



**EMERGENCY REGULATION FOR
THE CONTROL AND PREVENTION OF COVID-19
SUPPLEMENTING THE REGULATION GOVERNING THE IMMUNIZATION AND
TREATMENT OF NEWBORNS, CHILDREN, AND ADOLESCENTS
(VACCINE INFORMATION STATEMENTS)**

WHEREAS, the Pennsylvania Disease Control and Prevention Act of 1955, 1956, April 23, P.L. 1510, 35 P.S. § 52.1 *et seq.*, (the “DCPA”) and Chapter 6-200 of The Philadelphia Code authorize the Board of Health to establish lists of reportable diseases and conditions, and further provide that the Board and the Department of Public Health are responsible for implementing appropriate disease control and prevention measures in order to limit the spread of disease in an epidemic emergency; and

WHEREAS, on March 6, 2020, in response to the 2019 novel coronavirus disease, COVID-19, the Governor of Pennsylvania issued a Proclamation of Disaster Emergency, and on March 11, 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, or global epidemic; and

WHEREAS, on March 12, 2020, the Board added COVID-19 to the City’s list of reportable and quarantinable diseases; and

WHEREAS, there have been more than 16,000 COVID-19 hospitalizations and 3,500 COVID-19 deaths in Philadelphia since the beginning of the pandemic; and

WHEREAS, on January 20, 2021, the Philadelphia Board of Health approved a “Consolidated and Restated Supplemental Emergency Regulation Governing the Control and Prevention of COVID-19 (Consolidated Safer at Home Restrictions and Delegation of Authority),” which expressly authorized the Health Commissioner to issue such additional orders as the Health Commissioner determines are necessary or appropriate control or prevention measures to limit the spread of COVID-19; and

WHEREAS, safe, highly effective COVID-19 vaccines are now widely available in the United States; and

WHEREAS, administration of a COVID-19 vaccine is a medically accepted form of prophylactic treatment that dramatically reduces the likelihood of experiencing a symptomatic SARS-CoV-2 infection, and recent studies show that available COVID-19 vaccines also reduce asymptomatic infection and transmission; and

WHEREAS, broad distribution and uptake of COVID-19 vaccines is essential to ending the COVID-19 pandemic; and

WHEREAS, Section 4 of the Board of Health’s *Regulations Governing the Immunization and Treatment of Newborns, Children, and Adolescents* authorizes minors 11 and older who are able to give informed consent to consent to receive a vaccine for a reportable disease, such as COVID-19, and requires that they be provided with a Vaccine Information Statement (“VIS”) for such vaccine; and

WHEREAS, similarly, Pennsylvania’s Minors’ Consent to Medical Care Act, 35 P.S. § 10103, and the Pennsylvania Code, 28 Pa. Code § 27.97, authorize minors to give consent for medical and health services to treat reportable diseases, such as COVID-19; and

WHEREAS, a VIS is a document produced by the U.S. Centers for Disease Control and Prevention (the “CDC”) that provides information to vaccine recipients about the vaccine they are receiving, but a VIS is not available for any of the COVID-19 vaccines currently authorized under an Emergency Use Authorization (“EUA”) issued by the U.S. Food and Drug Administration (the “FDA”); and

WHEREAS, an FDA-issued COVID-19 Fact Sheet for Recipients and Caregivers contains information similar to the information provided by a VIS and the CDC has identified it as the appropriate substitute for a VIS with respect to COVID-19 vaccines currently authorized for emergency use by the FDA; and

WHEREAS, at least one COVID-19 vaccine has been authorized under an EUA for people sixteen years of age and older since December 2020; and

WHEREAS, on April 21, 2021, the Health Commissioner issued an Emergency Order Concerning COVID-19 Vaccine Information Statements, which clarified that an FDA-issued COVID-19 Fact Sheet for Recipients and Caregivers is an appropriate substitute for a VIS for purposes of Section 4 of the Board of Health’s *Regulations Governing the Immunization and Treatment of Newborns, Children, and Adolescents*; and

WHEREAS, on May 10, 2021, the FDA authorized a COVID vaccine for use in people twelve years of age or older pursuant to an EUA; and

WHEREAS, the Board of Health hereby reaffirms, consistent with Section 4 of its *Regulations Governing the Immunization and Treatment of Newborns, Children, and Adolescents*, that minors eleven (11) years of age and older are typically capable of providing informed consent on their own behalf to be vaccinated for a reportable disease, subject to a vaccine provider’s individual determination that the minor is able to and does provide such informed consent, and the Board hereby clarifies that an FDA-issued COVID-19 Fact Sheet for Recipients and Caregivers is an appropriate substitute for a VIS; and

NOW, THEREFORE, the Board of Health hereby adopts the following emergency regulation, effective upon delivery to the Department of Records, while the remaining procedures and formalities of Section 8-407 are followed to promulgate this as a formal regulation:

Section 1. Temporary Emergency Supplement to Board of Health Regulations Governing the Immunization and Treatment of Newborns, Children, and Adolescents

With respect to a minor eleven (11) years of age or older, the Emergency Use Authorization Fact Sheet for Recipients and Caregivers for a COVID-19 vaccine authorized by the U.S. Food and Drug Administration for use in persons of the age of the vaccine recipient, if and when such an authorization exists, may be provided for the purposes of Section 4 of the Board of Health's *Regulations Governing the Immunization and Treatment of Newborns, Children, and Adolescents*, when a Vaccine Information Statement does not exist for the COVID-19 vaccine being administered.

Section 2. Interaction With April 21, 2021 Emergency Order Concerning COVID-19 Vaccine Information Statements

This regulation approves of and supersedes the April 21, 2021 Emergency Order Concerning COVID-19 Vaccine Information Statements. The Health Commissioner remains authorized to issue emergency orders as appropriate to control the spread of COVID-19 consistent with the authority provided by the Board's Consolidated and Restated Supplemental Emergency Regulation Governing the Control and Prevention of COVID-19 (Consolidated Safer at Home Restrictions and Delegation of Authority).

Section 3. Effective Date and Duration

This regulation shall be effective immediately upon filing with the Department of Records and shall remain in effect indefinitely, until rescinded, superseded, or amended by further regulation.