## 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 ADDITIONAL HEALTH CARE PRACTITIONERS

## DCA Administrative Order No. 2021-07 and DCA Waiver No. 2021-03

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 available through the training materials CDC website at https://www.cdc.gov/vaccines/ed/index.html and the Skills Checklist Vaccine for 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 to expressly recognize that certified medical assistants, 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, although DOH ED-20-037 expressly identifies dentists to be "health care providers" authorized to administer COVID-19 vaccines, and dentists' current scope of practice includes the administration of medications, dentists are not authorized to conduct the requisite training at PODs or to determine the competency of other health care professionals who may, pursuant to Executive Directive or Administrative Order, administer a COVID-19 vaccine; and

WHEREAS, licensed practical nurses and certified homemaker home health aides, although not expressly authorized by N.J.S.A. 45:11-23 to independently administer vaccines, are authorized within their current scope of practice to administer vaccinations if that task is delegated and supervised by a registered nurse, advanced practice nurse, or physician; and

WHEREAS, respiratory care therapists are licensed pursuant to N.J.S.A. 45:14E-9 and are specifically included in the definition of "health care provider" set forth in the Emergency Health Powers Act (EHPA) at N.J.S.A. 26:13-2, and while their current scope of practice, as set forth at N.J.A.C. 13:44F-3.1, does not expressly include the authority to administer vaccines, it does

include authorization to administer medication and drugs under the direction of a physician, advanced practice nurse, or physician assistant, and accordingly, during the continued public health emergency, to facilitate the broadest deployment of COVID-19 vaccines as quickly as possible under the State's Vaccination Plan as implemented pursuant to DOH ED-20-035, with the training as referenced in DOH ED-20-037, respiratory care therapists can develop the competency, knowledge, and skill to safely administer COVID-19 vaccines; and

WHEREAS, perfusionists are licensed pursuant to N.J.S.A. 45:9-37.94 and N.J.S.A. 45:9-37.101, and are specifically included in the definition of "health care provider" set forth in the EHPA at N.J.S.A. 26:13-2, and while their current scope of practice, as set forth at N.J.A.C. 13:35-2, does not expressly include the authority to administer vaccines, it does include authorization to administer pharmacological and therapeutic agents and blood products, including through intravenous lines under the supervision of a physician, and accordingly, during the continued public health emergency, to facilitate the broadest deployment of COVID-19 vaccinations as quickly as possible under the State's Vaccination Plan as implemented pursuant to DOH ED-20-035, with the training as referenced in DOH ED-20-037, perfusionists can develop the competency, knowledge, and skill to safely administer COVID-19 vaccines; and

WHEREAS, podiatrists are licensed pursuant to N.J.S.A. 45:5-1, and while N.J.S.A. 45:5-7 currently limits their scope of practice to treat any ailment of the foot or ankle, including by performing surgery or through the use of medical means, including injectable prescription medication intended to affect a local area, and accordingly, during the continued public health emergency, to facilitate the broadest deployment of COVID-19 vaccinations as quickly as possible under the State's Vaccination Plan as implemented pursuant to DOH ED-20-035, with the training as referenced in DOH ED-20-037, podiatrists can develop the competency, knowledge, and skill to safely administer COVID-19 vaccines; and

WHEREAS, optometrists are licensed pursuant to N.J.S.A. 45:12-1, and while their current scope of practice, as set forth at N.J.A.C 13:38-24, does not expressly include the authority to administer vaccines, they are authorized to prescribe and administer injectable prescription medications, and accordingly, during the continued public health emergency, to facilitate the broadest deployment of COVID-19 vaccinations as quickly as possible under the State's Vaccination Plan as implemented pursuant to ED-20-035, with the training as referenced in ED-20-037, optometrists can develop the competency, knowledge, and skill to safely administer COVID-19 vaccines; and

WHEREAS, physical therapists are licensed pursuant to N.J.S.A. 45:9-37.11 and N.J.S.A. 45:9-37.19, and while their current scope of practice, as set forth at N.J.A.C 13:39A-2.2, does not include the authority to administer vaccines or prescribe medication, they have extensive training in the use of a wide variety of physical modalities, and accordingly, during the continued public health emergency, to facilitate the broadest deployment of COVID-19 vaccines as quickly as possible under the State's Vaccination Plan, as implemented pursuant to DOH ED-20-035, with the training as referenced in DOH ED-20-037, physical therapists can develop the competency, knowledge, and skill to safely administer COVID-19 vaccines; and

