How does the administration of the COVID-19 vaccine affect my medical professional liability exposure?

Executive Summary

The Declaration under the federal Public Readiness and Emergency Preparedness Act (PREP Act) for Medical Countermeasures Against COVID-19 provides liability immunity to covered persons who administer a covered countermeasure(s). The terms "immunity," "covered persons" and "covered countermeasure" are legal terms and have specific definitions under the PREP Act and the Declaration's Fourth Amendment. These terms are defined and described in greater detail below.

In brief, a healthcare provider who administers the COVID-19 vaccination following public health guidelines and State law qualifies for liability immunity under the PREP Act. The only exception is for claims of death or serious physical injury due to willful misconduct. Willful misconduct cannot be found against a healthcare provider who acts in accordance with applicable directions, guidelines, or recommendations issued by the HHS regarding administrating and use of a countermeasure as long as HHS or the State or local health authority is notified about the serious injury or death within seven days of its discovery. Immunity under the PREP Act became available when the Department of Health and Human Services ("HHS") issued the Declaration which is applicable as of February 4, 2020 and effective through October 1, 2024.

Covered Countermeasures

The Declaration was first issued on March 10, 2020 (although it is applicable as of February 4, 2020) by the Secretary of HHS (the "Secretary), the fourth, and most recent amendment, was published on December 9, 2020. Under the December 9, 2020 Fourth Amendment to the Declaration a "covered countermeasure" includes any:

- Antiviral, or any other drug, any biological product, any diagnostic, any other device, or any vaccine **(including the vaccines developed by Pfizer and Moderna)**, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating from SARS-CoV-2, or;

- Device used in the administration of any such product, and all components and constituent materials of any product, including any respiratory protective devices;

- A product manufactured, used, designed, developed, modified, licensed, or produced to diagnose, mitigate, prevent, treat or cure a serious or life-threatening disease or condition caused by a product described above;

- A product or technology intended to enhance the use of, or effect of a product described above, or;

- Any device used in the administration of any product, and all components and constituent materials of any product.

Covered countermeasures include any drug, device or biological product authorized for emergency use with respect to COVID-19 under an Emergency Use Authorization (EUA) **(again, including the Pfizer and Moderna vaccines)**, described in Emergency Use Instructions (EUI) issued by the CDC, or being researched under certain investigational provisions to treat COVID-19 is a covered countermeasure.

Distribution of Covered Countermeasures

The Secretary may specify that liability protections are in effect only for covered countermeasures obtained through a particular means of distribution, the Declaration has widened the approved means of distribution to include certain private-distribution channels. Covered distribution channels now include Recommended Activities that are related to any covered countermeasure that is:

- Related to present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreement, or memorandum of understanding or other federal agreements;

- Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction (meaning the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (e.g., city, country, tribal, state or federal boundary lines) or functional (e.g., law enforcement, public health) range or sphere of authority) to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure following a declaration of any emergency;

- Licensed, approved, cleared, or authorized by the FDA (or that is permitted to be used under an INDA or IDE under the FD&C Act or PHS Act) to treat, diagnose, cure, prevent mitigate or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom; or

- A respiratory protective device approved by NIOSH, or certain other regulations that the Secretary determines to be a priority for use during a public health emergency to prevent, mitigate or limit the harm from COVID-19.

Example: A manufacturer, distributor, program planner, or qualified person is engaged in manufacturing, testing, development, distribution, administration, or use of a COVID-19 vaccine pursuant to an FDA EUA for that COVID-19 vaccine. If the Covered Person satisfies all other requirements of the PREP Act and Declaration, there will be PREP Act coverage even if there is no federal agreement to cover those activities and those activities are not part of the authorized activity of an Authority Having Jurisdiction.

Finally, the Declaration states that a person or entity that otherwise meets the requirements for PREP Act immunity will not lose its immunity even if the product is ***not*** a covered countermeasure if that person or entity reasonably could have believed that the product was a covered countermeasure. There may also be situation where not administering a covered countermeasure to a particular individual can fall within the PREP Act and the Declaration's liability protections.

Example: FDA has issued EUAs for certain COVID-19 tests and PPE. A covered person purchases 500,000 tests or respirators that appears to be authorized under a EUA. The covered person has taken reasonable steps – under the current, emergency circumstances – to substantiate the authenticity of the products. But it turns out that some or all of the products are counterfeit. Under those circumstances, that person would be immune against a claim arising out of the use of a counterfeit test or respirator.

Liability protections for all Covered Countermeasures extend through October 1, 2024.

