Memorandum: Vaccine Distribution Liability Under PREP Act

Background

On March 10, 2020, the Secretary of Health and Human Services (Secretary) issued a Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act), effective February 4, 2020, for certain medical products to be used against COVID-19. The PREP Act authorizes the Secretary to issue a declaration to provide liability immunity to certain individuals and entities against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of [vaccines] (referred to as covered countermeasures). It is ASCP’s view that these declarations under the PREP Act cover various activities related to the distribution of a future Food and Drug Administration (FDA) approved COVID-19 vaccine in long-term care facilities (LTCF) and assisted living facilities (ALF).

PREP Act Covered Entities

It is the intent of congress to ensure that all individuals acting in good faith and taking “reasonable steps” to help treat COVID-19 are extended immunity under the PREP Act. A “covered-person” under the PREP Act means:

B) a person or entity that is—
   (i) a manufacturer of such countermeasure;
   (ii) a distributor of such countermeasure;
   (iii) a program planner of such countermeasure;
   (iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or
   (v) an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv).

The PREP Act offers broad immunity to all individuals who are engaged in the COVID-19 vaccination effort, but the PREP Act does not replace the need for individual contracts and agreements to be put in place when working to manufacture, distribute, or administer a COVID-19 vaccine. It is important to note that individuals provided immunity under the PREP Act may still be sued for equitable relief related to personal injury or damage to property and the federal government still has the ability to bring enforcement actions against individuals who are covered entities under PREP Act immunity. It is our view, however, that any individual involved in the manufacturing, distribution, or administration of a COVID-19 vaccine that participates with the federal government (an Authority Having Jurisdiction) as part of a federal government provider authorization is a covered entity afforded immunity under the PREP Act.