

COVID-19: PENNSYLVANIA - EXECUTIVE ORDER ON PPE AND MEDICAL SUPPLIES

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U.S. Health Care Alert

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As of April 20, 2020 there were over 32,000 confirmed cases of COVID-19 in Pennsylvania.¹ In an effort to ensure hospitals and other facilities have the personal protective equipment (“PPE”) and supplies needed to fight COVID-19, on April 8, 2020 Pennsylvania Governor Tom Wolf signed an executive order intended to provide for targeted distribution of such supplies if necessary.² Governor Wolf asserted that the order would allow the “transfer of supplies and information between medical facilities to both high-population, high-impact areas and lower population areas that might not have as many existing medical resources.”³

ACTIONS TO DATE

The order details that as of April 5, the state has already procured over \$24 million in PPE and supplies using emergency procedures.⁴ Additional supplies have been received from the U.S. Department of Health and Human Services Strategic National Stockpile.⁵ Two additional field medical systems have been established with the support of the Federal Emergency Management Agency and the U.S. Army Corps of Engineers.⁶ Pennsylvania also has a Statewide Mutual Aid Agreement, which facilitates resource transfers between regions and healthcare facilities.⁷ The order notes that all Pennsylvania hospitals and most skilled nursing facilities are signatories to the agreement.⁸

THE EXECUTIVE ORDER – ALLOCATION AND EFFECTIVE USE OF CRITICAL MEDICAL RESOURCES ISSUED ON APRIL 8, 2020

The order was issued pursuant to section 7301(f)(4) of the Emergency Management Services Code, which reads:

Subject to any applicable requirements for compensation under section 7313(10) (relating to powers and duties), [the Governor may] commandeer or utilize any private, public or quasi-public property if necessary to cope with the disaster emergency.⁹

The order authorizes the Pennsylvania Emergency Management Agency (“PEMA”) and other state agencies to commandeer and utilize all PPE, pharmaceuticals, and other medical resources (collectively, “Medical Supplies”) from “private, public, and quasi-public health care providers and facilities, as well as manufacturers and suppliers of PPE, pharmaceuticals, and other medical resources (collectively, “Medical Entities”) located within the Commonwealth of Pennsylvania.”¹⁰ The order requires Medical Entities to:

- As directed by PEMA, submit a current (and as requested, subsequent) inventory of PPE, pharmaceuticals, and other medical resources by 11:59 on April 16, 2020.
- Report information as directed by PEMA or the Department of Health (“DOH”) and cooperate in data sharing and information exchanges.¹¹

Using such information, PEMA and other state agencies will coordinate the use of identified Medical Supplies.¹² While the state has the authority under Sec. 7313(10) and Sec. 7301(f)(4) of the Emergency Management Code as stated in the order, it does provide for payment to affected manufacturers as required by law. Therefore, Medical Entities will be compensated at a rate based on the average local price of the item during the week prior to March 6.¹³ State agencies will provide such payment under the terms and conditions agreed upon with the Medical Entity.¹⁴ The text of the order does not contemplate exceptions to the inventory and reporting requirements for Medical Entities.¹⁵

A DOH website now has an Inventory Collection Tool for Medical Entities to report. Also note that PEMA has a Critical Medical Supplies Procurement Portal for manufacturers, distributors, and suppliers to update the state on supplies available for purchase.

In an FAQ, the DOH clarifies that the order applies to:

- manufacturers
- suppliers (including national suppliers with stock based in Pennsylvania)
- physician practices
- hospitals
- skilled nursing facilities
- home health agencies
- ambulatory surgical facilities
- hospices
- end stage renal facilities
- other Department of Health licensees
- non-licensed healthcare facilities.¹⁶

Veterinary practices are also encouraged, but not required to comply with the order.¹⁷ Providers who have closed their offices are expected to provide an initial report, but will not need to make subsequent reports.¹⁸

How the order will be enforced is not specifically detailed, although the “Governor strongly believes that everyone included in this order will cooperate to assist the Commonwealth in addressing the pandemic.”¹⁹

RESPONSE TO THE ORDER

The Hospital and Healthsystem Association of Pennsylvania (“HAP”) released a statement expressing optimism that the order would make use of “existing infrastructure,” such as the statewide mutual aid agreement, to “ensure that critical resources and supplies are distributed quickly and efficiently.”²⁰ HAP, in conjunction with the DOH, manages the statewide mutual aid agreement.²¹

The Pennsylvania Association of Staff Nurses and Allied Professionals supported the order, as protection against the hoarding of PPE.²² However, the president of the Pennsylvania Manufacturers Association and the president of the Pennsylvania Chemistry Industry Council were both critical of the order.²³ Smaller, rural hospitals are equally concerned by this order for fear those systems will deplete inventory that will go to larger urban areas that have immediate needs.

