New Jersey Office of the Attorney General
Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, P.O. Box 45013
Newark, New Jersey 07101
(973) 504-6450

Pharmacist Hormonal Contraceptives Protocol

Background

On January 13, 2023, Governor Phil Murphy signed into law P.L. 2023, c. 2 (codified at N.J.S.A. 45:14-67.9), which states:

> "Notwithstanding any other law to the contrary, a pharmacist shall be authorized to furnish self-administered hormonal contraceptives to a patient, in accordance with standardized procedures and protocols to be jointly developed and approved by the Board of Pharmacy and the State Board of Medical Examiners, in consultation with the American Congress of Obstetricians and Gynecologists, the New Jersey Pharmacists Association, and other appropriate entities, and in accordance with the 'Administrative Procedure Act,' P.L.1968, c.410 (C.52:14B-1 et seq.) and the provisions of this subsection."

This protocol ("Protocol") was developed jointly by the State Board of Medical Examiners and the Board of Pharmacy after consulting with professional associations and other appropriate entities. It was approved by the State Board of Medical Examiners on April 10, 2024 and by the Board of Pharmacy on April 24, 2024.

Pursuant to this Protocol, the Commissioner of the New Jersey Department of Health (or the Commissioner's designee) issued a statewide standing order authorizing New Jersey licensed pharmacists to furnish self-administered hormonal contraceptives to patients without an individual prescription. The State Board of Medical Examiners regulations implementing the Protocol are found at N.J.A.C. 13:35-6.28. The Board of Pharmacy regulations implementing the Protocol are found at N.J.A.C. 13:39-14.1 through 14.7.

A pharmacist who furnishes self-administered hormonal contraceptives pursuant to a standing order **must follow this Protocol** and the regulations of the Board of Pharmacy. Copies of all documents and templates referenced in this Protocol are available on the Board of Pharmacy's website at www.njconsumeraffairs.gov/phar/Pages/default.aspx.

Pharmacist Authorization

In order for a pharmacist to be authorized to furnish self-administered hormonal contraceptives pursuant to this Protocol, the pharmacist shall:

1. Complete a training program compliant with N.J.A.C. 13:39-14.7;

2. Affirm, in writing, that the pharmacist has completed a training program compliant with N.J.A.C. 13:39-14.7 and will follow pertinent guidelines offered by the Federal Centers for Disease Control and Prevention, including the United States Medical Eligibility Criteria for Contraceptive Use. This written affirmation shall be retained by the pharmacist and a copy shall be retained by the pharmacy as a medical record pursuant to N.J.A.C. 13:39-14.6; and

3. Submit to the Board:

   i. The pharmacist's written affirmation from 2 above; and

   ii. A certificate of completion of the training course required by 1 above.

A pharmacist must keep a written copy of this Protocol and the standing order under which the pharmacist furnishes hormonal contraceptives at each pharmacy practice site at which the pharmacist furnishes self-administered hormonal contraceptives. This Protocol must include the names of each pharmacist authorized pursuant to N.J.A.C. 13:39-14 to furnish self-administered hormonal contraceptives at the pharmacy practice site on the final page. The pharmacist must make a copy of the Protocol and the standing order available upon the request of a representative of the Board of Pharmacy.

A pharmacist who is authorized to furnish a self-administered hormonal contraceptive pursuant to this protocol is prohibited from delegating the furnishing of hormonal contraceptives to any other person. A pharmacy intern or pharmacy technician may prepare the self-administered hormonal contraceptive for dispensing, but the steps at N.J.A.C. 13:39-14.4 and 14.5(a) through (f) must be completed by the pharmacist authorized to furnish a hormonal contraceptive pursuant to this Protocol.

A pharmacist authorized to furnish hormonal contraceptives pursuant to this subchapter shall comply with mandatory child abuse reporting obligations at N.J.S.A. 9:6-8.10, including but not limited to, reports of sexual offenses at N.J.S.A. 2C:14-1 et seq.

Hormonal Contraceptives Authorized Pursuant to this Protocol

Pharmacists may furnish the following self-administered hormonal contraceptives pursuant to this Protocol:

1. Combined oral contraceptive pill;

2. Progestin-only oral contraceptive pill;

3. Patch;

4. Ring; and

5. Injectable hormonal contraceptive.

A pharmacist may not furnish any other self-administered hormonal contraceptives pursuant to the Protocol. An injectable hormonal contraceptive furnished pursuant to the Protocol must be self-administered and cannot be administered by the pharmacist.

