

Guiding Principles for Safe and Efficacious COVID-19 Vaccine Development, Distribution, Allocation, and Mass Immunization

The efficient, well-coordinated distribution, allocation, and mass vaccination activities against the novel coronavirus (SARS-CoV-2) will help ensure vaccination is an effective countermeasure to the current pandemic. High COVID-19 vaccination rates with an effective vaccine are essential to mitigating the pandemic now and protecting against future outbreaks.

The Pharmaceutical Supply and Payment Chain Coalition offers the following guiding principles for the safe and efficacious development, distribution, and allocation of a vaccine(s) to achieve coordinated mass vaccination against COVID-19:

- **COVID-19 vaccine development, approval, and post-marketing surveillance must adhere to transparent and scientifically rigorous processes that engender public trust in the safety and efficacy of these products.** The U.S. Food & Drug Administration (FDA) is the global “gold standard” for the safety and efficacy of medical products. In addition to FDA, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) has unparalleled experience and expertise in defining use considerations and guidelines for vaccines so they are used safely and effectively by hundreds of millions of people. Widespread confidence in all licensed or authorized COVID-19 vaccines is critical for individuals to choose to be vaccinated and to overcome vaccine hesitancy. In furtherance of this trust, the FDA should continue to facilitate timely access to vaccine pharmacovigilance data and other relevant safety information as the vaccination process unfolds.
- **Equitable allocation of COVID-19 vaccine is paramount, and priority should be given to achieving the greatest public health impact.** Decision-making about who should be granted priority access to the initial supply of COVID-19 vaccine(s) must be transparent, comprehensive, inclusive, and adhere to the highest possible ethical standards. Timely national dialogue, through multiple forms of community engagement, will encourage public trust in fair vaccine allocation and distribution strategies.
- **Consistent public engagement and clear communication on initial and subsequent prioritization decisions by ACIP will be needed.** Public health officials recognize that initial supply and subsequent availability may be insufficient for the vaccination of all priority groups. Decision-making processes for subsequent prioritization by ACIP must adhere to the same high standards and transparent processes as initial decisions. Vaccine selection and immunization decisions should continue to be made based on updated evidence of vaccine effectiveness, including evidence demonstrating relative effectiveness for specific patient populations (e.g., pediatrics, pregnancy, older adults, patients with complex health conditions, and other sub-groups).
- **Distribution must be guided by a well-coordinated national strategy that is aligned with existing strategies for the distribution of routine vaccines.** Deliberate planning at all levels of government and in collaboration with state and local public health stakeholders, and the private sector, will be necessary for appropriately executing national guidelines to the unique and changing needs of local communities. Distribution should leverage existing mechanisms and infrastructure; this includes ensuring equitable access and availability across the country, particularly in rural and underserved areas.

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- **Vaccination program policies and deployment strategies must account for the readiness of local vaccination infrastructure and safety of the immunizer workforce.** Policies and deployment strategies must ensure vaccinations are conducted under safe conditions, with the immunizer workforce and other essential health care workers prepared and protected from associated risk. As front-line health care workers, the immunizer workforce – consisting of pharmacists, physicians, nurses, pharmacy technicians, and other health care professionals – requires priority access to the initial vaccine supply. Those responsible for local vaccine infrastructure will need to adhere to the FDA-approved labeling instructions for each respective vaccine for proper storage and handling of vaccines throughout the supply chain. Strategies must also account for specific instructions for storage, handling, and administration of vaccines, including proper handling of sharps.
- **Vaccination for the prevention and management of infectious disease, including COVID-19, is a core health service that should be prioritized and promoted.** Achieving high COVID-19 vaccination rates will require minimizing vaccine hesitancy and misinformation and ensuring vaccines are administered properly and in accordance with national clinical guidance. Health care professionals, including pharmacists, will be relied on to provide patient education about vaccine options and safety, and manage patients with complex health care conditions. National clinical guidance for immunization providers should be issued and should include considerations for differing clinical application of various COVID-19 vaccines and where booster doses are needed to maintain efficacy. There also needs to be clear communication regarding how long the vaccine is effective and when individuals may need booster doses. A coordinated vaccine registry approach and record-keeping guidance, particularly to track vaccines requiring booster doses, also may be needed.
- **Ensuring affordability and access, including by preventing and removing financial barriers, will be critical to a successful public health response to COVID-19.** Upon FDA licensure or authorization, and once recommendations are issued by ACIP, manufacturers, payors, physicians, pharmacists, and other critical stakeholders, such as community health centers, should promote broad access and affordability following national clinical guidance. ACIP should ensure that its recommendations are made immediately available so there is not a lag between the licensure or authorization decision and the ACIP recommendation. Reimbursement of immunization providers for reasonable administration fees is essential to maximizing access.