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RULE ADOPTIONS

Reporter
56 N.J.R. 906(a)

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Agency

LAW AND PUBLIC SAFETY > DIVISION OF CONSUMER AFFAIRS > STATE BOARD OF MEDICAL EXAMINERS > BOARD OF PHARMACY

Administrative Code Citation

Jointly Adopted New Rules: N.J.A.C. 13:35-6.28 and 13:35-6.28 Appendix; and 13:39-14.1 through 14.7 and 13:39-14 Appendices A through D

Text

Furnishing of Hormonal Contraceptives by Pharmacists

Proposed: December 4, 2023, at 55 N.J.R. 2384(a).

Adopted: April 10, 2024, by Board of Medical Examiners, Otto F. Sabando, D.O., President, and April 24, 2024, by Board of Pharmacy, Mitch G. Sobel, R.Ph., President.

Filed: April 26, 2024, as R.2024 d.048, **with non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 45:9-2, 45:14-48, and 45:14-67.9.

Effective Date: May 20, 2024.

Expiration Dates: April 3, 2025, N.J.A.C. 13:35;

March 11, 2031, N.J.A.C. 13:39.

Summary of Public Comments and Agency Responses:

The official comment period ended on February 2, 2024. The State Board of Medical Examiners and Board of Pharmacy (together, "the Boards") received comments from:

1. Elise M. Barry, MS, CFRE, Chief Executive Officer, New Jersey Pharmacists Association;

2. Jackie Cornell, MPAP, Executive Director, Planned Parenthood Action Fund of New Jersey;

3. Jeenu Philip, R.Ph., Director, Pharmacy Affairs, Walgreen Co. (comment to State Board of Medical Examiners);

4. Jeenu Philip, R.Ph., Director, Pharmacy Affairs, Walgreen Co. (comment to Board of Pharmacy); and

5. Grace Sesi, PharmD, Executive Director, Pharmacy Regulatory Affairs, CVS Health.

1. COMMENT: One commenter asked that the training requirements at N.J.A.C. 13:35-6.28(b) and 13:39-14.7(a) be amended from a four-hour requirement to a two-hour requirement to increase participation among pharmacists. This commenter also asked whether the training requirement could be stated in terms of the number of credits rather than the number of hours. This commenter thanked the Boards for their flexibility in recognizing training from colleges of pharmacy accredited by the Accreditation Council for Pharmacy Education (ACPE), from providers approved by ACPE, and from programs approved by the Boards.

RESPONSE: The Boards believe that four credits of training is necessary to train pharmacists in screening patients, selecting a hormonal contraceptive, and counseling patients on how to use it. The participating pharmacist must be trained to counsel patients on the self-administration of each of the five types of hormonal contraceptives. The Boards do not believe that two credits of training would be sufficient for this purpose. It is important to note, however, that a participating pharmacist is only required to complete the training once. The training requirement is not an annual or biennial requirement. Moreover, the continuing education credits may be applied toward the pharmacist's existing biennial continuing education requirement. The rules, therefore, will not increase the total number of required continuing education credits. For these reasons, the Boards decline to reduce the length of the continuing education requirement.

The Boards will change N.J.A.C. 13:35-6.28(b) and 13:39-14.7(a) to express the training requirement in terms of credits rather than hours for consistency with N.J.A.C. 13:39.

[page=907] 2. COMMENT: One commenter asked for clarification regarding whether the affirmation of training, which is addressed at N.J.A.C. 13:39-14.2, is retained at the pharmacy or by the individual pharmacist.

RESPONSE: The statute requires that the pharmacist retain the affirmation. N.J.S.A. 45:14-67.9.b(1)(ii) requires the pharmacist to affirm, in writing, that the pharmacist has completed the appropriate training and will follow pertinent guidelines offered by the Federal Centers for Disease Control and Prevention, "which written affirmation shall be retained by the *pharmacist* as a medical record, in a manner and for such periods of time, as required by law" (emphasis added). The Boards believe that it is also important for a pharmacy to maintain documentation that the pharmacists participating in the Pharmacist Hormonal Contraceptives Protocol (Protocol) at that pharmacy are appropriately trained and have fulfilled the statutory affirmation requirement. Therefore, the Boards are changing N.J.A.C. 13:39-14.2(a)2 upon adoption to require the pharmacy to keep a copy of the affirmation of pharmacists furnishing hormonal contraceptives at that pharmacy, in addition to each pharmacist maintaining a record of the pharmacist's own affirmation. The Boards believe that this change will have a negligible impact on pharmacy recordkeeping requirements and will help to protect patients by ensuring that information regarding the authorization of the pharmacist to furnish hormonal contraceptives is readily available at the pharmacy.

