

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

**ADMINISTRATIVE ORDER AND NOTICE OF RULE ADOPTION
PURSUANT TO P.L. 2020, c. 18; P.L. 2021, c. 103**

**COVID IMMUNIZATION ADMINISTRATION BY PHARMACISTS,
PHARMACY INTERNS AND EXTERNS TO INDIVIDUALS AGES THREE AND OVER
AND ADMINISTRATION OF COVID -19 THERAPEUTICS**

**DCA Administrative Order No. 2021-18
Modifying DCA Administrative Order 2021-01**

Administrative Order and Temporary Rule Adoption by Sean P. Neafsey, Acting Director,
Division of Consumer Affairs

Date: January 5, 2021, as modified on December 14, 2021

Authority: P.L. 2020, c. 18; P.L. 2021, c. 103

Effective Date: January 5, 2021, as modified on December 14, 2021

Expiration Date: January 11, 2022, unless extended by concurrent resolution of the legislature
pursuant to P.L. 2021, c. 103.

* * *

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, 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, N.J.S.A. 45:14-63, N.J.A.C. 13:39-4.21 and DCA AO 2020-19 (October 26, 2020) collectively permit pharmacists, registered pharmacy interns, and pharmacy externs to administer influenza vaccinations to patients seven years of age or older, subject to requirements

that vaccine administration to patients under 18 years of age be with the permission of the patient’s parent or legal guardian and that all administrations of influenza vaccine to children under the age of ten be pursuant to a prescription by an authorized prescriber; and

WHEREAS, N.J.S.A. 45:14-63, N.J.A.C. 13:39-4.21 and DCA AO 2020-19 (October 26, 2020) additionally permit pharmacists, registered pharmacy interns, and pharmacy externs to administer all vaccines and related emergency medications to patients eighteen and over, but only if such administration is: (a) pursuant to a prescription by an authorized prescriber for a vaccine and related emergency medications; (b) in immunization programs implemented pursuant to an authorized prescriber’s standing order for the vaccine and related emergency medications; or (c) in immunization programs sponsored by governmental agencies that are not patient specific; and

WHEREAS, N.J.S.A. 45:14-63(b)(3) provides that all immunizations administered to patients by pharmacy interns and/or pharmacy externs, whether by injection or other delivery method, must be under the direct supervision of a licensed pharmacist who has been pre-approved by the New Jersey Board of Pharmacy (Board) to administer vaccines and related emergency medications; 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, on August 24, 2020, the Secretary of HHS issued a Third Amendment to the Declaration issued under the PREP Act for medical countermeasures against COVID-19 (3rd Amendment), determining that licensed pharmacists should be authorized to order and administer vaccines including vaccines against childhood diseases and influenza, to children ages three and over, and that supervised pharmacy interns should also be authorized to administer those vaccines; and

WHEREAS, on September 3, 2020, the Assistant Secretary for Health at HHS issued “Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act,” (September Guidance) which found that pharmacists are positioned to increase access to vaccinations because of their location and convenience, as well as their relationships with their patients, medical providers and hospitals, and therefore, as an “Authority Having Jurisdiction” under the PREP Act, the September Guidance authorized State-licensed pharmacists to order and administer to persons three years of age and older, COVID-19 vaccines that have been authorized or licensed by the United States Food and Drug Administration (FDA); and

WHEREAS, on October 20, 2020, the Assistant Secretary for Health at HHS issued an additional Guidance (October Guidance) clarifying that even in states where pharmacy interns are not licensed or registered, if they are authorized by the state or the Board in which the pharmacy internship occurs, state-authorized interns are considered “qualified persons” under the PREP Act

and may administer FDA-authorized or FDA-approved COVID-19 vaccines to individuals ages three and over; and

WHEREAS, on December 3, 2020, the Secretary of HHS issued a Fourth Amendment to the Declaration under the PREP Act (4th Amendment), that, among other things, incorporated the terms of the September Guidance and October Guidance to clarify that pharmacists and pharmacy interns are “Qualified Persons” for purposes of the PREP Act when they administer certain vaccines, including vaccines against COVID-19, and clarified certain training requirements for pharmacists and pharmacy interns; and

