

**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**

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

DCA Administrative Order No. 2021-03

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 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"), citing to a Centers for Disease Control and Prevention ("CDC") report that found that the rate of childhood immunizations had decreased, possibly because of reduced healthcare access due to the COVID-19 pandemic, and that pediatric practices surveyed stated that they were not likely to be able to accommodate new patients for vaccines; that licensed pharmacists are positioned to increase access to vaccinations, particularly in areas with fewer pediatricians and primary care providers; and that therefore 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 be authorized to administer said vaccines; and

WHEREAS, on December 3, 2020, the Secretary of HHS issued a Fourth Amendment to the Declaration under the PREP Act, wherein certain modifications and clarifications were made to requirements which had previously been set forth in the Third Amendment for licensed pharmacists to order and administer, and for pharmacy interns to administer, childhood vaccinations; and

WHEREAS, the Declaration under the PREP Act, as modified by the Fourth Amendment, specifies that state-licensed pharmacists who order and administer, and supervised pharmacy interns who administer, vaccines that the Advisory Committee on Immunization Practices ("ACIP") recommends to persons ages three through 18 according to ACIP's standard immunization schedule, 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;
- the vaccine must be ordered and administered according to ACIP's standard immunization schedule;
- the licensed pharmacist must have completed the immunization training that the licensing State requires in order for pharmacists to order and administer vaccines;
- 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;
- 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

WHEREAS, prefatory language included within the "Description of [the Third] Amendment by Section" explains that pharmacists should be limited to administering immunizations to children three and over only because administering injections to patients three and older involves intra-muscular injections in the deltoid, and is therefore less complicated and requires less training than administering immunizations to children younger than three in the thigh; and

WHEREAS, the term "pharmacy intern," as used within the Fourth Amendment, includes both registered "pharmacy interns" and "pharmacy externs," as those terms are respectively defined by New Jersey law at N.J.A.C. 13:39-2.6(a) and

WHEREAS, in consideration of the Fourth Amendment, the Division finds good cause, following consultation with the Department of Health, for the duration of the state of emergency, to expand the pool of individuals authorized to administer childhood vaccinations to include pharmacists, registered pharmacy interns and pharmacy externs, as pediatric patients may have suffered reduced access to necessary vaccinations because of closures of primary care practices and/or reductions in the number of office hours for in-person visits at such practices; and

WHEREAS, expanding the availability of childhood vaccines and access to those vaccines, by authorizing pharmacists to order and pharmacists, registered pharmacy interns and pharmacy externs to administer those vaccines currently and for the duration of the state of emergency, may additionally be helpful in maintaining childhood immunities and mitigating the risk to children and their communities of outbreaks of vaccine-preventable diseases; and

WHEREAS, because authorizing pharmacists to order, and pharmacists, pharmacy interns and pharmacy externs to administer, vaccines to children in no way substitutes for or replaces the need for regular well visits with a patient's pediatrician or primary care practitioner, pharmacists, registered pharmacy interns and pharmacy externs are herein being required to inform patients, and their parents or guardians, that there remains a need for regular well visits, 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, 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, N.J.A.C. 8:57-3.16 requires that every health care provider that administers vaccines to children less than seven years of age must register as an New Jersey Immunization Information System ("NJiIS") site and authorized user and report the administration of a vaccine to a child less than seven years of age within 30 days of administration; 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, because there is a vital need to ensure that records of administration of all vaccines to children by pharmacists, pharmacy interns and/or pharmacy externs are available and accessible to current and/or future health care providers, the Division herein is requiring (1) that all vaccine administrations be reported to the NJiIS, to include vaccinations administered to children aged seven and above, unless the parent or guardian has specifically withdrawn the child from enrollment in the NJiIS; (2) that documentation concerning each vaccination administration be provided to a child's identified pediatrician or primary care provider (collectively "PCP"), unless the parent or guardian declines to identify a PCP and/or to authorize the provision of vaccine

related documentation to the identified PCP; and (3) that pharmacists, pharmacy interns or pharmacy externs not administer vaccines to children who have been both withdrawn from enrollment in the NJIIS and who do not have an identified PCP authorized to receive documentation of the vaccination; and

WHEREAS, recognizing that there may be unique requirements that are imposed on the administration of any vaccines that are authorized or approved for COVID-19 that could differ from the requirements herein, vaccinations for COVID-19 are excluded from the scope of this Order, and instead will be addressed in a separate order;

NOW, THEREFORE, I, Paul R. Rodríguez, 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. Pharmacists, registered pharmacy interns and pharmacy externs, as defined by N.J.A.C. 13:39-2.6, are authorized to administer vaccines and related emergency medications, which shall be limited to diphenhydramine and epinephrine, to patients who are three years of age through and including seventeen years of age, 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 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.
 - 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 authorized users 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 when vaccines are administered by registered pharmacy interns and/or pharmacy externs and is responsible for accuracy and safety with respect to the actions of the registered pharmacy interns and/or pharmacy externs.
 - e. All vaccines administered must be either approved or authorized by the FDA, included in the latest recommended immunizations as approved by the ACIP,

and administered according to the ACIP-recommended schedules for children 18 years of age or younger that can be found at <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>.

