FTCA, PREP and FVPA: Volunteer Liability Protections and COVID-19 Vaccine Administration at FQHCs

As Oregon’s community health centers begin vaccinating their populations and those in their communities, questions about the use of clinical volunteers to help administer COVID-19 vaccines have risen to the forefront. This document clarifies which liability protections are afforded under three Federal programs that cover health centers: The Federal Tort Claims Act, the Public Readiness and Emergency Preparedness Act, and the Federal Volunteer Protection Act. Below, relevant information about each type of coverage and their applicability regarding protecting health centers and their vaccine volunteers from legal liability, including a summary table (Table 1).

**Federal Tort Claims Act**
The Federal Tort Claims Act (FTCA) provides medical malpractice liability protection for FQHCs and their “covered individuals” (governing board members, officers, employees, and certain individual contractors) if the reason for the tort falls within their approved scope of project. This means that when someone makes a malpractice claim against a covered individual at an FQHC, the claimant cannot sue the health center but instead must make a claim with the Department of Health and Human Services (HHS). The Federal government (HHS) assumes all costs associated to the claim, including any monetary damages awarded to the claimant. In other words, the health center and provider are shielded from any costs or financial liabilities associated with the malpractice claim.

The FTCA has special rules for when responding to emergency events, such as the Declared Public Health Emergency due to the COVID-19 Pandemic, and a significant topic of interest is the utilization of volunteers during the vaccine rollout and whether they are covered by FTCA protections. Unfortunately, volunteers generally are not “covered individuals” and are thus not protected under the FTCA. However, liability protection is available for Volunteer Health Professionals (VHPs) if the health center has gone through the separate deeming process to sponsor VHPs.

For more information regarding FTCA coverage during the COVID-19 Pandemic, please see Section F of Federal Tort Claims Act Health Center Policy Manual.

**Public Readiness and Emergency Preparedness Act**
The Public Readiness and Emergency Preparedness Act (“PREP Act” or “PREPA”) allows the Secretary of HHS to issue a declaration that provides liability immunity to “covered persons” who are involved in the development or administration of countermeasures against public health threats (such as pandemics or chemical/biological terrorist attacks). Relevant to health centers, covered persons include:

- **Program planners,** are those who supervise or administer a program with respect to the administration, dispensing, distribution, provision, or use of a Covered Countermeasure,” which include private sector employers.
- **Qualified persons** includes individuals who dispense or administer the “countermeasure,” which in this case would be the COVID-19 vaccines.

HHS issued a PREP Act Declaration last year in March authorizing liability protections for those involved in countermeasures related to the COVID-19 pandemic. On Feb. 2, 2021, an amendment regarding
vaccine administration was made authorizing PREP Act protections to any healthcare provider dispensing or administering the vaccine who meet the following:

- Is licensed or certified in a state to prescribe, dispense, and/or administer COVID-19 vaccines in any other state or U.S. territory, OR
- Any physician, registered nurse, or practical nurse whose license or certification expired within the past five years in any state or U.S. territory so long as the license or certification was active and in good standing prior to the date it went inactive. Those without licenses/certifications will require a period of on-site supervision by healthcare professional currently practicing, AND
- Complete a CDC COVID-19 vaccine training, which can be found here.

Based on Declaration and Amendment made by HHS, health centers and their health care providers working or volunteering who meet the above requirements are covered by PREP Act protections.

**Federal Volunteer Protection Act**

The Federal Volunteer Protection Act (FVPA) provides liability protection for volunteers at nonprofit and government entities as long as they:

- Are acting within the scope of the responsibilities
- Are properly licensed/credentialed for their responsibilities
- Were not acting in a manner that was grossly negligent, reckless, or willful or criminal misconduct
- Do not operate a vehicle

There are minor exceptions to volunteer liability protection, found here for reference. Unfortunately, the FVPA does not shield organizations from torts or civil suits brought about by the actions of their volunteers. Health centers could still face malpractice or other claims from patients if an incident were to occur.

**Summary**

While the FTCA does not cover volunteers for liability protections (unless the health center has been deemed to have VHPs), the PREP Act does (along with health centers). Providers who are licensed or credentialed in the past five years can volunteer to administer COVID-19 vaccines. Furthermore, the Federal Volunteer Protection Act provides liability protection to volunteers at FQHCs as they are non-profits.

If you have any FTCA, PREP Act, or Federal Volunteer Protection Act questions, please contact OPCA’s FTCA lead Rob Schlegel at rschlegel@orpca.org.

Updated 3/15/2021
<table>
<thead>
<tr>
<th>Who is covered?</th>
<th>FTCA</th>
<th>PREP</th>
<th>FVPA</th>
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<tr>
<td>FQHCs and their “covered individuals” (governing board members, officers, employees, and certain individual contractors)</td>
<td>“Covered persons” who were involved the development or administration of countermeasures against public health threats (such as pandemics or chemical/biological terrorist attacks). Covered persons include: • “Program planners,” are those who supervise or administer a program with respect to the administration, dispensing, distribution, provision, or use of a Covered Countermeasure,” which include private sector employers. • “Qualified persons” includes individuals who dispense or administer the “countermeasure,” such as the COVID-19 vaccine.</td>
<td>Volunteers at nonprofit and government entities as long as they: • Are acting within the scope of the responsibilities • Are properly licensed/credentialed for their responsibilities • Were not acting in a manner that was grossly negligent, reckless, or willful or criminal misconduct • Do not operate a vehicle</td>
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<tr>
<td>Does it cover volunteers administering vaccine?</td>
<td>No, unless the health center has gone through the deeming process to sponsor Volunteer Health Professionals (VHPs).</td>
<td>Yes</td>
<td>FVPA does not shield organizations from torts or civil suits brought about by the actions of their volunteers. Health centers could still face malpractice or other claims from patients if an incident were to occur.</td>
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<td>Specifics/Additional Details</td>
<td>PREP Act protections to any healthcare provider dispensing or administering the vaccine that: • is licensed or certified in a state to prescribe, dispense, and/or administer COVID-19 vaccines in any other state or U.S. territory, or • any physician, registered nurse, or practical nurse whose license or certification expired within the past five years in any state or U.S. territory so long as the license or certification was active and in good standing prior to the date it went inactive. Those without licenses/certifications will require a period of on-site supervision by healthcare professional currently practicing, and • Complete a CDC COVID-19 vaccine training.</td>
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