

# **COVID-19: Vaccination Protocols and Regulatory & Legal Considerations for Employers**

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Thursday, September 24, 2020

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# COVID-19 and a Potential Vaccine (or Vaccines)

- Multiple vaccine candidates are in Stage 3 trials, with the fourth recently announced this week.
- The Food and Drug Administration has said that to win regulatory approval any COVID-19 vaccine will have to prevent disease, or decrease its severity, in at least 50% of the people who receive it. However, it is expected to spell out a tough new standard for an emergency authorization of a coronavirus vaccine soon.
- Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, has testified before Congress that he is confident that a COVID-19 vaccine will be ready by early 2021.



# Vaccine vs. Vaccination

- Will Americans voluntarily get vaccinated?
  - Morning Consult has been tracking this question for months - an April poll found that 72% would get the vaccine; in an early September poll that number was down to 51%.\*
  - A poll taken from September 18-21 by Axios and Ipsos found 60% of those polled were not very or not at all likely to get the first wave of vaccines when they are made available, with 39% saying that they would.\*\*



\* <https://morningconsult.com/2020/09/11/vaccine-acceptance-public-poll>

\*\* <https://www.axios.com/axios-ipsos-poll-coronavirus-index-vaccine-doubts-e9205f29-8c18-4980-b920-a25b81eebd84.html>

# So what is an employer to do?

- Follow a typical “flu vaccine approach” (for non-healthcare employers).
  - Offer free to employees on a voluntary basis or encourage employees to get the vaccine (with or without reimbursement).
- Create a hybrid approach
  - Mandate the COVID-19 vaccine for certain categories of workers (for example those who cannot work remotely or cannot fully social distance).
  - Must have an exemption process for religion and disability.
- Mandate the COVID-19 vaccine for all employees (with an exemption process).





# Lessons Learned in the Flu Vaccine Trenches

- Employers looking to put in place a COVID-19 vaccine protocol need look no further than to caselaw and guidance developed over the past several years following the decision by many healthcare providers put in place mandatory flu vaccine protocols for their employees (with exemptions available for religion and disability).
- Now is the time to put in place and implement a COVID-19 vaccine protocol.



# Lessons Learned in the Flu Vaccine Trenches

- ✓ Create an exemption policy and process.
- ✓ Identify who will decide exemption requests.
- ✓ Educate the decisionmakers as to what process to use.
- ✓ Roll out the process to employees.
- ✓ Make decisions and convey them to employees so that when the vaccine comes out you are ready to go.



# Religious Exemption

- Title VII (and the Pennsylvania Human Relations Act or other similar state law):
  - Prohibits discrimination “because of . . . religion.”
  - Requires reasonable accommodation.
  - Religion includes “all aspects of religious observance and practice, as well as belief, unless an employer demonstrates that he is unable to reasonably accommodate to an employee’s or prospective employee’s religious observance or practice without undue hardship on the conduct of the employer’s business.”
- “Undue hardship” under Title VII if employer can demonstrate the accommodation would require “more than a *de minimis* cost.”





# Third Circuit Flu Vaccination Case – 877 F.3d 487 (3d Cir. 2017)

- In 2012, the Hospital began requiring employee flu vaccinations.
- Employees seeking exemption needed to fill out a form.
- Fallon, an employee since 1994, submitted requests for exemption in 2012 and 2013 outlining his “sincerely held beliefs” regarding the harmfulness of vaccines.
- The Hospital approved the exemption requests in both years.



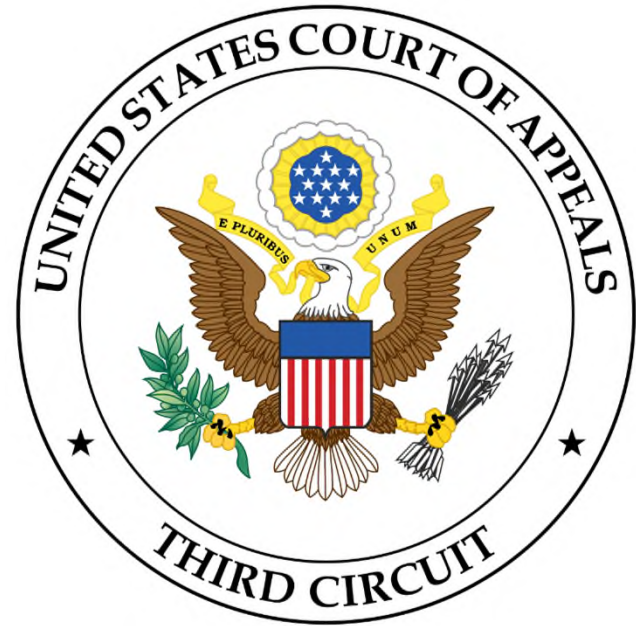
# Third Circuit Flu Vaccination Case – 877 F.3d 487 (3d Cir. 2017)