2. Pharmacists, registered pharmacy interns and pharmacy externs may administer ACIP-recommended immunizations and related emergency medications, limited to epinephrine and diphenhydramine, to eligible individuals ages 3 and older, pursuant to an order for a vaccine entered by the pharmacist; a patient-specific prescription by an authorized prescriber for a vaccine and related emergency medications; an authorized prescriber's standing order in an immunization program for the vaccine and related emergency medications; or as part of an immunization program sponsored by a government agency or agencies that is not patient specific.
 - a. Documentation of the pharmacist's order, the authorized prescriber's prescription or of an authorized prescriber's standing order must be maintained at the pharmacy practice site, and if applicable, at the immunization location, as required by N.J.A.C. 13:39-4.21(f).
 - b. When any vaccine is to be administered pursuant to a pharmacist's order, the ordering pharmacist shall review the vaccine registry or other available vaccination records prior to entering the order, to ensure that the order for the vaccine requested is appropriate for the child and that the vaccine has not been administered by another provider.
3. Prior to administering any vaccine, a pharmacist, registered pharmacy intern and/or pharmacy extern shall:
 - a. Ensure that the patient is screened using CDC established criteria for each specific vaccine to be administered, to include determining whether the patient has any contraindications or precautions to vaccination as determined by the ACIP, that can be found at <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html>.
 - b. In all instances where vaccine administration is being performed other than pursuant to the pharmacist's order for the vaccine, review the NJIIS, both to determine whether the child is enrolled in the NJIIS and, if applicable, to ensure that the requested vaccine has not been administered by another provider.
 - c. Counsel the patient and/or the patient's 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.

- d. Inform the patient and/or the patient's parent or guardian, in writing, in specific and readily understood terms, about the risks and benefits of the vaccine and provide the patient and/or the patient's representative, parent or guardian with a vaccine information sheet and/or fact sheets published by the CDC.
 - e. Inform the patient and/or the patient's 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. Obtain a signed informed consent form from the patient and/or the patient's parent or guardian. The informed consent form shall include a section where the patient and/or the patient's parent or guardian shall be requested to identify the patient's pediatrician or other primary care provider (collectively "PCP") and to authorize the provision of copies of the patient's vaccine documentation to the identified PCP.
 - g. A pharmacist, pharmacy intern or pharmacy extern shall not administer a vaccine to any patient who is not enrolled in the NJIIS and for whom no authorization is given to provide copies of the patient's vaccine documentation to an identified PCP. Information concerning other vaccination options, to include information identifying nearby Federally Qualified Health Centers, shall be provided to the parents and guardians of any such children.
 - h. Provide a copy of all patient related documentation and a copy of the signed informed consent form to each patient receiving an immunization, and/or to the patient's parent or guardian, and to the patient's PCP, if identified and if authorization has been provided on the informed consent form (see 3f above).
4. 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 to children enrolled in the NJIIS, including vaccinations administered to children aged seven and above, are reported to the NJIIS within thirty days of such administration, or any shorter time period that may hereafter be mandated by amendments to reporting timeframes.
 5. Pharmacists, registered pharmacy interns and pharmacy externs 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, informed consent, 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.
6. 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 any pediatrician or primary care practitioner identified on the informed consent form, and to the primary-care practitioner who signed the prescription or standing order, if applicable. The pharmacist or supervising pharmacist shall, within 72 hours, ensure that such events are reported to the appropriate government reporting system.
7. The pharmacist administering the vaccine, or the supervising pharmacist if a vaccine was administered by a registered pharmacy intern or pharmacy extern, shall 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.
8. 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.
9. All vaccines to be administered at a pharmacy practice site or other location must be stored and handled consistent with the Board's regulations at N.J.A.C. 13:39-5.11, manufacturer's directions, the CDC Vaccine Storage and Handling toolkit, found at <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>, and any other applicable requirements of law.
10. The provisions of N.J.S.A. 45:14-63 are waived insofar as they prohibit immunizations of children under the age of seven, limit children's immunization to vaccines for influenza, and require that influenza vaccines for children ages 7 to 9 may only be provided pursuant to a prescription.
11. 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.
12. The terms of this Order shall not apply to any vaccine that is, or may hereafter be, authorized or approved for COVID-19.

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, looping initial "P" and a distinct "R".

Date: January 5, 2021

Paul R. Rodríguez, Director