WHEREAS, the 4th Amendment specifies that state-licensed pharmacists who order and administer, and supervised pharmacy interns who administer, vaccines that are FDA-authorized or FDA-licensed COVID-19 vaccines to persons ages three and older, will be considered “qualified persons” under the PREP Act if the following requirements are met:

- the vaccine must be authorized, approved or licensed by the FDA; and
- the vaccine must be ordered and administered according to ACIP’s COVID-19 vaccines recommendations; and
- the licensed pharmacist must have completed the immunization training that the licensing State requires in order for pharmacists to order and administer vaccines; and
- the licensed or registered pharmacy intern must complete a practical training program that is approved by the Accreditation Council for Pharmacy Education (ACPE), which program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines; and
- the licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation;
- the licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period;
- the licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient’s primary care provider when available, submitting required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby a person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine; and

- the licensed pharmacy and the licensed or registered pharmacy intern must comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention (CDC) COVID-19 Vaccination Program Provider Agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s); and

WHEREAS, the Board has established by regulation, at N.J.A.C. 13:39-4.21, the education and training qualifications for pharmacists to administer vaccines and related emergency medications, limited to diphenhydramine and epinephrine, which requirements are equivalent to or exceed the education and training established as threshold requirements for pharmacists to qualify to administer vaccines to individuals ages three and older set forth in the Fourth Amendment; and

WHEREAS, for purposes of administration of the vaccine permitted by the 4th Amendment, the term “pharmacy intern” was deemed to include both “pharmacy interns” and “pharmacy externs” as those terms are respectively defined by N.J.A.C. 13:39-2.6(a); and

WHEREAS, DCA Administrative Order 2020-19, entered on October 26, 2020, provides that registered pharmacy interns and pharmacy externs must meet the same education and training qualifications currently required of licensed pharmacists to administer vaccines and related emergency medications; and

WHEREAS, on December 4, 2020, through EO 207, Governor Murphy required that all individuals, regardless of age, shall be enrolled in the New Jersey Immunization Information System (NJIS) prior to or concurrent with receipt of a COVID-19 vaccination in New Jersey, if the individual is not already participating in the NJIS at the time of vaccine administration, to enable appropriate tracking of vaccines against COVID-19; and

WHEREAS, to effectuate the purpose of tracking vaccines as set forth in EO 207, it is anticipated that all COVID-19 immunizations administered to patients of all ages will be required to be reported to the NJIS, all pharmacists that intend to administer vaccines against COVID-19 must ensure that the pharmacy practice site at which administration occurs is registered with NJIS, that authorized users of the system are registered, and that those who will administer vaccines at the site are identified, as well as comply with the reporting requirements as set forth by the New Jersey Department of Health (DOH) and the CDC, as well as any other requirements imposed by federal law and/or the CDC COVID-19 Vaccination Program Provider Agreement; and

WHEREAS, pursuant to N.J.S.A. 45:14-63(c), the obligation to report any immunizations required to be reported to the NJIS for inclusion in a patient’s registry is placed upon the supervising pharmacist only, even if the vaccine is administered by a pharmacy intern or pharmacy extern; and

WHEREAS, New Jersey submitted to the 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, 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, PODs are required to operate consistent with the Plan, implemented by DOH in Executive Directive 20-035 (DOH ED-035), through organizations that have entered into COVID-19 Vaccination Program Provider Agreements 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 remain high over the coming months 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, in consideration of the 4th Amendment, the DCA Director independently found that because pharmacists, registered pharmacy interns, and pharmacy externs have experience and training in the administration of vaccines to patients, they should be permitted to administer vaccines against COVID-19 to all patients ages three and older, consistent with the approval or authorization of the FDA for such a vaccine; and

WHEREAS, on January 5, 2021, this Order, permitting pharmacists, pharmacy interns and pharmacy externs to administer childhood vaccines and the emergency medications diphenhydramine and epinephrine to children ages three through seventeen, and FDA-approved COVID-19 vaccines to patients ages three and older, was entered by Paul Rodriguez, then DCA Director; and