- In 2014, after evaluating his request and detailed essay setting out his religious beliefs, the Hospital denied Fallon's request, citing changes in its standards for exemption.
- The Hospital requested a letter from a clergyperson supporting Fallon's requested exemption which he was not able to provide because he did not belong to any religious organization.
- He was subsequently terminated and filed suit alleging religious discrimination and failure to accommodate his religion (as well as wrongful termination in violation of public policy).



# Third Circuit Flu Vaccination Case – 877 F.3d 487 (3d Cir. 2017)

- The Hospital's Motion to Dismiss was granted by the E.D. Pa. and Fallon appealed to the Third Circuit, which examined whether Fallon's beliefs, as articulated in his Complaint and the exemption form and essay he submitted to the Hospital, were religious under Title VII.



# Third Circuit Flu Vaccination Case – 877 F.3d 487 (3d Cir. 2017)

- The Third Circuit set out a 3-part test to determine whether the alleged beliefs are religious and therefore protected by Title VII:
  1. A religion addresses **fundamental and ultimate questions** having to do with deep and imponderable matters.
  2. A religion is **comprehensive** in nature; it consists of a belief system as opposed to an isolated teaching.
  3. A religion often can be recognized by the presence of certain **formal and external signs**.



# Third Circuit Flu Vaccination Case – 877 F.3d 487 (3d Cir. 2017)

1. His beliefs did not address fundamental and ultimate questions having to do with deep and imponderable matters:
  - **“Generally he simply worries about the health effects of the flu vaccine, disbelieves the scientifically accepted view that it is harmless to most people, and wishes to avoid the vaccine.”**
2. His beliefs were not comprehensive in nature:
  - **He applies one general moral commandment “one should not harm their [sic] own body” which is an “isolated moral teaching” and “not a comprehensive system of beliefs about fundamental or ultimate matters.”**
3. There were no formal or external signs:
  - **His views were not manifested in signs such as “formal services, ceremonial functions, the existence of clergy, structure and organization, efforts at propagation, observation of holidays and other similar manifestations associated with the traditional religions.”**



# Third Circuit Flu Vaccination Case – 877 F.3d 487 (3d Cir. 2017)

- Certain anti-vaccination beliefs are not religious.
- However, if anti-vaccination beliefs are a part of a broader religious faith, they are protected.
  - Example given - Christian Scientists who “regularly qualify for exemptions from vaccination requirements.”
- Religious beliefs can be demonstrated in various ways.



# EEOC Guidance

- “In most cases whether or not a practice or belief is religious is not at issue. However in those cases in which the issue does exist, the Commission will define religious practices **to include moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views.** This standard was developed in *United States v. Seeger*, 380 U.S. 163 (1965) and *Welsh v. United States*, 398 U.S. 333 (1970)” (emphasis added).
- “The Commission has consistently applied this standard in its decisions. **The fact that no religious group espouses such beliefs or the fact that the religious group to which the individual professes to belong may not accept such belief will not determine whether the belief is a religious belief of the employee or prospective employee.**”

# EEOC Guidance

- *U.S. v. Seeger*, 380 U.S. 163 (1965) (and *Welsh v. U.S.*) - Cases involving conscientious objection under § 6(j) of the Universal Military Training and Service Act. Individuals were imprisoned because of failure to serve in the military.
  - That Act exempts from combatant training and service in the armed forces of the United States those persons who by reason of their religious training and belief are conscientiously opposed to participation in war in any form.
  - Religious training and belief: defined as “**an individual’s belief in relation to a Supreme Being involving duties superior to those arising from any human relation, but [not including] essentially political, sociological, or philosophical views or a merely personal moral code**” (emphasis added).
  - Narrow question before the Court was “[d]oes the term ‘Supreme Being’ as used in § 6(j) mean the orthodox G-d or the broader concept of a power or being, or a faith, ‘to which all else is subordinate or upon which all else is ultimately dependent.’”

