



## POSITION STATEMENT

### The Development, Allocation, Administration and Acceptance of a COVID-19 Vaccine

The development, deployment, administration and acceptance of a safe and effective COVID-19 vaccine will be critical to halting the devastating effects of the pandemic. It also will be essential to re-building the economy, ensuring safe workplaces, schools, and communities, and lifting the undue burden the disease has placed on communities already impacted by structural health disparities resulting from systemic racism and discrimination. The impact of a COVID-19 vaccine will confirm our knowledge that immunizations are the greatest public health achievement of the 20<sup>th</sup> and 21<sup>st</sup> centuries. With regard to COVID-19 vaccine development, deployment and acceptance, Immunize Colorado adopts the following positions and looks forward to working with local, state and national partners to ensure the following positions become reality. For Immunize Colorado's broader policy priorities beyond the vaccine for COVID-19, visit our website.

#### **INTEGRITY**

The Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH) and any other federal agencies involved in regulating and overseeing COVID-19 vaccine development must ensure the process is guided by the highest scientific and ethical principles and enforces the strongest standards available to maintain rigorous scientific integrity. This rigor must rely solely on data and evidence and operate independently, outside the influence of politics, economics or societal pressures, which become especially evident during a pandemic.

#### **TRANSPARENCY**

Pharmaceutical manufacturers must commit to and exercise complete transparency when it comes to developing or modifying clinical trial protocols, study documents and results and release all participant-level data.

Pharmaceutical manufacturers and the above-mentioned regulatory agencies must commit to providing timely and clear communication to the public on potential adverse events during and after the development and deployment of COVID-19 vaccine; this will be imperative to sustaining confidence and public trust in the COVID-19 vaccine and our country's vaccination infrastructure generally.

#### **EQUITY**

These same federal agencies must ensure equitable distribution and prioritize limited first round quantities for highly affected populations, especially those on the front lines of the pandemic response

and those most adversely impacted by the pandemic. This of course includes healthcare professionals, essential workers, seniors and people living with chronic health conditions.

It also includes communities of color, who have experienced COVID-19 case, hospitalization and death rates as much as 5 times higher than White, Non-Hispanic Americans. This trend reiterates that race and ethnicity are indicators for underlying risk factors that impact health (such as access to health care, socioeconomic status and occupation) and therefore that these communities should be prioritized for vaccine allocation.

Building and maintaining confidence and trust in vaccines is paramount, especially in communities hardest hit by COVID-19 and in those targeted more often and intentionally with vaccine misinformation.

Immunization partners and trusted community leaders and organizations must be proactive, clear, consistent, and highly visible in their communications to communities of color and others experiencing health inequities in order to keep highly affected populations informed of vaccine development, safety processes, and approval and recommendation criteria.

All vaccine clinical trials, including for COVID-19, should recruit diverse participants. Recruitment must be culturally competent, include clear, transparent, and language-of-origin communication, and include opportunities for participants to serve on community advisory boards. These advisory boards should allow participants authentic opportunity to provide input and make recommendations for improving clinical trial experience.

Manufacturers must publicly demonstrate their commitment to develop timely, affordable, and equitably distributed COVID-19 vaccines for patients worldwide, which include commitments to expanding trials to include children and account for diverse representation in lower-income settings, scaling up manufacturing faster and earlier than usual, and maintaining public confidence and trust in vaccines.

## **ACCESS**

Obtaining a COVID-19 vaccine should be easy and not be hindered by cost, insurance status, transportation, language, immigration status, zip code or any other barrier. It should be made clear to community members when, where, and how they can get vaccinated once it is available.

Vaccine affordability and access must be assured to address rural, socio-economic, and racial and ethnic disparities, and to increase immunization access among communities of color, persons with chronic illness, and populations experiencing barriers to care.

## **ACCOUNTABILITY**

FDA approval or Emergency Use Authorization (EUA) should not be sought by pharmaceutical developers until safety, efficacy and supply manufacturing capacity has been publicly demonstrated.