WHEREAS, on January 6, 2021, the New Jersey Commissioner of Health issued Executive Directive 20-037 (DOH ED-20-037), authorizing physicians, physician assistants, dentists, nurses, pharmacists and paramedics to administer COVID-19 vaccines and recognizing that ancillary health care personnel, including pharmacy interns and pharmacy externs, 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 responsible for providing training are also responsible for determining and validating 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, allowing pharmacists, pharmacy interns and pharmacy externs to be supervised in the administration of COVID-19 vaccines by other health care practitioners, including 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.), or a physician assistant (P.A.) (collectively, supervising health care practitioners), will aid in expanding the workforce available to administer vaccines and in New Jersey’s efforts to control and mitigate the effects of the pandemic; and

WHEREAS, HHS issued a 7th Amendment to the Declaration (7th Amendment) on March 10, 2021, which provided that additional categories of health care providers including pharmacists and pharmacy interns, who are currently licensed or certified in any state, are or can be deemed “Qualified Persons” authorized to prescribe, dispense or administer COVID-19 vaccines; and

WHEREAS, the 7th Amendment also recognizes that certain additional categories of health care providers, including pharmacists and pharmacy interns who were licensed in any state and practiced within the past five years should be eligible to prescribe, dispense or administer COVID-19 vaccines; and

WHEREAS, the 7th Amendment also provides that pharmacy students with appropriate training in administering vaccines, as determined by the school or training program, should be permitted to administer COVID-19 vaccines if certain conditions are satisfied, including completion of the CDC COVID-19 Vaccine Training Modules and the additional training required by this state, a current CPR certificate and documentation of an observation period by a currently practicing health care professional experienced in administering intramuscular injections; and

WHEREAS, for purposes of the 7th Amendment, pharmacy externs are pharmacy students, who would be required to satisfy the training and experience requirements set forth in DCA 2020-19 in order to administer vaccines as well as the requirements set forth in the 7th Amendment, and as students, would not be permitted independently to prescribe or order the vaccine; 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 practitioners are authorized to prescribe, dispense, and administer COVID-19 vaccines pursuant to the 7th Amendment, and these

classes of practitioners have the requisite training and experience in regularly administering intramuscular injections to supervise the administration of vaccines and an ability similar to physicians and pharmacists to observe, assess, and take any necessary action regarding effectiveness, adverse reaction, or any emergency; and

WHEREAS, to facilitate the greatest degree of flexibility in staffing at PODs while still ensuring that supervision, training and validation of competency are provided, pharmacists, pharmacy interns, pharmacy externs, and students in pharmacy training programs may be supervised by pharmacists or other health care practitioners, specifically, doctors of medicine (M.D.), doctors of osteopathic medicine (D.O.), registered professional nurses (R.N.s), advanced practice nurses (A.P.N.s), or physician assistants (P.A.s); and similarly, pharmacists should be authorized to supervise, train and validate the competency of other health care practitioners; and

WHEREAS, on June 4, 2021, through Executive Order No. 244, the facts and circumstances of which are adopted by reference herein, Governor Murphy terminated the public health emergency declared in EO 103, as extended, and signed into law P.L. 2021, c. 104, which authorized the head of any State agency to modify previously issued orders that relied on the existence of the public health emergency and to issue orders related to vaccination distribution, administration, and management, and continued such orders until January 11, 2022 unless extended for 90 days by concurrent resolution of the legislature; and

WHEREAS, HHS issued a 9th Amendment to the Declaration (9th Amendment) on September 9, 2021 which authorizes state-licensed pharmacists to order and administer and supervised pharmacy interns to administer FDA authorized, approved or licensed COVID-19 therapeutics subcutaneously, intramuscularly or orally, if the following requirements are met:

- the COVID-19 therapeutic must be authorized, approved, or licensed by the FDA;
- in the case of a licensed pharmacist ordering a COVID-19 therapeutic, the therapeutic must be ordered for subcutaneous, intramuscular, or oral administration and in accordance with the FDA approval, authorization, or licensing;
- the COVID-19 therapeutic must be administered subcutaneously, intramuscularly, or orally in accordance with the FDA approval, authorization, or licensing;
- in the case of COVID-19 therapeutics administered through intramuscular or subcutaneous injections, the licensed pharmacist and registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of COVID-19 therapeutics, the recognition and treatment of emergency reactions to COVID-19 therapeutics, and any additional training required in the FDA approval, authorization, or licensing;
- the licensed pharmacist and registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation;