One of the first state executive orders of its kind during the COVID-19 pandemic, Governor Wolf’s action echoes the order issued by Governor of New York Andrew Cuomo on April 7, 2020.²⁴ However, Cuomo went farther, stating that if necessary he would utilize the National Guard to redistribute supplies.²⁵ However, legality of Wolf’s order is being questioned. For instance, some have suggested that Section 7301(f)(4) of the Emergency Management Services Code may violate the non-delegation doctrine, that the order does not reflect an evidentiary basis for concluding that commandeering supplies is ‘necessary’ to ‘cope’ with the COVID-19 situation, and that the order may not provide for legally sufficient levels of compensation in exchange for the supplies.

Pennsylvania’s order is broad in regards to the types of pharmaceuticals included because it is unknown at this point which pharmaceuticals could become necessary. Since the order is broad as initially issued, the agency authorized for implementing (PEMA and/or DOH) will subsequently issue more details. However, the federal government has addressed this under the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”), which was recently passed by Congress and signed by the President in response to the COVID-19 pandemic, requiring drug manufacturers to report additional information about the amounts of medicines manufactured at registered establishments to the FDA in an effort to help the agency address and mitigate against medicine shortages. The CARES Act also requires manufacturers of certain medicines to have risk management plans in place to evaluate risks to the supply of those medicines.

CONCLUSION AND HOW WE CAN HELP

Stakeholders can access the Executive Order and additional guidance below:

[Executive Order](#)

[Department of Health FAQ](#)

[Pennsylvania Emergency Management Agency](#)

K&L Gates lawyers and government affairs professionals will continue to closely monitor and track policy proposals, compliance regulations, and penalty provisions pursuant to the general enforcement authority of the order. These efforts include assisting with the development and refinement of legislative proposals and messaging; facilitating client engagement with the state legislature, the executive branch, advocacy groups, and stakeholders; and identifying opportunities for clients to serve as trusted advisors and thought leaders.

K&L Gates’ health care practice assists residential, outpatient, and facility-based providers and private equity investors in the health care industry with legal advice, including licensure, certification, reimbursement, regulatory compliance, transactional due diligence, and strategic considerations. Our team pairs its substantive experience

in health care law and policy with the political insights of more than 50 bipartisan lawyers and government affairs professionals to develop comprehensive advocacy and legal strategies for our clients.

The present uncertainty concerning the current landscape only highlights the importance of staying engaged and active as state and federal government restrictions and policy proposals begin to take shape. K&L Gates' public policy and law and health care and FDA practices are ready to assist stakeholders engage in the debate on these proposals and develop government relations and regulatory strategies to position them in the months ahead. Additionally, up-to-date information and resources regarding the broader legal landscape surrounding the impact of COVID-19, generated by K&L Gates professionals in a variety of practices.

FOOTNOTES

¹ Pennsylvania Department of Health, Coronavirus (COVID-19) (April 13, 2020).

² Executive Order 2020-408, *Order Of The Governor Of The Commonwealth Of Pennsylvania To Ensure The Efficient Allocation And Effective Use Of Critical Medical Resources* (April 8, 2020).

³ Press Release, *Gov. Wolf Signs Order to Provide Targeted Distribution of COVID-19 PPE and Supplies to Hospitals*, April 8, 2020.

⁴ See *supra* note 2.

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ 35 Pa.C.S. § 7301(f)(4). Section 7313(10) authorizes PEMA to “plan and make arrangements for the availability and use of any private facilities, services and property and, if necessary and if in fact used, provide for payment for use under terms and conditions agreed upon.”

¹⁰ *Supra* note 2.

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*

¹⁵ See *id.*

¹⁶ Pennsylvania Department of Health, *Frequently Asked Questions: Executive Order for Targeted Distribution of COVID-19 PPE and Supplies*.

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ The Hospital and Healthsystem Association of Pennsylvania, Press Release, *HAP Statement on Governor Wolf's COVID-19 Executive Order*, April 8, 2020.

²¹ The Hospital and Healthsystem Association of Pennsylvania, *State Fact Sheet: Emergency Preparedness in Pennsylvania*, March 1, 2018.

²² Paul Gough, *Strong reaction to governor's order to commandeer PPEs for targeted distribution*, PITTSBURGH BUSINESS TIMES (April 8, 2020).

²³ *Id.*

²⁴ Executive Order 202.14, *Continuing Temporary Suspension and Modification of Laws Relating to the Disaster Emergency* (April 7, 2020).

²⁵ Marie French, *Cuomo plans to use National Guard to seize ventilators from upstate facilities*, POLITICO (April 3, 2020).

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