Procedures for Hormonal Contraceptive Screening and Selection

(a) When an individual requests a pharmacist to furnish a self-administered hormonal contraceptive, the pharmacist shall:

1. Have the patient complete the Health Screening Questionnaire prepared by the New Jersey Department of Health. Upon request and whenever possible, the Health Screening Questionnaire shall be provided in the recipient's primary spoken language. If the patient does not complete the Health Screening Questionnaire, the pharmacist shall not furnish a self-administered hormonal contraceptive pursuant to the Protocol;

2. Review the Health Screening Questionnaire with the patient and clarify responses, if needed;

3. Measure and record the patient's seated blood pressure, unless progestin-only oral contraceptive pills are requested by the patient. Seated blood pressure may be retaken if the first reading exceeds the level for eligibility according to the United States Medical Eligibility Criteria for Contraceptive Use (USMEC) prepared by the Federal Centers for Disease Control and Prevention (CDC). If the pharmacist uses a device other than a stethoscope and manual blood pressure cuff to take seated blood pressure, the device shall be kept behind the pharmacy counter and be used only by pharmacy staff; and

4. Complete the Algorithm for Self-Administered Hormonal Contraceptive Pills, Patches, and Rings or, if an injectable hormonal contraceptive is under consideration, the Algorithm for Self-administered Injectable Hormonal Contraceptives. As part of that process, the pharmacist must assess the health and history of the patient using the latest version of the USMEC. Pharmacists may use the Summary Chart of the USMEC, which is color-coded to match the Health Screening Questionnaire.

(b) The pharmacist must provide patient privacy during health screening and counseling consistent with the Federal Health Insurance Portability and Accountability Act, 45 C.F.R. Part 160 and Subparts A and E of Part 164, as may be amended and supplemented, and other applicable law.

(c) A pharmacist may furnish a self-administered hormonal contraceptive pursuant to this Protocol only if the patient's intended use is contraception and only if the patient has begun menstruating.

Procedures for Patient Counseling and Furnishing Hormonal Contraceptives

(a) If the pharmacist concludes based on "Procedures for Hormonal Contraceptive Screening and Selection" above that a self-administered hormonal contraceptive is indicated for the patient, the pharmacist may furnish one. The pharmacist shall:

1. Ensure that the patient is appropriately instructed in the administration of the self-administered hormonal contraceptive.

2. Provide the patient with appropriate counseling and the following information:

    i. An information sheet for the product furnished that includes, without limitation, when and how to take or use the hormonal contraceptive, when the contraceptive becomes effective, what to do if the patient misses a dose or the contraceptive patch or ring dislodges, possible side effects (including the risks, if any, of long term use), and when to seek medical attention;

    ii. The package insert for the product furnished;

    iii. The importance of receiving recommended preventative health screenings and following up with the patient's primary care provider or a medical clinic;

    iv. That the self-administered hormonal contraceptive does not protect against sexually transmitted infections or HIV, and that the use of a condom does provide protection against sexually transmitted infections and HIV; and

    v. Any other information relevant to the hormonal contraceptive furnished; if medroxyprogesterone acetate is furnished, counsel the patient that using it for more than two years is not recommended because of a risk of loss of significant bone mineral density.

3. Provide the patient with a written record of the self-administered hormonal contraceptive furnished. The pharmacist may use the Pharmacist Visit Summary and Referral template available at www.njconsumeraffairs.gov/phar/Pages/default.aspx to provide the written record and may customize the template by adding to it, but may not remove any elements from the template. At a minimum, the written record provided by the pharmacist to the patient must include:

    i. The patient's name and date of birth;

    ii. The name, address, permit number, and telephone number of the pharmacy practice site, and the name, license number, and signature of the pharmacist;

    iii. The date of the visit and the date on which the self-administered hormonal contraceptive was furnished;

    iv. The name and strength (if applicable) of the contraceptive that was furnished;

v. The quantity furnished and how many refills were authorized (if any);

vi. Any recommended follow-up; and

vii. A statement that information on reproductive rights, health care coverage and services, and other resources can be found at the New Jersey Reproductive Health Information Hub, www.nj.gov/health/reproductivehealth/.

4. Offer to provide counseling to the patient about other forms of contraception, including contraception not included in "Hormonal Contraceptives Authorized Pursuant to this Protocol" above, that have been approved by the Federal Food and Drug Administration, and, if the patient accepts the offer for counseling, the pharmacist must provide the patient with specific and appropriate information about such other forms of contraception, based on the results of the Health Screening Questionnaire.

5. At each patient encounter, provide the patient with a referral to the patient's primary care provider, or, if the patient does not have a primary care provider, to an appropriate and nearby medical clinic that provides primary and contraceptive care. The Pharmacist Visit Summary and Referral template available at www.njconsumeraffairs.gov/phar/Pages/default.aspx may be used. A pharmacist may customize the template by adding to it, but may not remove any elements from the template.