3. COMMENT: One commenter stated that the limitation on administration of injectable hormonal contraceptives at N.J.A.C. 13:39-14.3(b) will create a barrier to care and that pharmacists have advanced training in methods of medication administration. This commenter did not request a specific amendment to this subsection.

RESPONSE: The Boards refer the commenter to N.J.S.A. 45:14-67.9(1)(a), which permits pharmacists to furnish *self-administered* hormonal contraceptives, but does not authorize pharmacists to administer the hormonal contraceptive to the patient. Pharmacists are permitted to teach patients how to self-administer the injectable hormonal contraceptive and to select another method of hormonal contraception for patients that are uncomfortable self-administering an injection. The Boards decline to change the rule to permit pharmacists to administer injectable hormonal contraceptives.

4. COMMENT: One commenter stated that blood pressure procedures are evolving to include measuring standing blood pressure in certain situations. The commenter stated that flexibility at N.J.A.C. 13:39-14.4(a)3 to accommodate evolving guidelines would be useful.

RESPONSE: Consistent with U.S. Centers for Disease Control standards, the Boards believe that measuring blood pressure with the patient sitting down remains the accurate method for measuring blood pressure. See, for example, U.S. Centers for Disease Control and Prevention, *Measure Your Blood Pressure*, available at http://www.cdc.gov/bloodpressure/measure.htm. The Boards decline to make this change.

5. COMMENT: Another commenter asked the Boards to remove from N.J.A.C. 13:39-14.4(a)3, the requirement for a certificate of calibration for a device used to measure blood pressure. This commenter suggested that the requirement is burdensome and would require pharmacies to purchase a professional grade manual or electronic pressure cuff system and send monitors and cuffs to manufacturers for recalibration on an ongoing basis. Pharmacies will need to purchase new equipment if a manufacturer goes out of business and can no longer provide the certificate. This commenter supported a pharmacist's ability to use professional judgment and knowledge from training to determine when to replace equipment. This commenter stated that the rule would impose an extreme financial hardship.

RESPONSE: The Boards appreciate this feedback. To maintain the integrity and accuracy of the device, the Boards believe that the device a pharmacist uses to measure blood pressure must be stored behind the pharmacy counter and not be made available for public use. The Boards agree with the commenter that requiring pharmacists to obtain a certificate of calibration is unduly burdensome. The Boards, therefore, will change N.J.A.C. 13:39-14.4(a)3 upon adoption to remove the requirement of a certificate of calibration and instead require that the device be stored behind the counter and be used only by pharmacy staff. The Boards believe that this change will reduce the burden on pharmacies identified by the commenter while ensuring that pharmacists obtain accurate information as to patients' blood pressure.

6. COMMENT: One commenter asked for clarification at N.J.A.C. 13:39-14.4(a)1 on the languages in which the New Jersey Department of Health would make the Health Screening Questionnaire available.

RESPONSE: The Boards refer the commenter to P.L. 2023, c. 263, which requires State entities providing direct services to the public to translate vital documents into at least the seven most common non-English languages spoken by individuals with limited English

proficiency in the State, based on U.S. Census Bureau American Community Survey data. P.L. 2023, c. 263, has a rolling implementation schedule.

7. COMMENT: One commenter requested that the written record provided to the patient not be required to include the pharmacy permit number or the pharmacist's name and license number. The commenter stated that this information is unnecessary, and the requirement is burdensome. The commenter stated that the name and number of the pharmacy should be sufficient. This commenter also submitted a revised form for the Boards to consider in amending the Pharmacist Visit Summary and Referral Template and stated that the commenter's form has all the necessary information.

RESPONSE: The Boards thank the commenter for this feedback. The Boards recognize that some towns may have more than one pharmacy in the same chain, and some pharmacies may relocate, change ownership, or change name. The pharmacy permit number is the unique identifier of each pharmacy throughout the pharmacy's existence. As a result, the Boards believe that including the pharmacy permit number will ensure that the Board of Pharmacy and the patient's other health care providers can identify the pharmacy that the patient visited. The pharmacist's name and license number are necessary for the Board of Pharmacy to know which pharmacist saw the patient and to be able to verify that the pharmacist is authorized to furnish self-administered hormonal contraceptives pursuant to the rule. The pharmacist's signature does not provide that information with sufficient clarity due to legibility issues and the potential for duplicate names.

