

**STATE OF NEW JERSEY
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS**

**ADMINISTRATIVE ORDER AND NOTICE OF RULE ADOPTION AND WAIVER
PURSUANT TO P.L. 2020, c. 18**

**COVID IMMUNIZATION ADMINISTRATION BY HEALTH CARE
PRACTITIONERS-IN-TRAINING**

**DCA Administrative Order No. 2021-12 and DCA Waiver No. 2021-07
Superseding DCA Administrative Order No. 2021-08 and DCA Waiver No. 2021-04**

Administrative Order and Temporary Rule Adoption and Waiver by Kaitlin A. Caruso, Acting Director, Division of Consumer Affairs

Date: May 20, 2021

Authority: P.L. 2020, c. 18

Effective Date: May 20, 2021

Expiration Date: Concurrent with the end of the state of emergency or the public health emergency declared pursuant to Executive Order No. 103 (2020) (EO 103), whichever is later.

* * *

WHEREAS, on March 9, 2020, through EO 103, the facts and circumstances of which are adopted by reference herein, Governor Murphy declared both a public health emergency and a state of emergency throughout the State due to the public health hazard posed by coronavirus disease 2019 (COVID-19), and authorized agency heads to waive, suspend, or modify existing rules where enforcement would be detrimental to the public interest during the emergency; and

WHEREAS, the public health emergency declared in EO 103 has been extended most recently by Executive Order No. ___ (2021), issued on May ___, 2021, and continues to exist today; and

WHEREAS, on April 14, 2020, Governor Murphy signed into law P.L. 2020, c. 18, which permits the Director of the Division of Consumer Affairs (Director) to issue administrative orders to suspend temporarily any provision of Title 45 of the Revised Statutes or suspend or modify temporarily any rule adopted pursuant to such authority, or to adopt temporarily any rule relating to the practice of any profession licensed or certified by a board in the Division of Consumer Affairs (Division), upon concurrence by the Attorney General, after determining that such order is necessary to promote the public welfare and further such other purposes of the state of emergency or public health emergency declared in EO 103; and

WHEREAS, New Jersey submitted to the Centers for Disease Control and Prevention (CDC) a required Interim COVID-19 Vaccination Plan (Plan) in October 2020, which was updated on December 15, 2020; and

WHEREAS, the Plan aims to provide equitable access to vaccines to all who live, work, and/or are educated in New Jersey; achieve community protection against COVID-19; and build sustainable trust in COVID-19 vaccines and other vaccines; and

WHEREAS, the process of vaccinating the population to levels sufficient to establish community immunity is expected to take many months and will require comprehensive and aggressive State efforts to maximize the benefits of vaccination across all communities as quickly as feasible; and

WHEREAS, it is critically important that residents receive the full course of a COVID-19 vaccine as quickly as supply allows in order to optimize protection against COVID-19; and

WHEREAS, vaccines have now received Emergency Use Authorizations (EUAs) from the United States Food and Drug Administration (FDA) to combat the spread of COVID-19 and are being dispensed at many points of dispensing (PODs), including mega-sites, hospitals, pharmacies, and local boards of health across the State; and

WHEREAS, PODs are required to operate in a manner consistent with the Plan, implemented by the Department of Health (DOH) in Executive Directive 20-035 (DOH ED-20-035), through organizations that have entered into CDC COVID-19 Vaccine Provider Agreements, and are required to comply with operational requirements; and

WHEREAS, the supply of COVID-19 vaccines is expected to increase over the coming months, in part due to the FDA's anticipated issuance of EUAs for additional COVID-19 vaccines, making it necessary to ensure that there are sufficient numbers of health care providers at PODs to ensure that vaccines are distributed quickly; and

WHEREAS, encouraging States to expand scope of practice, where needed, for non-physician health practitioners, including but not limited to physician assistants, pharmacists, and registered nurses, to surge the COVID-19 vaccinator workforce is part of the National Strategy for the COVID-19 Response and Pandemic Preparedness (Jan. 2021); and