- the licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers COVID-19 therapeutics, including informing the patient's primary-care provider when available and complying with requirements with respect to reporting adverse events;
- The licensed pharmacist, and the registered pharmacy must comply with any applicable requirements (or conditions of use) that apply to the administration of COVID-19 therapeutics; and

WHEREAS, expanding patient access to COVID-19 therapeutics in a manner consistent with the 9th Amendment may provide increased access to these treatments for patients at high risk for progression to severe COVID-19, including hospitalization or death, and potentially reduce the burden on the State's health care systems and hospitals;

NOW, THEREFORE, I, Sean P. Neafsey, 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:

A. Requirements applicable to vaccinations:

1. In addition to all other vaccines that pharmacists, registered pharmacy interns, and pharmacy externs are authorized to administer, pharmacists are authorized to order and administer, and registered pharmacy interns and pharmacy externs are authorized to administer, any and all vaccines that may hereafter be approved or authorized by the FDA for COVID-19, to patients who are three years of age or older, subject to the following conditions:
 - a. A registered pharmacy intern or pharmacy extern who administers vaccines and related emergency medications shall act under the direct supervision of a supervising health care practitioner: a doctor of medicine, a doctor of osteopathic medicine, registered professional nurse, advanced practice nurse, a physician assistant, or a supervising pharmacist, who shall be a licensed pharmacist pre-approved by the Board to administer vaccines and related emergency medications, pursuant to N.J.A.C. 13:39-4.21, or a pharmacist licensed in another state who has completed an attestation that the pharmacist satisfies the requirements of the 4th Amendment to be qualified to order and administer COVID-19 vaccines, including: (i) the licensed pharmacist must have completed the immunization training that the licensing State requires in order for pharmacists to order and administer vaccines; (ii) the licensed pharmacist must have a current certificate in basic cardiopulmonary resuscitation; and (iii) the licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period.
 - b. If the pharmacy extern is being supervised by a pharmacist, the supervising pharmacist shall confirm that the pharmacy extern satisfies the education and training requirements of N.J.A.C. 13:39-4.21(b)1 and 2, and shall document that information in the pharmacy's

records, prior to including the extern on the list of those qualified to immunize when registering with the NJIIS pursuant to paragraph 6 below. If the pharmacy extern is being supervised by a supervising health care practitioner other than a pharmacist, that supervising health care practitioner is responsible for ensuring that the extern is properly qualified to administer COVID-19 vaccines.

- c. The supervising pharmacist must be physically present at the pharmacy practice site or other POD and readily and immediately available when immunizations will be administered by registered pharmacy interns, pharmacy externs, CMAs, other health care personnel, or health care practitioners-in-training authorized to administer COVID-19 vaccines pursuant to DCA AO 2021-06, 2021-07, and 2021-08, or any superseding administrative order. The supervising pharmacist is responsible for accuracy and safety with respect to the actions of all those being supervised.
 - d. The supervising pharmacist is responsible for providing training to all pharmacy interns, pharmacy externs, CMAs, other health care personnel, and health care practitioners-in-training authorized to administer COVID-19 vaccines pursuant to DCA AO 2021-06, 2021-07, and 2021-08, or any superseding administrative order, in a manner consistent with CDC's "COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals" and FDA COVID-19 vaccination guidance, and is responsible for validating vaccine administration knowledge, skill, and current competency of any such 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>.
 - e. All vaccines administered must be either approved, authorized or licensed by the FDA and administered consistent with the ACIP's COVID-19 vaccine recommendations.
2. Prior to administering a vaccine at a pharmacy practice site or other POD under the control or supervision of a pharmacist, pharmacists, registered pharmacy interns and/or pharmacy externs shall:
- a. Ensure that the patient 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. Ensure that a review of the patient'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 are appropriate.

