Designation of Authorized Health Care Activities Pursuant to the PREP Act

Pursuant to the federal Public Readiness and Emergency Preparedness Act (“PREP Act”), the Secretary of the U.S. Department of Health and Human Services issued a Declaration providing immunity from liability to certain individuals and entities against claims arising out of the manufacture, testing, development, distribution, administration, or use of Covered Countermeasures to address the COVID-19 outbreak. 85 Fed. Reg. 15198 (Mar. 17, 2020). The Secretary’s Declaration provides that the immunity extends to activities authorized by the “Authority Having Jurisdiction” to prescribe, administer, deliver, distribute, or dispense “Covered Countermeasures” following a declaration of an emergency. *See id.* at 15202, § VII(b).

As Governor and the Authority Having Jurisdiction to direct the Commonwealth of Massachusetts’s response to the COVID-19 outbreak, I hereby designate the following activities as authorized in accordance with the Commonwealth’s public health and medical response to the COVID-19 outbreak following my declaration of a state of emergency on March 10, 2020:

1. 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
2. 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 effect of these designations shall be to provide the covered persons and entities with civil immunity to the fullest extent provided in the PREP Act in their efforts to contribute to the Commonwealth’s public health and medical response to the COVID-19 outbreak.

Accordingly, a Health Care Professional and a Health Care Facility shall be immune from suit or civil liability for any harm caused by, arising out of, relating to, or resulting from such Professional’s or Facility’s authorized activities as defined above, except for harm caused by willful misconduct as defined in 42 U.S.C. § 247d–6d(c). This immunity shall extend to any Program Planner involved in the supervision or administration of Health Care Facility programs for the treatment, diagnosis, prevention, or mitigation of COVID-19.

For the purposes of this designation, the following words have the following meanings:

“Covered Countermeasure”, has the meaning set forth in Section VI of the Secretary of the U.S. Department of Health and Human Services’ Notice of Declaration under the PREP Act for medical countermeasures against COVID-19: “any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID–19, or the transmission of SARS-CoV–2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product. Covered Countermeasures must be ‘qualified pandemic or epidemic products,’ or ‘security countermeasures,’ or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.” 85 Fed. Reg. 15202.

“Health care facility”, means:

1. Hospitals, including acute and chronic disease rehabilitation hospitals, as licensed under section 51 of chapter 111 of the General Laws;
2. State hospitals, mental health centers and other mental health facilities under the control of the department of mental health pursuant to section 7 of chapter 19 of the General Laws;
3. Hospitals operated by the Department of Public Health pursuant to chapter 62I of the General Laws, section 69E of chapter 111 of the General Laws, and chapter 122 of the General Laws;
4. Psychiatric Hospitals, as licensed under section 19 of chapter 19 of the General Laws;
5. Skilled Nursing Facilities, as licensed under section 71 of chapter 111 of the General Laws;
6. Assisted Living Residences, as defined in section 1 of chapter 19D of the General Laws;
7. Rest Homes, as referenced in section 71 of chapter 111of the General Laws;
8. Community Health Centers, as defined in 130 CMR 405.000 and Mental Health Centers, as defined in 130 CMR 429.000;
9. Home Health Agencies that participate in Medicare; or
10. A site designated by the Commissioner of Public Health to provide COVID-19 health care services, including, without limitation, step-down skilled nursing facilities, field hospitals, and hotels.

“Health Care Professional”, a licensed, registered, or certified health care or emergency worker, whether compensated or uncompensated, who (i) is providing health care services in response to the COVID-19 outbreak; or (ii) is working under the direction of the Massachusetts Emergency Management Agency or the Massachusetts Department of Public Health in response to the Commonwealth’s state of emergency; provided that the Health Care Professional acts within the scope of his or her license, registration, or certification, as those licenses have been modified by Executive Order or by Order of the Commissioner of Public Health. Health Care Professional includes a student or trainee in an approved health care professional services academic program who is performing services under the supervision of the program, and as part of an education and training course offered by the program, and unlicensed individuals authorized to practice nursing pursuant to an order of the Commissioner of Public Health.

“Program Planner”, a state or local government, including an Indian tribe; a person employed by the state or local government; or any other person or entity who supervises or administers a program for the treatment, diagnosis, prevention, and mitigation of COVID-19, including a person who establishes requirements, provides policy guidance, or supplies technical or scientific advice or assistance or provides a facility for the treatment, diagnosis, prevention, and mitigation of COVID-19.  For the purposes of this definition, a private sector employer or community group or other “person” can be a program planner when it carries out the described activities.

The provisions of this designation shall be effective as of March 10, 2020. Nothing in this designation shall be construed to invalidate or diminish any immunity or protection provided by the PREP Act or other applicable law.

Given in Boston at \_\_\_\_\_ PM this 8th day of April, two thousand and twenty

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Charles D. Baker

Governor

Commonwealth of Massachusetts