The Boards appreciate the suggested patient visit summary form submitted by the commenter. N.J.S.A. 45:14-67.9.b(7) requires the pharmacist to refer each patient to whom the pharmacist furnished a self-administered hormonal contraceptive, or for whom the pharmacist determined that a self-administered hormonal contraceptive is not recommended, to the patient's primary care provider, or, if the patient does not have one, to an appropriate and nearby medical clinic. The Boards determined that an appropriate clinic must provide both primary care, as required by the statute, and contraceptive care, to address the reason the patient visited the pharmacist. The commenter's suggested form does not require the pharmacist to refer the patient to a specific provider, or to a provider of both primary and contraceptive care. The Boards, therefore, decline to adopt the commenter's proposed form.

The Boards also believe it is important to provide space in the template for the pharmacist to recommend particular follow-up care based on the individual circumstances of that patient. In addition, the

Boards believe that designated space on the template for the strength and quantity of the hormonal contraceptive and the number of refills authorized is necessary to ensure that the pharmacist conveys that information in one page that the patient can reference and share with other health care providers. The commenter's proposed template does not include space either for recommendations concerning individualized follow-up care or for the pharmacist to indicate the strength and quantity of the hormonal contraceptive and the number of refills authorized.

Furthermore, the Patient Visit and Referral Template is more comprehensive than the commenter's suggested form regarding the reason the patient did not receive hormonal contraception. For example, the template includes the reason a patient with high blood pressure cannot receive a progestin-only pill and a box for "other" with space for the pharmacist to include a reason not enumerated; this information is not included in the commenter's form. However, in an effort to shorten the form without removing essential information, the Boards revised the template at N.J.A.C. 13:39-14 Appendix D to include a "notes" line with the reasons the patient did not receive hormonal contraception only once, rather than including a "notes" line under each reason, as the commenter's form does.

[page=908] Finally, the Boards note that the commenter's form uses the term "prescribed," and the pharmacist does not have prescriptive authority.

8. COMMENT: One commenter requested changes at N.J.A.C. 13:39-14.5(b), (c), and (d). This commenter asked that the pharmacist be able to furnish a supply of 12 months unless there is a clinical reason not to do so or the patient requests a smaller amount. This commenter also requested that the Boards remove the three-month recheck at N.J.A.C. 13:39-14.5(c), which requires the pharmacist to ask all patients if their responses to the Health Screening Questionnaire have changed and to recheck the blood pressure of patients not taking progestin-only pills. This commenter asked that N.J.A.C. 13:39-14.5(d) be amended to allow the pharmacist to provide a 12-month supply regardless of whether there is a change in the formulation or method, without a recheck at three months.

RESPONSE: The Boards believe that the pharmacist checking whether the patient's responses to the Health Screening Questionnaire have changed at three months is necessary to determine if the patient is experiencing any side effects from the hormonal contraceptive. The Boards further believe that monitoring the blood pressure of patients not taking progestin-only pills is necessary to identify hypertension associated with use of the hormonal contraceptive.

9. COMMENT: One commenter strongly supported expanded access to contraception, including allowing pharmacists to provide hormonal methods of contraception. This commenter noted that increasing access to contraception is especially important in light of the overturning of *Roe v. Wade*. This commenter was proud of New Jersey's efforts to expand access to contraception through this rulemaking, particularly the issuance of a Statewide standing order so that any pharmacist in the State will be able to provide hormonal contraception without needing to find a willing physician as a partner. This commenter also appreciated the Boards' recognition of the important social and economic impacts of expanded access to contraception.

RESPONSE: The Boards thank the commenter for supporting the new rules.

10. COMMENT: One commenter recommended that the provisions of the new rules related to referrals and the Pharmacy Visit Summary and Referral Template be modified to direct patients to New Jersey's Reproductive Health Information Hub, http://www.nj.gov/health/reproductivehealth/, to find a list of contraceptive health centers across the State, available at http://njfpl.org/find-a-health-center. The commenter stated that both links should be used on the referral form, as the Reproductive Health Information Hub also includes important consumer information on how to avoid "so-called 'crisis pregnancy centers.'"

RESPONSE: The statutory provision on referrals states that the standardized procedures and protocols shall "require a pharmacist, upon furnishing a self-administered hormonal contraceptive to a patient, or upon determining that a self-administered hormonal contraceptive is not recommended, to refer the patient 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." N.J.S.A. 45:14-67.9.b(7). The statutory requirement for the referral applies to patients who have received hormonal contraceptives from the pharmacist and to patients whom the pharmacist determined to be ineligible to receive hormonal contraceptives due to the patient's responses on the Health Screening Questionnaire.