# EEOC Guidance

- The Supreme Court held that “within [the] phrase” “a conviction based upon religious training and belief” **“would come all sincere religious beliefs which are based upon a power or being, or upon a faith, to which all else is subordinate or upon which all else is ultimately dependent”** (emphasis added)
- The test might be stated in these words: **“A sincere and meaningful belief which occupies in the life of its possessor a place parallel to that filled by the G-d of those admittedly qualified for the exemption comes within the statutory definition.”**
  - This holding embraced a broader, non-theistic formulation of “religious training and belief.”



# EEOC Guidance

- The EEOC Compliance Manual states that “beliefs are not protected merely because they are strongly held. Rather, **religion typically concerns ‘ultimate ideas’ about ‘life, purpose, and death.’ Social, political, or economic philosophies, as well as mere personal preferences, are not ‘religious’ beliefs protected by Title VII.**” Compliance Manual at 12-I, A, 1.
- EEOC Informal Discussion Letter dated March 5, 2012:
  - **“It is unlikely that ‘religious’ beliefs would be held to incorporate secular philosophical opposition to vaccination.”**  
[www.eeoc.gov/eeoc/foia/letters/religious\\_accommodation.html](http://www.eeoc.gov/eeoc/foia/letters/religious_accommodation.html)
  - “Facts relevant to undue hardship . . . would presumably include, among other things, **the assessment of the public risk posed at a particular time, the availability of effective alternative means of infection control, and potentially the number of employees who actually request accommodation.**” (emphasis added).



# Pandemic Preparedness in the Workplace and the Americans with Disabilities Act

- Issued in 2009 during the H1N1 virus and updated on March 21, 2020 in response to the COVID-19 pandemic (with an explicit statement that employers should follow CDC guidance).

## **13. May an employer covered by the ADA and Title VII of the Civil Rights Act of 1964 compel all of its employees to take the influenza vaccine regardless of their medical conditions or their religious beliefs?**

**No.** An employee may be entitled to an exemption from a mandatory vaccination requirement based on an ADA disability that prevents her/him from taking the influenza vaccine. This would be a reasonable accommodation barring undue hardship (significant difficulty or expense).

# Pandemic Preparedness in the Workplace and the Americans with Disabilities Act (continued)

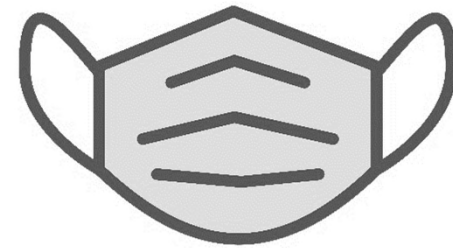
“Similarly, under Title VII of the Civil Rights Act of 1964, once an employer receives notice that an employee’s sincerely held religious belief, practice, or observance prevents him from taking the influenza vaccine, the employer must provide a reasonable accommodation unless it would pose an undue hardship as defined by Title VII (‘more than a de minimis cost’ to the operation of the employer’s business, which is a lower standard than under the ADA). **Generally, ADA-covered employers should consider simply encouraging employees to get the influenza vaccine rather than requiring them to take it.**”

# Key Takeaways

- Employees do not need to belong to an organized religion to be exempt from vaccination.
- Employers can ask employees to explain their religious beliefs in order to assess whether to approve a religious exemption.
- Employers cannot require a clergy letter in order to consider an exemption request.
- Both theistic and non-theistic beliefs can qualify as religious.

# If the beliefs qualify as religious, then what?

- Consider reasonable accommodation.
  - Let the science and the dictates of the particular workplace and the particular employee situation guide you.
    - Is a mask a reasonable accommodation?
    - Is remote work a reasonable accommodation?
    - Is a transfer into an open position where the employee does not work in close proximity to others a reasonable accommodation?
    - Is a leave of absence a reasonable accommodation?



# Other Considerations

- Coinfection concerns - Influenza and COVID-19.
- Consider a more robust influenza vaccination program.
  - Address how to implement with a workforce that is partially remote.
- Be ready to address potential disability-related exemption requests.
  - Will depend on the components of the particular vaccine (or vaccines) and medical contraindications.