- c. Counsel the patient and/or the patient's representative, parent, or guardian about contraindications and proper care of the injection site, and provide 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. Provide the patient and/or the patient's representative, parent, or guardian with a vaccine information sheet and/or EUA fact sheets published by the CDC or FDA.
 - e. Inform the patient and/or the patient's representative, parent, or guardian that all vaccines for COVID-19 must be reported to the NJIIS system.
3. Pharmacists, registered pharmacy interns, and pharmacy externs who administer vaccines at pharmacy practice sites or at PODs under the control or supervision of a pharmacist must comply with all other requirements of N.J.A.C. 13:39-4.21, including but not limited to those pertaining to reporting, documentation, and policies and procedures.
 - a. For purposes of N.J.A.C. 13:39-4.21(i)4, the name and address of the supervising pharmacist must be included in the record.
 - b. For purposes of N.J.A.C. 13:39-4.21(j), the supervising pharmacist is responsible for ensuring that all clinically adverse events are reported to the appropriate governmental authority.
 - c. To the extent any records or information must be recorded in the pharmacy's patient profile system required by N.J.S.A. 45:14-68, such data shall be entered only by pharmacists, registered pharmacy interns, pharmacy externs, or registered pharmacy technicians, and may not be entered by other supervising health care practitioners, CMAs, other health care personnel, or health care practitioners-in-training.
 4. The pharmacist administering the vaccine, or the supervising pharmacist if a vaccine is administered by a (i) registered pharmacy intern, (ii) pharmacy extern, (iii) CMA, (iv) other health care personnel, or (v) health care practitioner-in-training authorized to administer COVID-19 vaccines pursuant to DCA AO 2021-06, 2021-07, and 2021-08, or any superseding order, shall document in detail and immediately report all clinically significant adverse events to the appropriate government reporting system within 72 hours, or such other time as required by DOH, the FDA, and/or the CDC.
 5. The pharmacist administering the vaccine, or the supervising pharmacist if a vaccine is administered by a (i) registered pharmacy intern, (ii) pharmacy extern, (iii) CMA, (iv) other health care personnel, or (v) health care practitioner-in-training authorized to administer COVID-19 vaccines pursuant to DCA AO 2021-06, 2021-07, and 2021-08, or any superseding

order, shall ensure that all vaccines administered 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.

6. The pharmacist-in-charge of a pharmacy practice site where vaccines are administered shall ensure that the pharmacy practice site, as well as all authorized users at the site, register with the NJIIS and that all recordkeeping requirements imposed at N.J.A.C. 13:39-4.21 are satisfied.
7. All vaccines to be administered at a pharmacy practice site or other POD under the control and supervision of a pharmacist must be stored and handled consistent with the Board's regulations at N.J.A.C. 13:39-5.11, manufacturer's directions, and the CDC Vaccine Storage and Handling toolkit, found at <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>.
8. If vaccines are to be administered at any POD or site other than a pharmacy practice site or other POD under the control or supervision of a pharmacist, then pharmacists, registered pharmacy interns, or pharmacy externs shall ensure that the necessary screening and other tasks set forth in paragraph 2 are performed prior to vaccination, all records will be maintained by a health care practitioner authorized to maintain such records, and that all vaccinations will be timely reported to the NJIIS as may be required by DOH and the CDC.

B. Requirements applicable to COVID-19 Therapeutics

1. A licensed pharmacist may order and administer, and a registered pharmacy intern or pharmacy extern may administer COVID-19 therapeutics that are FDA approved, authorized or licensed subject to the following conditions:
 - a. The licensed pharmacist, registered pharmacy intern and pharmacy extern must: 1) complete a practical training program that is approved by the ACPE, which training program must include hands-on injection technique, clinical evaluation of indications and contraindications of COVID-19 therapeutics, the recognition and treatment of emergency reactions to COVID-19 therapeutics, and any additional training required in the FDA approval, authorization, or licensing and 2) have a current certificate in basic cardiopulmonary resuscitation.
 - i. Licensed pharmacists and registered pharmacy interns must maintain proof of completion of the required training, and any prerequisite training required for the COVID-19 therapeutics training. The proof of training must be available at the pharmacy practice site where the COVID-19 therapeutics are administered or dispensed.
 - ii. The supervising pharmacist shall confirm that a pharmacy extern has completed the necessary coursework and holds a current certificate in CPR and shall document that information in the pharmacy's records, prior to permitting an extern to administer COVID-19 therapeutics to any patient.

