

**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
CERTIFIED MEDICAL ASSISTANTS**

DCA Administrative Order No. 2021-06 and DCA Waiver No. 2021-02

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

Date: February 19, 2021

Authority: P.L. 2020, c. 18

Effective Date: February 19, 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. 222 (2021), issued on February 17, 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), and are required to comply with operational requirements set forth in the CDC COVID-19 Vaccination Program Provider Agreement that each POD must enter into with the CDC; 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, concurrently with this Order, I am issuing an Administrative Order further expanding the pool of health care providers available to administer COVID-19 vaccines by recognizing that dentists, licensed practical nurses, and certified homemaker home health aides are trained to provide injections within their scope of practice and can provide vital support to the State's COVID-19 response by administering vaccines, and recognizing that providers not specifically referenced in DOH ED-037, including respiratory care therapists, perfusionists, podiatrists, optometrists, physical therapists, athletic trainers, and certain dental hygienists, once having been trained in accordance with DOH ED-20-037, can develop the competency, knowledge, and skill to safely administer COVID-19 vaccines; and

WHEREAS, concurrently with this Order, I am issuing an Administrative Order further expanding the pool of health care providers available to administer COVID-19 vaccines, by setting forth the training, supervision requirements and conditions for vaccination administration for health care professionals-in-training, including medical, physician assistant, and nursing students; and

WHEREAS, the State Board of Medical Examiners has established by regulation, at N.J.A.C. 13:35-6.4, the education and training qualifications for a certified medical assistant (CMA) to administer intradermal, intramuscular, and subcutaneous injections, which would include vaccines and related emergency medications to treat any severe acute vaccine reactions, including epinephrine; and

WHEREAS, pursuant to that rule, CMAs are required to have obtained a minimum of 330 hours of instruction and training, to include training in the administration of intramuscular and subcutaneous injection procedures, pertinent anatomy and physiology appropriate to injection procedures, choice of equipment, proper technique, hazards and complications, and emergency procedures; and

WHEREAS, more specifically, CMAs are required to have completed at least 10 hours of training in administering injections and satisfactory performance of at least 10 of each injection – intramuscular, subcutaneous, and intradermal; and

WHEREAS, these requirements demonstrate that CMAs are capable of functioning as vaccinators at any POD that may be established in the State to administer COVID-19 vaccines, subject to appropriate supervision; and

WHEREAS, although N.J.A.C. 13:35-6.4 authorizes a supervising physician to direct the administration of injections by CMAs within the physician’s medical office to the physician’s patients, no existing guidance addresses the delegation of tasks at PODs where COVID vaccines are being administered; and

WHEREAS, in addition, N.J.A.C. 13:35-6.4 requires that the physician examine each patient to determine the appropriate treatment including administration of an injection, assess the risks and direct all components of the treatment, including type of injection, dosage, method, and area of administration and other factors peculiar to the risks, such as avoidance of administration sites on certain parts of the body; and

WHEREAS, in addition, N.J.A.C. 13:35-6.4(d) limits the authority of a physician to direct the administration by a CMA of an injection of experimental drugs including any drug not having approval of the FDA; 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 the 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, the restrictions in N.J.A.C. 13:35-6.4 unduly limit the assistance that CMAs can provide in support of the State’s effort to vaccinate its residents and control the transmission of COVID-19; and

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. “Certified medical assistant” or “CMA” means a person who is a graduate of a post-secondary medical assisting education program accredited by a body recognized by the

Board of Medical Examiners in N.J.A.C. 13:35-6.4, which includes, at a minimum, 330 clock hours of instruction and encompasses training in the administration of intramuscular and subcutaneous injections; and who maintains current certification or registration from a body approved by the Board of Medical Examiners as reflected in N.J.A.C. 13:35-6.4.

- b. "COVID-19 vaccine" means a vaccine that is either approved or authorized 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, provides supervision at a POD to CMAs, and assumes responsibility for ensuring that CMAs 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 CMA.
2. The provisions of N.J.A.C 13:35-6.4 that (1) limit the setting in which physicians are authorized to direct CMAs to administer injections to a physician's office; (2) mandate that physicians make individualized patient-specific determinations with regard to the appropriateness of treatment; and (3) prohibit physicians from directing CMAs to administer a vaccine that has not received FDA approval, are suspended insofar as those provisions would otherwise preclude CMAs from administering COVID-19 vaccines in a manner consistent with this Order. Any other provisions of the rule remain in full force and effect.
3. Prior to directing a CMA to administer a COVID-19 vaccine to a patient, a supervising health care practitioner shall ensure that the CMA:
- a. Meets the qualifications set forth in paragraph 1(a) above.
 - 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 Training Modules, found at <https://www.cdc.gov/vaccines/covid-19/training.html>, and the Skills Checklist for Vaccine Administration available through the

Immunization Action Coalition website at <https://www.immunize.org/catg.d/p7010.pdf>, or as directed by DOH.

4. Prior to allowing a CMA to administer a COVID-19 vaccine to a patient, a supervising health care practitioner shall ensure that:
 - a. The patient to whom the CMA 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 any 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 CMAs at a POD to administer COVID-19 vaccines, the supervising health care practitioner shall ensure that such personnel:
 - a. Immediately report to them 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 CMAs to administer COVID-19 vaccines, the supervising health care practitioner shall:
 - a. Provide the CMA 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 NJIIS 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.
7. When directing a CMA 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 CMAs 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, CMAs will be deemed to be acting within their scope of practice and not engaging in the unlicensed practice of any other health care profession, to include without limitation the unlicensed practice of nursing and/or medicine.

This Order shall take effect immediately and shall 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: February 19, 2021

Kaitlin A. Caruso, Acting Director