Recording of the Third Committee Meeting Open Session. H1N1 Vaccine Sites, Chicago 2009-2010. August 10, 2020, available at: https://www.nationalacademies.org/event/08-07-2020/committee-on-equitable-allocation-of-vaccine-for-the-novel-coronavirus-committee-meeting-3

- 3. Mitigating vaccine hesitancy, especially among high-priority populations: Recommend funding to pharmacies and pharmacists for community-based education and outreach programs supporting recommended vaccines.
 - Pharmacists consistently rank among the most honest and ethical professionals in the US and are often the primary provider the public turns to for initial health care prevention and assistance, ¹⁴ particularly in underserved areas.
 - Due to the trusting relationships between pharmacists and their patients, pharmacists have ample opportunities to advance public health through immunization advocacy. Pharmacists are an important members of the immunization neighborhood and that trust will be important in addressing vaccine hesitancy for our nation's vulnerable populations—which is an invaluable asset that should be emphasized under the Committee's plan for the equitable distribution of a COVID-19 vaccine(s).
 - Pharmacists can facilitate disease prevention strategies, because many vulnerable populations at higher risk for COVID-19, influenza, and pneumococcal disease visit pharmacies more frequently than any other health care setting.
 - Working with local public health departments, state or national immunization coalitions, and other groups (e.g., state or local parent-teacher, diabetes, heart, lung, or retired persons' associations), pharmacists can promote vaccination among highrisk populations.
 - Newsletters, posters, brochures, and seminars may be used to explain the risk of preventable infections to pharmacy staff, other health care personnel, and patients.
 - CDC is also using new media, such as the #HowIRecommend Vaccination Video Series, provided by APhA President-elect Sandra Leal, PharmD, MPH, FAPhA, CDE and other providers, to offer strategies for health care practitioners to make a strong, effective recommendation to vulnerable populations, and address how health care practitioners can better answer patients' questions, particularly for high-risk groups, their contacts and caregivers.¹⁵

RECOMMENDATION: The Committee should recommend that Federal and State vaccine distribution and immunization plans include a fully-funded component for pharmacists and other accessible health care practitioners to conduct coordinated and consistent community--based-education and outreach campaigns supporting recommended vaccinations. These campaigns should focus on eliminating stigma,

¹⁴ Americans Rate Healthcare Providers High on Honesty, Ethics [news release]. Gallup website. news.gallup.com/poll/200057/americans-rate-healthcare-providers-high-honesty-ethics.aspx. Accessed January 15, 2018.

¹⁵ CDC. Adult #HowIRecommend Vaccination Video Series. National Center for Immunization and Respiratory Diseases. Page last reviewed: August 1, 2019, available at: https://www.cdc.gov/vaccines/howirecommend/adult-vacc-videos.html

addressing vaccine hesitancy, and improving prevention and health outcomes for high priority and vulnerable patient populations.

More than 360,000 pharmacists have been trained to administer vaccines across the lifespan and stand ready and able to meet the health care needs of their patients and communities. To ensure equitable allocation of a COVID-19 vaccine(s), the Committee should 1) recognize pharmacists in all practice settings in Tier 1 as essential front-line health care providers for priority vaccine allocation in the first tier of administration, 2) include a primary recommendation that ALL licensed pharmacies are given a priority designation in Federal and State vaccine allocation, distribution and immunization plans, and 3) recommend a fully-funded component for pharmacists to conduct education and outreach campaigns supporting recommended vaccinations to eliminate stigma, address vaccine hesitancy, and improve prevention and health outcomes for high priority and vulnerable patient populations.

The National Institutes of Health (NIH) and CDC have placed the Committee in an important position to ensure equitable allocation and distribution of a COVID-19 vaccine(s) that will allow health care practitioners to work together to defeat the COVID-19 pandemic and improve public health among our nation's vulnerable populations. Our organizations thank you for performing this valuable service and look forward to continuing to work alongside all of America's heroic healthcare workers to defeat COVID-19. Please contact Michael Baxter at mbaxter@aphanet.org if you need any additional information or would like to meet with our organizations.

Sincerely,

American Pharmacists Association (APhA)

Accreditation Council for Pharmacy Education (ACPE)

American Association of Colleges of Pharmacy (AACP)

American College of Clinical Pharmacy (ACCP)

Academy of Managed Care Pharmacy (AMCP)

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 Alliance of State Pharmacy Associations (NASPA)

National Association of Specialty Pharmacy (NASP)

National Community Pharmacists Association (NCPA)

National Pharmaceutical Association (NPhA)

CC: Dr. Francis Collins, Director, NIH, HHS

Dr. Robert R. Redfield, Director, CDC, HHS

Dr. Robert Kadlec, Assistant Secretary for Preparedness and Response (ASPR), HHS

The Honorable Alex Azar II, Secretary, HHS