OFFICE OF
THE GOVERNOR

NO. 23 FY 19/20
DATE March 26, 2020

AN ORDER SUSPENDING PROVISIONS OF THE MAINE PHARMACY ACT AND RELATED RULES IN ORDER TO FACILITATE THE CONTINUATION OF OUT-OF-STATE CLINICAL TRIALS OF INVESTIGATIONAL DRUGS DURING THE COVID-19 PANDEMIC

WHEREAS, the spread of the novel coronavirus disease referred to as COVID-19 has created a public health emergency; and

WHEREAS, COVID-19 is a highly contagious and sometimes fatal disease that has already infected over 55,000 persons and caused over 700 deaths in the United States; and

WHEREAS, on March 11, the COVID-19 outbreak was characterized as a pandemic by the World Health Organization; and

WHEREAS, on March 15, Governor Janet T. Mills declared a State of Civil Emergency in Maine to respond to the spread of COVID-19;

WHEREAS, the escalating COVID-19 public health emergency is likely to continue and necessitate that Maine residents curtail their movement and social interaction in order to mitigate the transmission of COVID-19; and

WHEREAS, during the state of emergency, individuals complying with state recommendations to shelter at home in order to slow the spread of COVID-19 may not be able to attend out-of-state health care appointments and treatment, and it is particularly inadvisable for Maine residents with compromising health conditions to travel to participate in out-of-state clinical trials of investigational drugs dispensed by pharmacies; and

WHEREAS, Maine residents who are currently participating in out-of-state clinical trials of investigational drugs dispensed by pharmacies not licensed in Maine may lose access to these drugs unless requirements for licensure under the Maine Pharmacy Act are modified or suspended to permit shipment of these investigational drugs to Maine residents by out-of-state dispensers; and

WHEREAS, 37-B M.R.S.§ 742(1)(C)(1) and (13)(c) authorize the Governor during a state of emergency declared due to the outbreak of COVID-19, to modify or suspend the requirements for professional or occupational licensing or registration by any agency, board, or commission if strict compliance with such requirements would in any way prevent, hinder, or delay necessary action in dealing with the emergency; and

WHEREAS, pursuant to this authority and the general emergency management powers of the Governor under law, the temporary suspension of selected state laws and rules is necessary to facilitate the response to the current public health situation.

NOW, THEREFORE, I, Janet T. Mills, Governor of the State of Maine, pursuant to 37-B M.R.S. Ch. 13, including but not limited by 37-B M.R.S. § 742(1)(C)(1) and (13)(c), do hereby Order the following:

I. ORDER

The relevant provisions of Maine Revised Statutes, Title 32, Chapter 117, including but not limited to §13751 and related rules as they apply to mail order pharmacies, are hereby suspended to the extent necessary to allow any out-of-state entity, which is dispensing an investigational drug necessary to conduct a clinical trial, to ship the investigational drug to any Maine resident participating in the trial provided that:

A. The clinical trial is subject to the authority of an institutional review board constituted in accordance with 45 C.F.R. Part 46 and/or 21 C.F.R. Part 56;

B. The entity is licensed to dispense prescription drugs in its state of location;

C. The entity is in good standing with the applicable licensing authority; and

D. Any Maine resident to whom the entity ships the investigational drug is unable to retrieve the drug from the out-of-state entity due to the public health emergency.

The Commissioner of the Department of Professional and Financial Regulation and the Maine Board of Pharmacy are directed to issue forthwith guidance to implement the provisions of this Order.

II. EFFECTIVE DATE

This Order is effective March 26, 2020 and shall remain in effect until rescinded or until the State of Civil Emergency to Protect Public Health is terminated, whichever occurs first.

Janet T. Mills
Governor