

CLIENT ALERT

Massachusetts Governor Affirmatively Employs PREP Act Protections in State Healthcare System

Apr.11.2020

On April 8, 2020, Massachusetts Governor Charlie Baker exercised his powers as an “Authority Having Jurisdiction” to issue a directive designating specific activities to which Public Readiness and Emergency Preparedness (“PREP”) Act immunity will apply in Massachusetts. The PREP Act provides expansive immunity from liability for claims of loss related to designated “Covered Countermeasures,” and was recently activated with respect to medical countermeasures against COVID-19 pursuant to a declaration issued by the Secretary of the Department of Health and Human Services. However, certain restrictions apply, and there is little precedent to provide guidance as to how PREP Act immunity may attach in practice.

Governor Baker’s directive, which is retroactive to March 10, 2020, clarified a critical question for PREP Act immunity, at least within Massachusetts: In the absence of federal authorization, how does this immunity apply for state-level use of Covered Countermeasures?

Per the PREP Act declaration issued by the Secretary of the Department of Health and Human Services, liability immunity applies broadly to the development, testing, manufacture, distribution, administration, and use of Covered Countermeasures, but only if they are “related to” “[a]ctivities authorized in accordance with the public health and medical response” of an “Authority Having Jurisdiction.” An Authority Having Jurisdiction is defined as a public agency or delegate that has legal responsibility and authority to respond following a Declaration of Emergency. The Governor of Massachusetts qualifies as an “Authority Having Jurisdiction.”

The Massachusetts directive served to delineate exactly which “activities” are “authorized in accordance with the public health and medical response” in the Commonwealth. These activities are:

- a. The prescription, administration, delivery, distribution, or dispensing of Covered Countermeasures by a Health Care Professional for the treatment, diagnosis, prevention, and mitigation of COVID-19; and
- b. The prescription, administration, delivery, distribution, or dispensing of Covered Countermeasures as part of any program established, supervised, or administered by a Health Care Facility for the treatment, diagnosis, prevention, or mitigation of COVID-19 or as part of the Commonwealth’s response to the COVID-19 outbreak. This designation shall include authorization for the activities of Program Planners who supervise and administer such programs.

The directive defines “Health Care Professionals” to include any licensed, registered, or certified health care or emergency worker, including supervised students and trainees, so long as they are providing health care services in response to the COVID-19 pandemic or are working under the direction of the Massachusetts Emergency Management Agency or the Massachusetts Department of Public Health in response to the state of emergency.

The term “Health Care Facility” is even more broadly defined, to include state and private hospitals, psychiatric hospitals, skilled nursing facilities, assisted living homes, rest homes, community health centers, certain home health agencies, and any other site designated by the Commissioner of Public Health to provide COVID-19 health care services.

The directive does not override other PREP Act requirements and applicability. Accordingly, products distributed in the state pursuant to a federal contract would receive PREP Act immunity even if they fell outside of the scope of this directive, so long as they satisfied all of the other criteria listed in the Act. Furthermore, liability immunity does not apply to acts of “willful misconduct,” which is defined as any act or omission that is taken 1) intentionally to achieve a wrongful purpose; 2) knowingly without legal or factual justification; and 3) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

Governor Baker’s directive helps to make clear how and when PREP Act protections will apply in Massachusetts, thereby incentivizing the distribution and use of countermeasures to help combat the spread of COVID-19, and to facilitate treatment of those battling the illness. Although other states have issued orders granting immunity to health care professionals for acts performed in response to COVID-19, Massachusetts is one of the only states to specify the scope of the PREP Act’s more expansive immunity at the state level.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

Rebecca Baden Chaney

Partner – Washington, D.C.
Phone: +1 202.624.2772
Email: rchaney@crowell.com

Cheryl A. Falvey

Partner – Washington, D.C.
Phone: +1 202.624.2675
Email: cfalvey@crowell.com

John Fuson

Partner – Washington, D.C.
Phone: +1 202.624.2910
Email: jfuson@crowell.com

Scott L. Winkelman

Partner – Washington, D.C.
Phone: +1 202.624.2972
Email: swinkelman@crowell.com

Clifford J. Zatz

Partner – Washington, D.C.
Phone: +1 202.624.2810
Email: czatz@crowell.com

Stephanie L. Crawford

Associate – Washington, D.C.
Phone: +1 202.624.2811
Email: scrawford@crowell.com

Mariam Sarwar

Associate – Los Angeles
Phone: +1 213.443.5570
Email: msarwar@crowell.com