WHEREAS, on January 5, 2021, the Director issued Administrative Orders DCA AO 2021-01 and DCA AO 2021-02, which expanded the pool of health care providers available to administer COVID-19 vaccines to include pharmacists, pharmacy interns, pharmacy externs, and pharmacy technicians, specifying the obligations of supervising pharmacists; and

WHEREAS, on January 6, 2021, the New Jersey Commissioner of Health issued Executive Directive 20-037 (DOH ED-20-037), specifically authorizing physicians, physician assistants, dentists, nurses, pharmacists, and paramedics to administer COVID-19 vaccines and recognizing that ancillary health care personnel and health care providers-in-training could also perform

vaccination functions within their scope of practice or through a DCA Administrative Order setting forth training, supervision requirements and conditions for vaccination administration; and

WHEREAS, DOH ED-20-037 further requires that all health care providers who administer vaccines at PODs are to be provided with training by a physician, registered professional nurse, advanced practice nurse, physician assistant, or pharmacist proficient in reconstitution and drawing of medications in a manner consistent with the CDC's "COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals" and the FDA's COVID-19 vaccination guidance; and

WHEREAS, pursuant to DOH ED-20-037, those health care professionals charged with the responsibility to provide training also are charged with the responsibility to determine and validate vaccine administration knowledge, skill, and current competency of any health care providers before permitting them to administer a COVID-19 vaccine, including through the use of training materials available through the CDC website at <https://www.cdc.gov/vaccines/ed/index.html> and the Skills Checklist for Vaccine Administration available through the Immunization Action Coalition website at <https://www.immunize.org/catg.d/p7010.pdf>; and

WHEREAS, on February 19, 2021, I issued Administrative Order 2021-08 and DCA Waiver No. 2021-04, expanding the pool of health care providers available to administer COVID-19 vaccines, by setting forth the training, supervision requirements and conditions for vaccine administration by health care professionals-in-training, including medical, physician assistant, and nursing students; and

WHEREAS, the Public Readiness and Emergency Preparedness Act (PREP Act) was enacted on December 30, 2005, as Public Law 109– 148, Division C, § 2, and, on March 10, 2020, the United States Department of Health and Human Services (HHS) issued a Declaration under the PREP Act for medical countermeasures against COVID–19 (85 FR 15198, Mar. 17, 2020); and

WHEREAS, the HHS issued a 7th Amendment to the Declaration (7th Amendment) on March 10, 2021, which identified pharmacy, pharmacy intern, midwife, respiratory therapy, dental, podiatry, optometry, and veterinary students as categories of health care providers in training, in addition to the medical, nursing and physician assistant students enumerated in DCA AO 2021-08, who may be qualified to administer COVID-19 vaccines, subject to requirements that the student be determined to have appropriate training in administering vaccines by his or her school or training program, that the student is supervised by a currently practicing health care professional experienced in administering intramuscular injections, and subject to additional requirements specified in the 7th Amendment; and

WHEREAS, after having received training in compliance with the requirements of DOH ED-20-037 and subject to appropriate supervision, all of the above listed health care professionals-in-training, including but not limited to those specified in the 7th Amendment but not previously specified in AO 2021-08, should be recognized as capable of functioning as vaccinators at any PODs established in the State to administer COVID-19 vaccines; and

WHEREAS, the scope of practice of advanced practice nurses, physician assistants, and pharmacists includes the ordering and administration of vaccines, and the scope of practice of registered nurses includes administration of vaccines, and these classes of practitioners have the requisite training and experience to supervise the administration of vaccines and an ability similar to physicians to observe, assess, and take any necessary action regarding effectiveness, adverse reaction, or any emergency; and