# COVID-19 Vaccine Distribution

- Experts estimate 70% of U.S. population needs to be vaccinated to achieve herd immunity (*i.e.*, 200 million).
- This could require distribution of 400 million doses, if vaccines require 2 doses.
- H1N1 vaccination reached 81 million.
- CDC has overseen mass vaccination programs in the past, but the White House created Operation Warp Speed (OWS) to facilitate COVID-19 vaccination development and distribution.

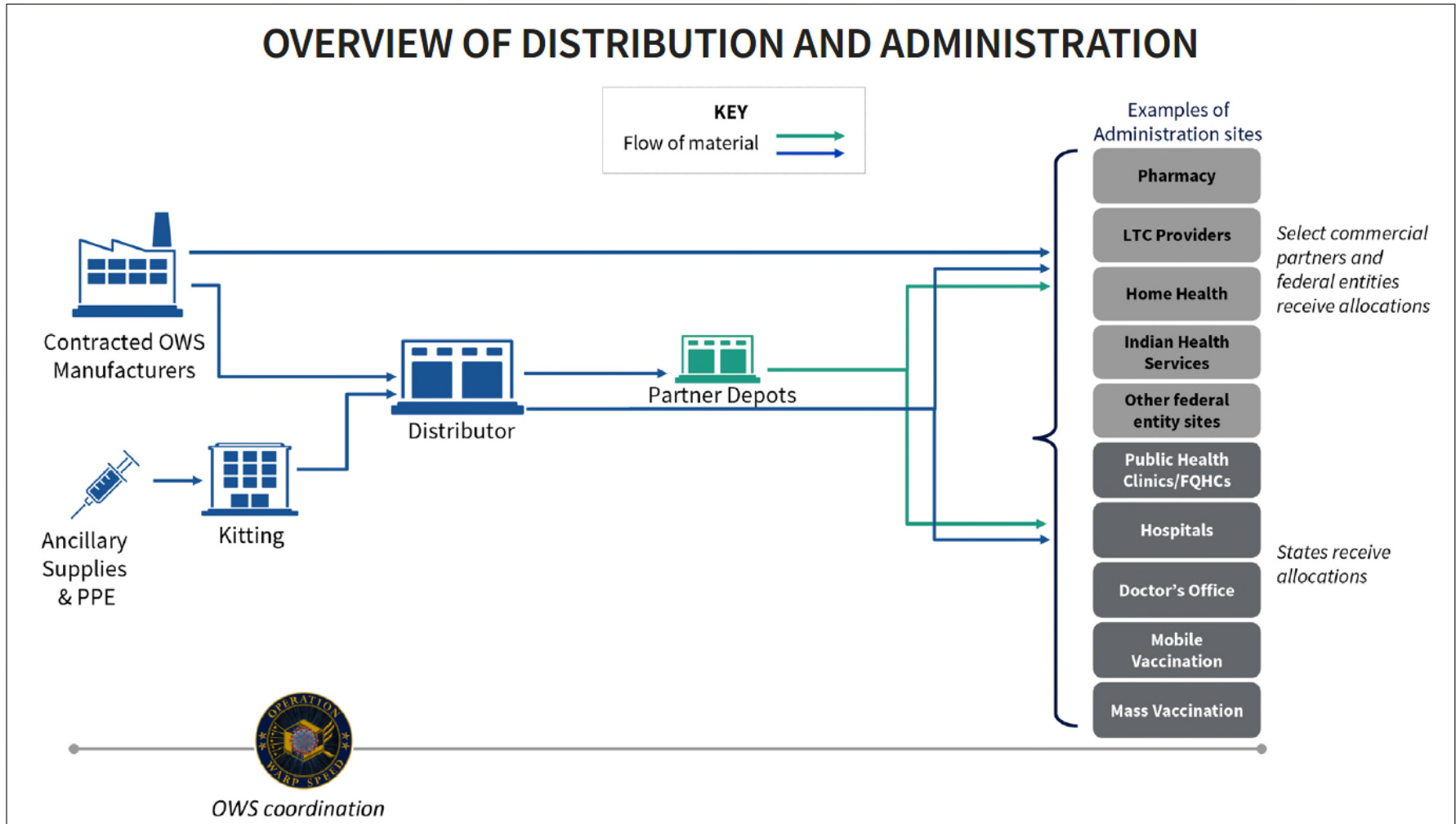


# CDC Guidance

- **Distribution will build on H1N1 framework**
  - Industry will deliver vaccine doses to centralized distributor (McKesson).
  - States/jurisdictions will receive weekly allocations based on population, and other factors.
  - Vaccination sites must enroll in state/jurisdiction immunization program. Enrolled providers will submit orders to state/jurisdiction, which will approve orders against allocations, based on priority guidelines.
  - Centralized distributor will distribute vaccine directly to providers.



