

The PREP Act Update: The Prevailing COVID-19 Immunities

Healthcare facilities are facing surges in the continuing spike of COVID-19 cases. Yet, among the continuing challenges of staffing shortages, insufficient supplies, and vaccine administration remains the applicability of immunity from civil liability during the ongoing pandemic.

Fortunately, the Secretary of Health and Human Services (HHS) continues to expand the applicable immunities under the PREP Act. The first declaration under the PREP Act was issued on March 10, 2020.¹ This declaration offers immunity for “covered persons” for all claims for loss to person or property caused/relating to the administration of a “covered countermeasure” or certain medical products to be used against COVID-19. Now, the HHS has issued a total of four declarations, all of which continue to increase the scope of the immunities.

The recent federal court trend was not so flattering. In hopes of a more uniform and favorable forum, health care entities have been attempting to remove these cases to federal courts. The issue was whether the applicability of the PREP Act immunity created a federal question to warrant federal jurisdiction. However, in recent months, federal courts have repeatedly rejected this argument. The federal courts held that the PREP Act immunity defense was not enough to create a federal question. Rather, whether the immunity applied was a question better determined by the state courts.

The first case on this issue was decided on August 12, 2020, by the U.S. District Court for the District of New Jersey. In *Estate of Maglioli v. Anderover Subacute Rehab. Ctr.*, plaintiffs brought wrongful death against the nursing home for the failure to exercise due care with respect to the COVID-19 pandemic.² The nursing home argued that a federal forum was appropriate in light of the PREP Act immunity.³ However, the court held that the PREP Act was not broad enough to occupy the field of negligence or malpractice claims to extract the matter from the state’s jurisdiction.⁴ Specifically, the court found that there were allegations at-issue outside of the countermeasures delineated under the PREP Act.⁵ For example, the complaint alleged that the nursing home had failed to enact proper social distancing measures, which was not a “covered countermeasure.”⁶ The court remanded the case holding that the state court must decide whether the PREP Act afforded immunity to the present claims.⁷ Adopting this same logic, other federal courts have issued similar rulings, including in Kansas, Florida, and Pennsylvania, finding that these cases did not belong in a federal forum.⁸

¹ See 85 Fed. Reg. 15,198, 15,202 (March 17, 2020); see also Pub. L. No. 109-148, Public Health Service Act § 319F-3, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e.

² 2020 U.S. Dist. LEXIS 145055, *3.

³ *Id.* at *8.

⁴ *Id.* at *29-31.

⁵ *Id.*

⁶ *Id.*

⁷ *Id.* at *32.

⁸ See *Lutz v. Big Blue Healthcare*, 2020 U.S. Dist. LEXIS 150020 (D. Kansas August 19, 2020); *Gunter v. CCRC OPCO-Freedom Square, LLC*, 2020 U.S. LEXIS 201622 (M.D. Fla. October 29, 2020); *Sherod v. Comprehensive Healthcare Mgmt. Servs. LLC*, 2020 LEXIS 191885 (W.D. Pa. October 16, 2020).

In response to this federal trend, on December 3, 2020, the HHS Secretary issued the fourth amendment to the declaration under the PREP Act again broadening the scope of liability protections and calling into question this recent federal court trend.

First, Section XI of the amendment highlights the unprecedented aspects of the global pandemic and federal interests at stake to conclude the importance of a uniform interpretation of the PREP Act. The amendment highlights the need for a consistent pathway for covered person to administer covered countermeasures. Arguably, this explicit statement demands a uniform interpretation far better situated with the federal courts.

Even more outstanding, Section IX clarified that there can be situations where the at-issue conduct is an omission and still be afforded the immunity protections under the PREP Act. For example, if the allegations consist of not administering a covered countermeasure to a particular individual, the healthcare entity may still be covered under the PREP Act.

Furthermore, the Declaration clarified that the sole exception to the immunity of covered persons under the PREP Act is an exclusive federal cause of action against a covered person for death of serious physical injury proximately caused by willful misconduct. This amendment even includes telehealth liability protections in the administration of countermeasures.

Despite the recent trend in federal cases, the fourth amendment to the declaration under the PREP Act provides optimism that this federal trend will cease, and the immunities will continue to expand.
