

**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**

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

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

Administrative Order and Temporary Rule Adoption by Paul R. Rodríguez, Director, Division of Consumer Affairs

Date: January 5, 2021

Authority: P.L. 2020, c. 18

Effective Date: January 5, 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

WHEREAS, the public health emergency declared in EO 103 has been extended through Executive Order Nos. 119, 138, 151, 162, 171, 180, 186, 191, 200, and 210 (2020) issued on April 7, May 6, June 4, July 2, August 1, August 27, September 25, October 24, November 22, and December 21, 2020, respectively, 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 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, on August 24, 2020, the Secretary of the United States Department of Health and Human Services ("HHS") issued a Third Amendment to the Declaration issued under the Public Readiness and Emergency Preparedness Act ("PREP Act") for medical countermeasures against COVID-19, which was first issued on March 10, 2020 ("Third Amendment"), issued pursuant to 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 (the "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, 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 Fourth 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 pharmacist must inform his or her childhood-vaccination patients and the adult caregiver accompanying the child of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate; 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 provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s); and

WHEREAS, the State Board of Pharmacy 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, the term “pharmacy intern” as used within the Fourth Amendment, includes 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 (“NJiIS”) prior to or concurrent with receipt of a COVID-19 vaccination in New Jersey, if the individual is not already participating in the NJiIS 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 NJiIS, all pharmacists that intend to administer vaccines against COVID-19 must ensure that the pharmacy practice site at which administration occurs is registered with NJiIS and that authorized users of the system and those who will administer vaccines are also registered, as well as comply with the reporting requirements as set forth by the New Jersey Department of Health and the CDC, as well as any other requirements imposed by federal law and/or the COVID-19 vaccination provider agreement; and

WHEREAS, pursuant to N.J.S.A. 45:14-63(c), the obligation to report any immunizations which are required to be reported to the NJiIS 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, in consideration of the Fourth Amendment, I independently find 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 that expanding the health care workforce able to administer such a vaccine will be essential to New Jersey's efforts to control and mitigate the effects of the pandemic;

**NOW, THEREFORE**, I, Paul R. Rodríguez, 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 was declared, and hereby ORDER as follows:

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 eligible patients who are three years of age or older, subject to the following conditions:
  - a. If not previously pre-approved by the Board, licensed pharmacists and registered pharmacy interns shall obtain pre-approval by the Board in accordance with N.J.A.C. 13:39-4.21 prior to administering vaccines;
  - b. A registered pharmacy intern or pharmacy extern who administers vaccines and related emergency medications shall act under the direct supervision of the 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;
  - c. 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;
  - d. The supervising pharmacist must be physically present at the pharmacy practice site or other location where immunizations will be administered by registered pharmacy interns and/or externs, and is responsible for accuracy and safety with respect to the actions of the registered pharmacy interns and pharmacy externs;
  - e. All vaccines administered must be either approved or authorized 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 location 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. 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 any adverse reaction;
  - c. 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;
  - d. For patients under the age of eighteen, inform the patient and/or the patient's representative, parent or guardian, both verbally and in writing, of the importance of a well-child visit with a pediatrician or other licensed primary care practitioner, and refer patients as appropriate.
  - e. Inform the patient and/or the patient's representative, parent or guardian of the potential costs of the vaccine, and that the cost may or may not be covered by the patient's insurance;
  - f. 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, and ask for consent to share the information with the patient's primary care practitioner.
3. Pharmacists, registered pharmacy interns and pharmacy externs who administer vaccines at pharmacy practice sites or at other locations 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.

4. The pharmacist administering the vaccine, or the supervising pharmacist if a vaccine was administered by a registered pharmacy intern or pharmacy extern, shall document in detail and immediately report all clinically significant adverse events to the patient's pediatrician or primary care practitioner, if one has been identified by the patient. The pharmacist or supervising pharmacist shall ensure that such events are reported to the appropriate government reporting system within 72 hours, or such other time as required by the Department of Health, the FDA and/or the CDC.
5. The pharmacist administering the vaccine, or the supervising pharmacist if a vaccine was administered by a registered pharmacy intern or pharmacy extern, shall ensure that all vaccines administered are timely reported to the NJIIS and/or such other reporting as may be required by the Department of Health and the CDC.
6. The pharmacist-in-charge of the 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 location 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 site other than a pharmacy practice site or other location under the control or supervision of a pharmacist, 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 the Department of Health and the CDC.
9. 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, and require that vaccines for children ages 7 to 9 may only be provided pursuant to a prescription or standing order.
10. 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 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.

A handwritten signature in black ink that reads "Paul Rodríguez". The signature is written in a cursive style with a large initial "P" and a distinct "R".

Date: January 5, 2021

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Paul R. Rodríguez, Director