# OWS Guidance



# CDC Guidance

- **Planning for Alternative Scenarios**

- Vaccine "A" –
  - Requires storage at  $-70^{\circ}\text{C} \pm 10^{\circ}\text{C}$
  - 2-dose series (21 days between doses).
  - Minimum order of 1000 doses.
- Vaccine "B"
  - Requires storage at  $-20^{\circ}\text{C}$
  - 2-dose series (28 days between doses).
- Vaccine A & B scenario.



# Unanswered Questions

- What will the DoD's role be?
- Will funding be provided to states to assist with distribution planning, and how much?
- Will the technology infrastructure be adequate?
- Will states be required to follow CDC allocation guidelines, or have discretion?
- How many doses will be available initially?

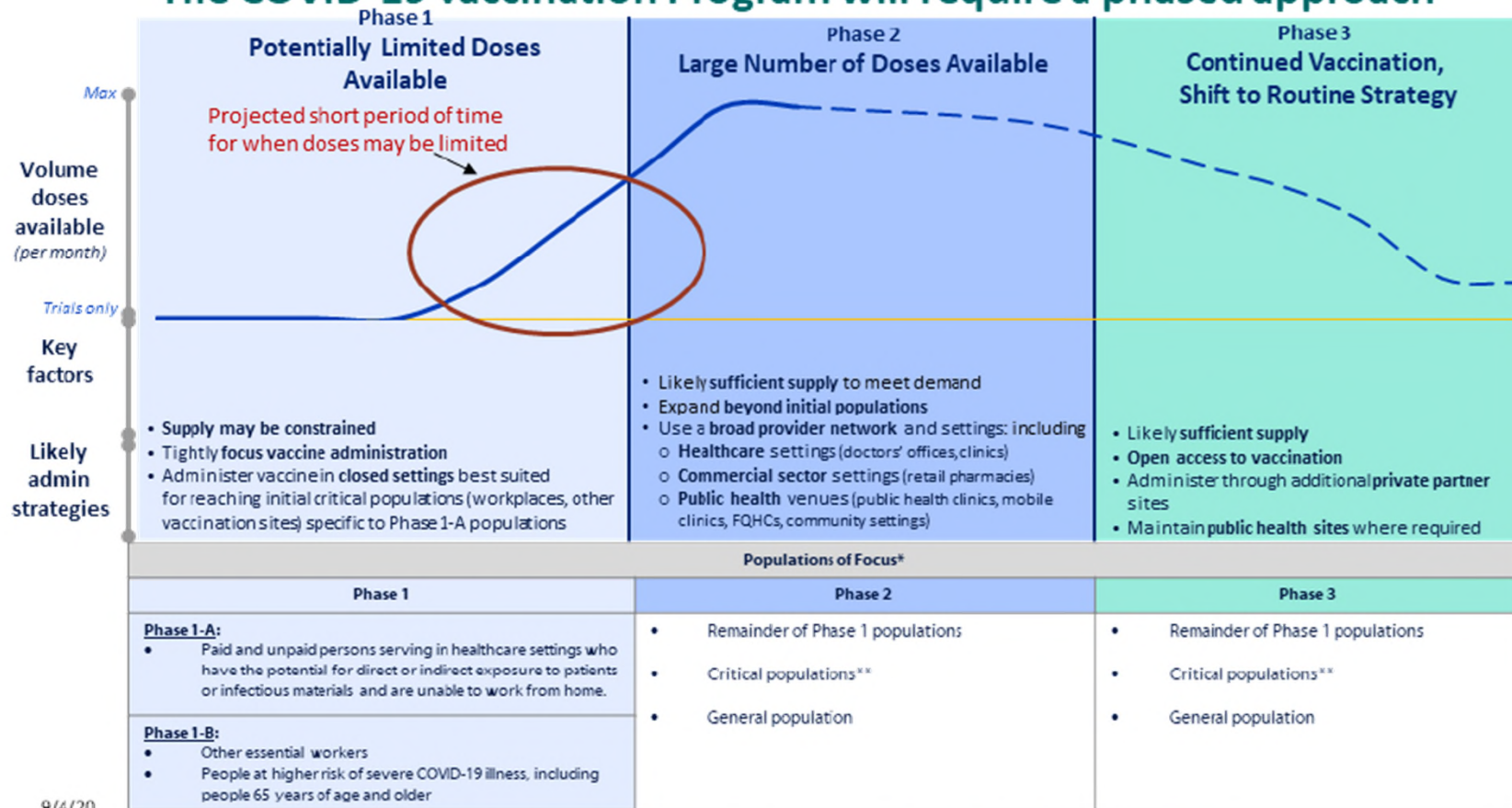


# Toward Allocation Guidelines

- CDC engaged ACIP and National Academy of Medicine/National Academy of Sciences, Engineering, and Medicine to develop interim prioritization guidelines.
- *Discussion Draft of Preliminary Framework for Equitable Allocation:*
  - Released for comment on September 1, 2020
  - Comments were due September 4, 2020

# Allocation Phases

## The COVID-19 Vaccination Program will require a phased approach



9/4/20

*\*Planning should consider that there may be initial age restrictions for vaccine products.*

*\*\*See Section 4: Critical Populations for information on Phase 1 subset and other critical population groups.*

# Discussion Draft of Preliminary Framework for Equitable Allocation

- Foundational Principles:
  - Maximization of benefit
  - Equal Regard
  - Mitigation of Health Inequities
  - Fairness
  - Evidence-based
  - Transparency
- Primary Goal: “Maximize societal benefit by reducing morbidity and mortality caused by transmission of the virus.”

# Allocation Phases

## Phase 1

### Phase 1a “Jumpstart Phase”:

- High-risk workers in health care facilities
- First responders

### Phase 1b:

- People of all ages with comorbid and underlying conditions that put them at significantly higher risk
- Older adults living in congregate or overcrowded settings

## Phase 2

- Critical risk workers—workers who are both in industries essential to the functioning of society and at substantially high risk of exposure
- Teachers and school staff
- People of all ages with comorbid and underlying conditions that put them at moderately higher risk
- All older adults not included in Phase 1
- People in homeless shelters or group homes for individuals with physical or mental disabilities or in recovery