Covered Persons

The fourth amendment to the Declaration, defines "covered persons" as follows:

- Manufacturers of countermeasures;
- Distributors of countermeasures;
- Program planners, i.e., individuals and entities involved in planning, administering, or supervising programs for distribution of a countermeasure (e.g., State or local governments, Native American tribes, or private sector employers or community groups that establish requirements or provide guidance, technical or scientific advice or assistance, or provide a facility);
- A qualified person who prescribed, administered, or dispensed such countermeasure, including a qualified person who ordered or administered a covered countermeasure via telehealth or;
- An official agent or employee of a person or entity described above.

Qualified Person

A "qualified person" means a licensed health professional or other individual who is authorized to prescribe, administer, or dispense countermeasures under the law of the State in which the countermeasure was prescribed, administered or dispensed. Examples of covered persons also include certain pharmacists, pharmacy interns, or pharmacy technicians who order or administer certain COVID-19 tests and certain vaccines.

State-licensed pharmacists and the State-licensed or registered interns under their supervision are qualified persons only if the following requirements are met:

- The vaccine must be authorized, approved, or licensed by the FDA;
- If the case of a COVID-19 vaccine, the vaccination must be ordered and administered according to the Advisory Committee of Immunization Practices (ACIP) COVID-19 vaccine recommendations;
- In the case of a childhood vaccine, the vaccination must be ordered and administered according to ACIP's standard immunization schedule;
- The licensed pharmacist must have completed the immunization training that the licensing State requires in order for pharmacist to order and administer vaccines. If the State does not specify training requirements for the licensed pharmacist to order and administer vaccines, the licensed pharmacist must complete a vaccination training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE) to order and administer vaccines;
- The licensed or registered pharmacy intern must complete a practical training program that is ACPE approved;
- The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic CPR;
- The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during east State licensing period;
- The licensed pharmacist must comply with record keeping and presorting requirements of the jurisdiction in which they are administering vaccines;

- The licensed pharmacist must inform the child-hood vaccination patients and the adult caregiver accompanying the child of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate;
- The licensed pharmacist and the pharmacy intern must comply with any applicable requirements (or condition of use) as set for in the CDC COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccinations.

Immunity

Immunity is extended to all covered countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction. Immunity means that courts must dismiss claims brought against any entity or person covered by the PREP Act. Claims that courts must dismiss include claims for any loss that is related to any stage of design, development, testing, manufacture, labeling, distribution, formulation, labeling, packaging, dispensing, prescribing, administration, licensing or use of a countermeasure recommended in a Declaration. This includes, but is not limited to, claims for:

- Death;
- Physical, mental or emotional injury, illness disability, or condition or fear of any such injury, illness disability, or condition;
- Any need for medical monitoring; or
- Property damage or loss, including business interruption loss.

The only exception is for claims of death or serious physical injury caused by willful misconduct. Willful misconduct is misconduct that is greater than any form of recklessness or negligence. It is defined in the PREP Act as an act or failure to act that is taken:

- Intentionally to achieve a wrongful purpose;
- Knowingly without legal or factual justification; and
- In disregard of a known or obvious risk that is great as to make it highly probable that the harm will outweigh the benefit.

All three of these conditions must be proven with clear and convincing evidence. Willful misconduct cannot be found against a program planner or qualified person who acts in accordance with applicable directions, guidelines, or recommendations issued by the HHS regarding administrating and use of a countermeasure as long as HHS or the State or local health authority is notified about the serious injury or death within seven days of its discovery.

The National Vaccine Injury Compensation Program is not affected by the Declaration. An injured party retains the ability to obtain compensation under that program.

Immunity under the PREP Act became available when HHS issued the Declaration which is applicable as of February 4, 2020.

Timeline

- **January 31, 2020** – The Secretary of HHS declared a public health emergency for the entire United States to aid in response to the COVID-19 outbreak, which subsequently became a global pandemic;
- **March 10, 2020** – The Secretary issued a Declaration under the PREP Act for medical countermeasures against COVID-19;
- **April 10, 2020** – The Secretary amended the Declaration to extend liability protections to covered counter measures authorized under the CARES Act;
- **June 4, 2020** – The Secretary amended the Declaration to clarify that covered countermeasures under the Declaration include qualified pandemic and epidemic products that limit the harm that COVID-19 might otherwise cause;
- **August 19, 2020** – The Secretary amended the Declaration to add additional categories of qualified persons and to amend the category of disease, health condition, or threat for which he recommends the administration or use of covered countermeasures;
- **December 9, 2020** – The Secretary amended the Declaration, the expansion of "covered countermeasures" and "covered persons" in this amendment are described below.