WHEREAS, changes to AO 2021-08 are warranted to conform to the 7th Amendment and my determination that appropriately trained and supervised health care practitioners-in-training covered by the 7th Amendment should be recognized as capable of functioning as vaccinators at any PODs established in the State to administer COVID-19 vaccines;

NOW, THEREFORE, I, Kaitlin A. Caruso, Acting Director of the Division of Consumer Affairs, by virtue of the authority vested in me by the statutes of this State, and upon concurrence by the Attorney General, determine that this ORDER is necessary to promote the public welfare and further such other purposes for which the state of emergency and public health emergency were declared, and hereby ORDER as follows:

1. The following words and terms, when used in this Order, shall have the following meanings, unless the context clearly indicates otherwise:
 - a. “Authorized health care practitioner-in-training” means a student who is matriculated or actively enrolled in a school or training program for medical, nursing, pharmacy, pharmacy intern, midwife, physician assistant, respiratory therapy, dental, podiatry, optometry, or veterinary students in New Jersey or any other state.
 - b. “COVID-19 vaccine” means a vaccine that is either approved, authorized or licensed by the FDA and administered consistent with the Advisory Committee on Immunization Practices’ (ACIP) COVID-19 vaccine recommendation(s).
 - c. “Supervising health care practitioner” means a doctor of medicine (M.D.), a doctor of osteopathic medicine (D.O.), a registered professional nurse (R.N.), an advanced practice nurse (A.P.N.), a physician assistant (P.A.), or a pharmacist (R.Ph.) who is proficient in reconstitution and drawing of medications, who is currently licensed and practicing in the State and is experienced with administering intramuscular injections, who provides supervision at a POD to authorized health care practitioners-in-training, and assumes responsibility for ensuring that authorized health care practitioners-in-training administering COVID-19 vaccines at the POD are trained and have the requisite competency, skill, and knowledge to administer COVID-19 vaccines.
 - d. “Supervision” means that one or more supervising health care practitioners must be physically present at the POD, able to respond to an emergency and responsible for accuracy and safety with respect to the actions of the authorized health care practitioner-in-training.

2. Any provision(s) of any statute or rule that would preclude a health care practitioner-in-training from administering a COVID-19 vaccine in a manner consistent with the requirements of this Order, is hereby suspended, including N.J.S.A. 45:11-23, referencing a prescribed course of study and training in clinical programs for nurses, and N.J.A.C. 13:37-1.1(b)(6), pertaining to the ratio of students to faculty in clinical programs. Any other provisions of such statutes and rules remain in full force and effect.
3. Prior to directing authorized health care practitioners-in-training to administer a COVID-19 vaccine to a patient, a supervising health care practitioner shall ensure that the health care practitioner-in-training:
 - a. Has obtained from the health care practitioner-in-training's school or training program an attestation from the program director or a faculty member that the health care practitioner-in-training:
 - i. Is matriculated or enrolled in the school or training program;
 - ii. Is in good standing in that program;
 - iii. Has been determined to have attained appropriate training in administering vaccines.
 - b. Has been provided with training, consistent with the CDC's "COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals" and the FDA's COVID-19 vaccination guidance, or such other training as may be subsequently mandated by DOH.
 - c. Has the competency, knowledge, and skill to administer the relevant COVID-19 vaccine in accordance with its FDA approval or its EUA.
 - d. Such competency, knowledge, and skill are validated using training materials available through the CDC website at <https://www.cdc.gov/vaccines/ed/index.html>, including the COVID-19 Vaccine Administration Competencies Assessment Form available through the website, or as directed by DOH. For any healthcare practitioner-in-training who begins administering vaccines after the effective date of this superseding order, this validation shall also require the healthcare practitioner-in-training to have been subject to a period of observation, in which a currently practicing healthcare professional experienced in administering intramuscular injections, and for whom administering intramuscular injections is in their ordinary scope of practice, confirms competency of the healthcare practitioner-in-training in the preparation and administration of the COVID-19 vaccine(s) to be administered, by, at a minimum, observing at least five (5) vaccine administrations by the health care practitioner-in-training.
4. Prior to allowing authorized health care practitioners-in-training to administer a COVID-19 vaccine to a patient, a supervising health care practitioner shall ensure that:

- a. The patient to whom the authorized health care practitioner-in-training is administering the COVID-19 vaccine is screened using CDC-established criteria for each specific vaccine to be administered, including determining whether the patient has any contraindications or precautions to vaccination as determined by the ACIP and available at <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html>.
 - b. A review of the person's vaccination history, COVID-19 Vaccination Record Card, or the New Jersey Immunization Information System (NJIS) has been undertaken to ensure that: (1) the patient has not already received a full course of a COVID-19 vaccine from another health care provider and (2) if the patient is presenting for the second dose of a vaccine that requires two administrations, the timing of and product used for the second dose is appropriate.
 - c. The patient and/or the patient's representative, parent, or guardian has been counseled about contraindications and proper care of the injection site, and provided instructions to contact a primary care practitioner or emergency care facility in the event of an adverse reaction necessitating evaluation by a health care provider.
 - d. The patient and/or the patient's representative, parent, or guardian is provided with a vaccine information sheet and/or EUA fact sheets published by the CDC or FDA.
 - e. The patient and/or the patient's representative, parent, or guardian is informed that the administration of all COVID-19 vaccines must be reported to the NJIS.
5. When allowing authorized health care practitioners-in-training at a POD to administer COVID-19 vaccines, the supervising health care practitioner shall ensure that such health care practitioners-in-training:
 - a. Immediately report all potential adverse events to the supervising health care practitioner.
 - b. Comply with all recordkeeping requirements pertaining to the administration of COVID-19 vaccines.
 6. When directing an authorized health care practitioner-in-training to administer a COVID-19 vaccine, the supervising health care practitioner shall:
 - a. Provide authorized health care practitioners-in-training with supervision.
 - b. Document in detail and immediately report all clinically significant adverse events to the appropriate government reporting system within the time required by DOH, the FDA, and/or the CDC.
 - c. Ensure that a record identifying each patient is maintained.
 - d. Ensure that all vaccinations are timely reported to the NJIS and that all other vaccination reporting requirements imposed by the Division, DOH, and/or the CDC are satisfied,

including all requirements set forth in the POD's CDC COVID-19 Vaccination Program Provider Agreement with the CDC.

- e. Periodically report to the school or training program, on the health care practitioner-in-training's performance regarding the administration of COVID-19 vaccines, if requested.
 - f. Immediately report to the school or training program any conduct by the health care practitioner-in-training that does not comply with this Order or represents a potential risk to the health and safety of patients or other personnel at the POD, in which case such health care practitioner-in-training is disallowed from continuing to administer COVID-19 vaccines pursuant to this Order.
7. When allowing authorized health care practitioners-in-training to administer COVID-19 vaccines in a manner consistent with the requirements of this Order, supervising health care practitioners will be deemed to be acting within their scope of practice and not in violation of any professional practice act or N.J.S.A. 45:1-21(n) for aiding and abetting the unlicensed practice of a health care profession.
 8. When authorized health care practitioners-in-training are trained and determined to have the requisite competencies, knowledge, and skill to administer COVID-19 vaccines, and act in a manner consistent with the requirements of this Order, authorized health care practitioners-in-training will not be deemed to be engaging in the unlicensed practice of a health care profession.
 9. This Order hereby supersedes DCA Administrative Order No. 2021-08 and DCA Waiver No. 2021-04.

This Order shall take effect immediately, and remain in effect until the end of the state of emergency or public health emergency declared by the Governor in EO 103, whichever is later, unless expressly revoked or superseded by a subsequent Administrative Order issued by the Director of the Division of Consumer Affairs.



Date: May 20, 2021

Kaitlin A. Caruso, Acting Director