- People in prisons, jails, detention centers, and similar facilities, and staff who work in such settings

## Phase 3

- Young adults
- Children
- Workers in industries essential to the functioning of society and at increased risk of exposure not included in Phase 1 or 2

## Phase 4

- Everyone residing in the United States who did not receive the vaccine in previous phases

### Equity is a crosscutting consideration:

In each population group, vaccine access should be prioritized for geographic areas identified through CDC's Social Vulnerability Index.

# Health Equity in Proposed Allocation Phases

- Acknowledges disparate impact of pandemic among people of color.
- Allocation criteria must be non-discriminatory.
- Mitigation of Health Inequities is an explicit goal.
- Vaccine access should be prioritized within each phase using the CDC's Social Vulnerability Index.

# Immunity – The Prep Act, 42 U.S.C. 247d-6d

- Subject to the other provisions of this section, a **covered person** shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a **covered countermeasure** if a **declaration under subsection (b)** has been issued with respect to such countermeasure.

# Immunity

## The Prep Act, 42 U.S.C. 247d-6d

- **“Covered person”**
  - A qualified person administering a countermeasure
  - “Program planners” - includes a person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration under subsection (b).



# Immunity

## The Prep Act, 42 U.S.C. 247d-6d

- **“Covered Person” (cont.)**
  - Under the HHS Sec’y Declaration of Public Health Emergency, a “program planner” includes a private sector employer or community group.
  - Under recent amendment to the Declaration, “covered persons” include pharmacists, subject to specific requirements.
- **“Covered countermeasure”** includes a vaccine approved by FDA or is authorized under EUA.
- **April 21, 2020 Advisory Opinion** – HHS applies a reasonable belief standard for “Covered Person” and “Covered countermeasure” definitions.

# Immunity

## The Prep Act, 42 U.S.C. 247d-6d

- **Exceptions to immunity:**
  - Federal enforcement actions.
  - Federal cause of action for “willful misconduct.” causing death or serious injury filed in the District of Columbia.
  - Compensation for serious injury or death may be obtained from the Covered Countermeasure Process Fund.
- **PREP Act Immunity does not eliminate need for appropriate insurance and risk management.**

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