- b. A licensed pharmacist may only order COVID-19 therapeutics for subcutaneous, intramuscular or oral administration, and in accordance with the FDA approval, authorization or licensing. The order shall be documented and maintained as part of the patient's record.
 - c. The COVID-19 therapeutic to be administered by a licensed pharmacist, registered pharmacy intern or pharmacy extern, must be administered subcutaneously, intramuscularly or orally in accordance with the FDA approval, authorization or licensing.
 - d. A registered pharmacy intern or pharmacy extern who administers COVID-19 therapeutics shall act under the direct supervision of a supervising pharmacist who has completed the necessary training set forth in (a)(i) above.
2. A pharmacist may not order or administer, nor may registered pharmacy interns or pharmacy externs administer, COVID-19 therapeutics by infusion.
3. Prior to administering COVID-19 therapeutics to a patient, the pharmacist, registered pharmacy intern or pharmacy extern shall:
 - a. Obtain a signed informed consent form from the patient or the patient's guardian. The informed consent form shall include a section where the patient or the patient's guardian shall be requested to identify the patient's primary care practitioner ("PCP") and to authorize the provision of copies of the patient's documentation to the patient's identified PCP;
 - b. Counsel the patient or the patient's guardian about contraindications and proper care of the injection site, and provide instructions to contact a PCP or emergency care facility in the event of any adverse reaction;
 - c. Provide a copy of all patient-related documentation and a copy of the signed informed consent form to each patient receiving COVID-19 therapeutics, or to the patient's guardian, and to the patient's PCP, if identified and if authorization has been provided on the informed consent form.
4. Pharmacists, registered pharmacy interns, and pharmacy externs who administer COVID-19 therapeutics must comply with the reporting and documentation requirements of N.J.S.A. 45:14-68 and N.J.A.C. 13:39-4.21, as well as any other reporting requirements as may be required by DOH, the FDA or any other government agency.
 - a. For purposes of N.J.A.C. 13:39-4.21(i)4, the name and address of the supervising pharmacist must be included in the record, if COVID-19 therapeutics are administered by a registered pharmacy intern or pharmacy extern.

- b. For purposes of N.J.A.C. 13:39-4.21(j), the supervising pharmacist is responsible for documenting in detail and immediately report all clinically adverse events to any PCP identified on the informed consent form, and shall, within 72 hours, ensure such events are reported to the appropriate governmental authority.
5. Pharmacists, registered pharmacy interns, and pharmacy externs who administer COVID-19 therapeutics must comply with any applicable requirements or conditions of use that apply to the administration of COVID-19 therapeutics.

C. General requirements

1. The provisions of N.J.S.A. 45:14-63 are waived insofar as they require all vaccines to be administered to adults pursuant to a prescription or standing order, prohibit immunizations of children under the age of seven, limit children’s immunization to vaccines for influenza, require that vaccines for children ages 7 to 9 may only be provided pursuant to a prescription or standing order, require supervision of registered pharmacy interns and pharmacy externs to be provided by a supervising pharmacist in all practice settings, and prohibit the ordering and administration of medication by a pharmacist, and administration of medication by a registered pharmacy intern or pharmacy extern, solely for purposes of administration of COVID-19 therapeutics consistent with this Order.
2. To the extent they conflict with this Order, the provisions of N.J.A.C. 13:39-4.21 are waived and suspended. Any provisions of these rules that are not inconsistent with this Order remain in full force and effect.

This Order shall take effect immediately and shall remain in effect until January 11, 2022, unless extended by concurrent resolution of the legislature pursuant to P.L. 2021, c. 103, or unless expressly revoked or superseded by a subsequent Administrative Order issued by the Director of the Division of Consumer Affairs.



Date: December 14, 2021

Sean P. Neafsey, Acting Director