

Publications

Health Care Alert: PREP Act Amendment Preempts State-Law Restrictions on the Use of Telehealth with Respect to “Covered Countermeasures”

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On December 3, 2020, the U.S. Department of Health and Human Services (HHS) amended the current declaration triggering federal immunity under the Public Readiness and Emergency Preparedness (PREP) Act. Among other things, this amendment provides that “qualified persons” potentially covered by the statute includes “healthcare personnel using telehealth to order or administer Covered Countermeasures for patients in a state other than the state where the healthcare personnel are permitted to practice,” subject to applicable requirements under the laws of the state where they *are* licensed or otherwise permitted to practice. The amendment expressly preempts “[a]ny state law that prohibits or effectively prohibits such a qualified person from ordering and administering Covered Countermeasures through telehealth,” effective beginning on February 4, 2020.

By way of background, the PREP Act authorizes the Secretary of HHS to issue a declaration providing liability protections to “Covered Persons” against any claim of loss caused by, arising out of, relating to, or resulting from, the manufacture, distribution, administration, or use of “Covered Countermeasures.” Under the current PREP Act declaration, the term “Covered Countermeasure” generally includes products that (1) the Food and Drug Administration (FDA) has approved, cleared, licensed, or authorized for emergency or investigational use; and that (2) are used to address COVID-19 or associated health threats, including harms that COVID-19 might otherwise cause (e.g., COVID-19 tests, treatments, and, once authorized for emergency use, vaccines). “Covered Persons” includes (in addition to several other subcategories of individuals and entities) “qualified persons,” defined as (1) licensed health professionals or other individuals authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the state in which the countermeasure was prescribed, administered, or dispensed; or (2) other persons identified in a declaration by the Secretary.

Importantly, the Act does **not** provide immunity from suit for claims involving “willful misconduct,” and it does not insulate Covered Persons from federal enforcement action. Further, it likely does **not** apply with respect to the provision of items or services that do not directly diagnose, mitigate, prevent, treat, or cure COVID-19 – although HHS has taken a broader view of what activities may be deemed to respond to COVID-19 in certain other contexts (e.g., for purposes of HHS Provider Relief Fund payments), the PREP Act limits the definition of “Covered Countermeasures” to include only “security countermeasures” and “qualified pandemic or epidemic products.” As pertinent here, a “qualified pandemic or epidemic product” means a drug or device that is (1) manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause; (2) manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by such a drug, biological product, or device; or (3) a product or technology intended to enhance the use or effect of such a drug, biological product, or device. That said, many states have temporarily waived or relaxed their usual restrictions on the provision of telehealth services for the duration of the pandemic, so federal immunity may not be necessary for providers to lawfully treat patients across state lines.¹

If you have questions about the PREP Act declaration or other legal issues affecting your telehealth practice, please contact Jolie Havens, Liam Gruzs, Jonathan Ishee, Mairi Mull, or your regular Vorys attorney.

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VORYS COVID-19 TASK FORCE

Vorys attorneys and professionals are counseling our clients in the myriad issues related to the coronavirus (COVID-19) outbreak. We have also established a comprehensive Coronavirus Task Force, which includes attorneys with deep experience in the niche disciplines that we have been and expect to continue receiving questions regarding coronavirus. Learn more and see the latest updates from the task force at [vorys.com/coronavirus](https://www.vorys.com/coronavirus).

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¹ For your convenience, information on the various state waivers is available from the Federation of State Medical Boards here: <https://www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirements-for-telehealth-in-response-to-covid-19.pdf>. Vorys has not independently verified this information and makes no representations regarding its accuracy or completeness.