All COVID-19 vaccine trials, including those conducted outside the US, must be registered in a publicly accessible registry. This includes both interventional and safety study trials.

Pharmaceutical manufacturers should pursue publishing COVID-19 vaccine trial results in peer-reviewed journals. This is critical for ensuring healthcare provider trust in a vaccine and subsequent recommendation to patients to receive it.

Pharmaceutical manufacturers should report a summary of results in a publicly accessible registry within one year after a trial is completed or 30 days after FDA approval.

All COVID vaccines should be continuously monitored for safety after licensure or EUA using existing robust vaccine-safety and reporting systems, including such systems as the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD).

## **CAPACITY**

Existing public health infrastructure at the state and local levels should be fully deployed and scaled up to support vaccine allocation and access through increased federal, state and other funding to state and local public health agencies and community-based organizations. Building and sustaining a robust immunization workforce will also require reinforcement of collaborative partnerships and robust training opportunities. Utilizing existing public health infrastructures will ensure the effective and efficient delivery of COVID-19 vaccines, especially to hard-to-reach populations and communities experiencing structural and historical health barriers.

COVID-19 vaccine delivery guidance strategies must be clear, understandable, and open for review, while also providing consistency between federal strategies and state and local efforts including mass vaccination campaigns. Training plans and guidance should be made available to all types of immunization providers.

The Colorado Immunization Information System (CIIS), the state's single consolidated immunization registry, must be optimized to meet current reporting needs so that all vaccines administered, including COVID-19 vaccine, are recorded in a timely, accurate manner. This will also help ensure that public health officials and others can use the data for outbreak response, including identifying pockets of need for immunization services, and that families can access and keep track of their own immunization status. CIIS must also support coordination, interoperability, and bidirectional communication between new technologies such as the Vaccine Administration Management System (VAMS).

## **CLARITY**

Once a vaccine is approved by FDA, the Advisory Committee on Immunization Practices (ACIP) must make strong and clear recommendations for immunization providers who will administer COVID-19 vaccines. These recommendations should include the dosing schedule, priority populations and allocation and timing considerations for the general population. Conflicting messages and intentional misinformation efforts around the COVID-19 and other vaccines must be combated by elevating the ACIP's longstanding role as the vaccine policy recommending body for the United States, and by clearly communicating with the public ACIP's transparent, independent, rigorous and thorough vetting process.

Vaccination communication and awareness building efforts are critical to ensuring all communities understand the importance and trust in the safety of all recommended immunizations. Community outreach campaigns must be informed by data and identified gaps and must deploy culturally competent strategies. Trusted messengers, especially from communities most adversely impacted by

COVID-19 and vaccine-preventable diseases, must be engaged to build confidence and trust in all vaccines.

### **COMPETENCY**

As a prioritized population, healthcare professionals must feel confident in both receiving the COVID-19 vaccine and in being able to make a strong recommendation to patients. Educating healthcare professionals about the COVID-19 vaccine (including safety and efficacy data) should be a priority. This education should include strategies for raising awareness among patients regarding the need to receive all ACIP-recommended vaccinations.

### **SUSTAINABILITY**

Healthcare providers must be adequately reimbursed for the costs of administering all vaccines, including COVID-19 vaccine. Compensation should not only include reimbursement for the fees to administer the vaccine, but also for the time and knowledge needed for counseling and making strong recommendations to patients, both in-person and through telehealth.

Reimbursement to Medicaid and Medicare providers should be adequate to incentivize, rather than discourage, providers to stock and administer vaccine. Also, all providers should be reimbursed for ancillary supplies needed to vaccinate during a pandemic, including Personal Protective Equipment (PPE), syringes, alcohol wipes, adequate refrigeration and storage systems, and other clinic needs.

**Approved by the Immunize Colorado Board of Directors on 1/21/2021.**