Patterson Belknap Webb & Tyler LLP

Products Liability Alert April 22, 2020

HHS Issues Advisory Opinion Further Clarifying Scope of PREP Act Immunity

Since invoking its powers under the PREP Act last month to shield certain actors aiding in the fight against COVID-19 from tort liability for their efforts (as we previously described here), the Department of Health and Human Services ("HHS") has been inundated with requests for advisory opinions about whether various activities qualify for immunity under its broadly-worded Declaration.

Citing its "limited resources" and seeking to "minimize the need" to respond to these requests individually, on April 14, 2020 HHS issued an "omnibus advisory opinion" ("Advisory Opinion") to "address most questions and concerns about PREP Act immunity" during the COVID-19 Pandemic. The full text of the Advisory Opinion can be found here.

The Advisory Opinion, which is broken into four sections, offers HHS's current thinking on what constitutes "Covered Countermeasures," who is a "Covered Person," what it means for those seeking immunity to take "Reasonable Precautions," and the scope of "Compensation for Injuries" under its Declaration.

Broadly speaking, the Advisory Opinion recognizes that the COVID-19 situation is constantly evolving, that there are many authorities issuing directives at the federal, state, and local level, and in many cases new developments are occurring faster than HHS and other regulators can keep up. As such, the Advisory Opinion counsels that covered persons and entities will generally be viewed as preserving their PREP Act immunity so long as they comply with the Declaration and "reasonably believe" their conduct was covered at the time it occurred.

The Advisory Opinion gives several illustrations of how this guidance plays out. For example, if a distributor of medical devices takes reasonable steps to import what it believes are covered products, including reasonable steps to verify the authenticity of those products, but the products later turn out to be counterfeit in whole or in part, the distributor's immunity would be preserved. Similarly, if a pharmacy allows its pharmacists to administer FDA-approved COVID-19 tests and it is later discovered that one of the pharmacists' state-law licenses had lapsed, the pharmacy would still retain its immunity.

To this end, the Advisory Opinion encourages all covered and potentially-covered actors to carefully document all steps that they take to comply, and make that documentation readily available to regulators and other interested parties (e.g., distributors should share their documented compliance steps with hospitals so that hospitals can make informed purchasing decisions).

The Advisory Opinion also clarifies that the scope of immunity under the PREP Act is broader than the available compensation for those injured by covered conduct. For example, while an injured person's out-of-pocket medical expenses and lost wages for "serious injury or death" are covered under the PREP Act compensation program, emotional injury, fear of injury, and business losses are not (and are therefore non-compensable).

Finally, the Advisory Opinion makes clear what it is not—it does not bind HHS or the federal courts, and does not have the force of law. As such, while acting in accordance with this guidance would certainly be evidence of "reasonable" conduct in any subsequent lawsuit, potentially-covered persons should work with their regulatory and compliance counsel and continue to be vigilant to ensure that their conduct complies not only with this guidance, but with all other federal, state, and local laws.

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