



ORDER OF THE SECRETARY OF HEALTH REQUIRING REPORTING OF DATA RELATED TO EACH ADMINISTRATION OF AN IMMUNIZATION FOR COVID-19

The 2019 novel coronavirus (COVID-19) is a contagious disease that spreads rapidly from person to person throughout the world, the United States, and this Commonwealth. COVID-19 can be transmitted from any person who is infected, even if they have no symptoms. Additionally, exposure is possible by touching a surface or object that has the virus on it and then touching one's mouth, nose, or eyes. Symptoms of COVID-19 may include fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, or diarrhea. Older adults and people who have serious chronic medical conditions are at a higher risk for serious illness.

Case numbers of COVID-19, along with the number of deaths attributable to the disease, are again increasing in the Commonwealth. The lack of a vaccine necessitated the Commonwealth's severe mitigation methods in the early stages of the pandemic, when the initial surge of the disease took a severe toll on the health care systems of surrounding states and endangered the lives of the most vulnerable Commonwealth residents. The steady increase of the virus at the present time has reached an all time high and still requires the continued practice of social distancing, masking, and other disease control methods. The introduction of an effective vaccine or vaccines is the least restrictive way to combat the pandemic and would allow Pennsylvanians to return to everyday pursuits with less fear of infection for themselves and their families. The Commonwealth, following the assurances of the federal government, anticipates that one or more effective vaccines to protect against disease will be introduced within a short period of time.

COVID-19 is a threat to the public's health, for which the Secretary of Health may order general control measures, including, but not limited to, closure, isolation, and quarantine. This authority is granted to the Secretary of Health pursuant to Pennsylvania law. See section 5 of the Disease Prevention and Control Law of 1955 ("the Act"), 35 P.S. § 521.5; sections 2102(a) and 2106 of the Administrative Code of 1929, 71 P.S. §§ 532(a), and 536; and the Department of Health's regulations at 28 Pa. Code §§ 27.60-27.68 (relating to disease control measures; isolation; quarantine; movement of persons subject to isolation or quarantine; and release from isolation and quarantine). Particularly, the Department of Health has the authority to take any disease control measure appropriate to protect the public from the spread of infectious disease. See 35 P.S. § 521.5; 71 P.S. §§ 532(a), and 1403(a); 28 Pa. Code § 27.60.

COVID-19 is a reportable disease under the Act and accompanying regulations. 35 P.S. §§ 521.2 and 521.4; see also 28 Pa. Code §§ 27.3, 27.4, 27.21a and 27.22. Requiring that each immunization of COVID-19 be reported to the Department will enable the Department to prevent and control the spread of that disease in the Commonwealth. With the data to be reported as directed in this Order, the Department will be

able to track the safety of a vaccine, including whether the vaccine has been stored appropriately at the right temperatures to remain effective (at least one vaccine under development must be stored in ultracold conditions in order to remain effective); the providers that received shipments of the various lots of vaccine; the locations to which additional shipments should be sent, particularly when a second dose of the same vaccine is required to complete the immunization; as well as manage any necessary recalls of vaccine lots.

In addition, in order to obtain the vaccine from the federal government, the Department is required to report certain information to the CDC. The CDC has stated that the reported information will enable it to ship the appropriate amounts and types of vaccine to each state, in the event that immunization requires that an individual receive more than one dose, and that individual crossed jurisdictional boundaries.

Accordingly, on this day, December 14, 2020, in order to prevent and control the spread of disease, I hereby order:

Section 1: Definitions:

- A. *Health care facility*-- A chronic disease, or other type of hospital, a home health care agency, a hospice, a long-term care nursing facility, a cancer treatment center using radiation therapy on an ambulatory basis, an ambulatory surgical facility, a birth center, and an inpatient drug and alcohol treatment facility, regardless of whether the health care facility is operated for profit, nonprofit or by an agency of the Commonwealth or local government.
- B. *Health care practitioner*--An individual who is authorized to practice some component of the healing arts by a license, permit, certificate or registration issued by a Commonwealth licensing agency or board.
- C. *Health care provider*--An individual, a trust or estate, a partnership, a corporation (including associations, joint stock companies and insurance companies), the Commonwealth, or a political subdivision, or instrumentality (including a municipal corporation or authority) thereof, that operates a health care facility.
- D. *Pharmacist* -- An individual duly licensed by the State Board of Pharmacy to engage in the practice of pharmacy under the Pharmacy Act, 63 P.S. §§ 390-1 – 390.13.

Section 2. Reporting of data related to the administration of an immunization deemed to be effective against COVID-19:

- A. A health care practitioner, health care provider, pharmacist, or other individual or entity authorized by state or federal law, regulation or order to administer vaccine, who has entered or intends to enter into a provider agreement with the Commonwealth or with the Federal government, or both, to receive and administer an immunization effective against COVID-

19 (COVID-19 immunization provider) shall report data related to each administration of an immunization for COVID-19 to the Department through the Department's Pennsylvania Statewide Immunization Information System (PA SIIS).

- B. An individual or entity that is or intends to become a COVID-19 immunization provider that does not currently have access to PA SIIS will be contacted by the Department with instructions on how to register and onboard users.
- C. A COVID-19 immunization provider shall report the following information into PA SIIS within 24 hours of administering a COVID-19 immunization:
 - Patient Information
 - First, middle and last names
 - Date of birth
 - Gender
 - Race and ethnicity
 - Address (street, city, county, state, zip)
 - Primary phone number
 - Vaccine Administration Information
 - Lot number, expiration date, CVX and MVX codes
 - Date of vaccine
 - Route of vaccine administration
 - Body site of vaccine administration
- D. Within 24 hours of receipt of inventory or administration of a vaccine, a COVID-19 immunization provider shall access the PA SIIS web application to record receipt of shipments of COVID-19 immunization inventory, to record reduction in inventory levels as vaccines are administered, and to reconcile inventory levels.
- E. A COVID-19 immunization provider must submit a CDC Supplemental COVID-19 Vaccine Redistribution Agreement to the Department and receive the Department's approval before transferring COVID-19 vaccine inventory to another location of that provider or to another COVID-19 immunization provider. If the Department approves the redistribution plan, the COVID-19 immunization provider must update its inventory levels in PA SIIS to reflect the transfer of this inventory.
- F. A COVID-19 immunization provider shall inform its patients of the requirement to report information to PA SIIS and through PA SIIS to the CDC.

Section 3. Effective Date and Duration:

This Order is effective at 12:01 a.m. on December 15, 2020 and shall remain in effect until further notice.

Handwritten signature of Rachel L. Levine, MD, consisting of stylized cursive letters 'RL' followed by '22' and 'MD'.

Rachel L. Levine, MD
Secretary of Health