WHEREAS, athletic trainers are licensed pursuant to N.J.S.A. 45:9-37.35 and N.J.S.A. 45:9-37.40, and while their current scope of practice, as set forth at N.J.A.C 13:35-10.7, does not include the authority to administer vaccines or prescribe medication, they have extensive training in the use of a wide variety of physical modalities, as overseen by a physician, and accordingly, during the continued public health emergency, to facilitate the broadest deployment of COVID-19 vaccines as quickly as possible under the State's Vaccination Plan, as implemented pursuant to DOH ED-20-035, with the training as referenced in DOH ED-20-037, athletic trainers can develop the competency, knowledge, and skill to safely administer COVID-19 vaccines; and

WHEREAS, dental hygienists are licensed pursuant to N.J.S.A. 45:6-50, and some dental hygienists are authorized to administer certain types of local anesthesia after obtaining a local anesthesia permit from the Board of Dentistry pursuant to N.J.S.A. 45:6-69.1 and N.J.A.C. 13:30-1A.5, and while the current scope of practice of dental hygienists who hold such a permit, as set forth at N.J.A.C 13:30-1A.3 to -1A.6, does not expressly include the authority to administer vaccines, they have training in anatomy and physiology, pharmacology, performing patient assessments, administering local anesthesia, and responding to medical emergencies, as overseen by a dentist, and accordingly, during the continued public health emergency, to facilitate the broadest deployment of COVID-19 vaccinations as quickly as possible under the State's Vaccination Plan, as implemented pursuant to DOH ED-20-035, with the training as referenced in DOH ED-20-037, dental hygienists who hold a local anesthesia permit can develop the competency, knowledge, and skill to safely administer COVID-19 vaccines; and

WHEREAS, all classes of health care practitioners set forth above should be recognized as capable of functioning as vaccinators at any POD that may be established in the State to administer COVID-19 vaccinations after receiving training in compliance with the requirements of DOH ED-20-037 and subject to appropriate supervision; 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

**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 personnel" includes dentists, licensed practical nurses, certified homemaker home health aides, respiratory care therapists, perfusionists,

- podiatrists, optometrists, physical therapists, athletic trainers, and those dental hygienists who hold a local anesthesia permit.
- 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 authorized health care personnel, and assumes responsibility for ensuring that authorized health care personnel 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 personnel.
- 2. The provisions of N.J.S.A 45:5-7 (podiatrists), N.J.A.C. 13:30:1A.1 (dental hygienists), N.J.A.C. 13:35-2 (perfusionists), N.J.A.C. 13:35-10.7 (athletic trainers), N.J.A.C. 13:38-24 (optometrists), N.J.A.C. 13:39A-2.2 (physical therapists), and N.J.A.C. 13:44F-3.1 (respiratory care practitioners) are suspended insofar as those provisions would exclude from the relevant scope of practice administration of COVID-19 vaccines in a manner consistent with this Order. The provisions of N.J.S.A. 45:11-23 (certified homemaker-home health aides) are suspended insofar as they would otherwise require a certified homemaker-home health aide to be employed by a home care services agency when administering COVID-19 vaccines in a manner consistent with this Order. Any other provisions of the statutes and rules remain in full force and effect.
- 3. Prior to directing authorized health care personnel to administer a COVID-19 vaccine to a patient, a supervising health care practitioner shall ensure that such personnel:
  - a. Hold a license, temporary emergency license issued by the Division, registration, or permit in good standing.
  - 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 <a href="https://www.cdc.gov/vaccines/ed/index.html">https://www.cdc.gov/vaccines/ed/index.html</a>, including the COVID-19 Vaccine Training Modules, found at <a href="https://www.cdc.gov/vaccines/covid-19/training.html">https://www.cdc.gov/vaccines/covid-19/training.html</a>, and the Skills Checklist for Vaccine Administration available through the Immunization Action Coalition website at <a href="https://www.immunize.org/catg.d/p7010.pdf">https://www.immunize.org/catg.d/p7010.pdf</a>, or as directed by DOH.
- 4. Prior to allowing authorized health care personnel 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 personnel 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 (NJIIS) 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 NJIIS.
- 5. When allowing authorized health care personnel at a POD to administer COVID-19 vaccines, the supervising health care practitioner shall ensure that such personnel:
  - 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 authorized health care personnel to administer a COVID-19 vaccine, the supervising health care practitioner shall:

- a. Provide the authorized health care personnel 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 allowing authorized health care personnel 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 personnel 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 personnel will be deemed to be acting within their scope of practice and not in violation of any relevant professional practice act for having engaged in unlicensed practice. Nothing herein shall be construed to permit authorized health care personnel to conduct the requisite training at PODs or to determine the competency of other health care professionals who may, pursuant to Executive Directive or Administrative Order, administer a COVID-19 vaccine.

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