(b) If the patient is eligible to receive a self-administered hormonal contraceptive from the pharmacist, the pharmacist may furnish an initial supply of up to three months at one time, with refills for up to nine months, for a total of twelve months.

(c) At three months, the pharmacist shall recheck the patient's blood pressure and ask if there are any changes to the patient's responses to the Health Screening Questionnaire, provided that measuring seated blood pressure is not necessary if the patient is taking progestin-only oral contraceptive pills.

(d) If, after twelve months, the patient requests a refill, the pharmacist shall repeat the procedures in "Procedures for Hormonal Contraceptive Screening and Selection" above. The patient shall complete the Health Screening Questionnaire at least once every twelve months.

1. If there is no change in the formulation or method of contraceptive furnished to the patient, the pharmacist may authorize refills for a supply of up to twelve months.

2. If there is a change in the formulation or method of hormonal contraceptive furnished to the patient, then the pharmacist may furnish an initial supply of up to three months at one time, with refills for up to nine months, for a total of twelve months. At three months, the pharmacist shall recheck the patient's blood pressure and ask if there are any changes to the patient's responses to the Health Screening Questionnaire, provided that rechecking seated blood pressure is not necessary if the patient is taking progestin-only oral contraceptive pills.

(e) A pharmacist shall not continue to furnish medroxyprogesterone acetate after two years without a prescription from a healthcare provider. If a patient has used medroxyprogesterone acetate for one year and nine months, the pharmacist shall refer the patient to a health care provider to obtain a prescription.

(f) If the evaluation indicates that hormonal contraceptives are contraindicated for the patient, the pharmacist must not furnish one.

1. The pharmacist must offer to provide counseling to the patient about other forms of contraception, including contraception not included in "Hormonal Contraceptives Authorized Pursuant to this Protocol" above, that have been approved by the Federal Food and Drug Administration, and, if the patient accepts the offer for counseling, the pharmacist must provide the patient with specific and appropriate information about such other forms of contraception, based on the results of the Health Screening Questionnaire.

2. The pharmacist must provide the patient with a referral to the patient's primary care provider, or, if the patient does not have a primary care provider, to an appropriate and nearby medical clinic that provides primary and contraceptive care. The Pharmacist Visit Summary and Referral template available at www.njconsumeraffairs.gov/phar/Pages/default.aspx may be used. A pharmacist may customize the template by adding to it, but may not remove any elements from the template. The referral must include the reason the pharmacist did not furnish a self-administered hormonal contraceptive to the patient.

(g) The dispensing of the self-administered hormonal contraceptive furnished pursuant to a standing order shall be processed in the same manner that a prescription drug or device is dispensed, pursuant to the applicable statutes and rules for the dispensing of prescription drugs and devices. When furnishing self-administered hormonal contraceptives per this Protocol, the name and National Provider Identifier number of the physician issuing the standing order is entered in the patient profile as the prescriber.

Recordkeeping

The pharmacist must keep the following records for seven years according to the requirements at N.J.A.C. 13:39-14.6(b) through (e):

1. A written or electronic record for any patient screened and for any self-administered hormonal contraceptive that is furnished under the Protocol, including, without limitation, any completed Health Screening Questionnaire, Pharmacist Visit Summary and Referral form, and all of the information required at N.J.A.C. 13:39-7.6; and

2. Documentation of the pharmacist's successful completion of the self-administered hormonal contraceptive training program, the affirmation required at N.J.A.C. 13:39-14.2(a) and a copy of the Protocol with the names of pharmacists who may furnish self-administered hormonal contraceptives under the standing order at the pharmacy practice site as required at N.J.A.C. 13:39-14.2(b).

Pharmacists Authorized to Furnish Self-Administered Hormonal Contraceptives

Pharmacy Name: _____
Pharmacy Practice Site Address: _____
Pharmacy Permit Number: _____
Pharmacy Phone Number: _____

By signing below, the pharmacist affirms that the pharmacist has completed a training program compliant with N.J.A.C. 13:39-14.7, will follow pertinent guidelines offered by the Federal Centers for Disease Control and Prevention, including the United States Medical Eligibility Criteria for Contraceptive Use, and is authorized to furnish self-administered hormonal contraceptives pursuant to the New Jersey Pharmacist Hormonal Contraceptives Protocol. This form will be retained as a medical record for seven years.

	Names	**Signatures**
1)	_____	_____
2)	_____	_____
3)	_____	_____
4)	_____	_____
5)	_____	_____
6)	_____	_____
7)	_____	_____
8)	_____	_____
9)	_____	_____
10)	_____	_____