The Boards believe that "an appropriate and nearby medical clinic" must provide both preventive and contraceptive care. The statute requires a referral to the primary care provider or an appropriate and nearby medical clinic. Pharmacists advise patients who receive hormonal contraception through the Protocol to follow up with their primary care provider because the Protocol is not a substitute for primary care. Pharmacists advise patients who do not receive hormonal contraception through the Protocol to see a primary care provider to address the medical reason they are ineligible pursuant to the Protocol and to access contraception. The Boards require that the provider to whom the

patient is referred be able to provide contraceptive care, in addition to preventive care to ensure that the provider is able to address the patient's contraceptive needs; the provider to whom the patient is referred cannot be limited to one that provides only reproductive care.

The Boards appreciate the important resources that consumers can find through the Reproductive Health Information Hub. However, while the Reproductive Health Information Hub and the list of contraceptive health centers across New Jersey point consumers to providers of *contraceptive* care, they do not provide referrals to providers of *primary* care. Accordingly, the Boards decline to substitute referrals to the Reproductive Health Information Hub and the list of contraceptive health centers for the statutory requirement that the pharmacist refer the patient to the patient's primary care provider or, if the patient does not have one, to an appropriate and nearby medical clinic.

However, the Boards recognize the value of these resources and, therefore, upon adoption will add N.J.A.C. 13:39-14.5(a)3vii to include the Reproductive Health Information Hub website in the Pharmacist Visit Summary and Referral Template as a useful resource for patients, in addition to the referral to a provider of primary and contraceptive care.

11. COMMENT: One commenter stated that the proposed rule is burdensome and should be withdrawn because the Board of Pharmacy has created onerous barriers that include, but are not limited to, the use of burdensome patient intake forms, complicated assessment algorithms, and taxing recordkeeping requirements. This commenter stated that the rules do not align with the legislative intent of expanding pharmacists' prescriptive authority and thereby providing patients with safe access to pharmacist-provided care that improves clinical outcomes. This commenter stated that it "cannot participate in this program in New Jersey with the current proposed rules" and requests that the Boards withdraw the notice of proposal and "involve industry stakeholders in redrafting a protocol that eliminates unnecessary barriers and simplifies the process."

RESPONSE: The new rule aims to expand access to contraception while also protecting patient safety. For example, the new rule allows for a Statewide standing order so that pharmacists do not need to identify a physician to provide the standing order. The new rule also permits authorized pharmacists to furnish five forms of hormonal contraceptives to provide as many options as possible. The Boards sought and considered feedback from stakeholders in developing the new rule. See 55 N.J.R. 2384(a), 2384.

The Boards appreciate the commenter's feedback and can respond only to the specific provisions of the notice of proposal that the commenter references. When the commenter refers to "burdensome patient intake forms," the Boards believe the commenter is referring to the Health Screening Questionnaire. The statute requires the pharmacist to evaluate the patient by administering a questionnaire developed by the Department of Health that will identify risk factors based on the United States Medical Eligibility Criteria for Contraceptive Use (US MEC). See N.J.S.A. 45:14-67.9.b(5). The Boards believe that in addition to being a statutory requirement, using the US MEC is essential to protect patient safety, and the Health Screening Questionnaire will equip pharmacists to use this critical tool.

This commenter stated that the recordkeeping requirements are "taxing." N.J.S.A. 45:14-67.9.b(1)ii requires the pharmacist to affirm, in writing, that the pharmacist completed the appropriate training and to retain the affirmation as a medical record, in a manner and for such periods of time, as required by law. N.J.S.A. 45:14-67.9.b(5) requires the pharmacist to retain the patient's responses to the written questionnaire as a medical record, in a manner and for such periods of time, as required by law. The Boards also refer the commenter to the explanation of the recordkeeping requirement in the prefatory language of the notice of proposal. See 55 N.J.R. 2384(a), 2386. As the pharmacist's records regarding hormonal contraception furnished pursuant to these rules are the patient's medical record in addition to the pharmacy record, the Boards believe that the thorough recordkeeping requirements are necessary to protect patient safety and fulfill the statutory requirements regarding recordkeeping.

Regarding the algorithms that the commenter stated are "complicated," the Boards created these documents as a graphic representation to aid pharmacists in using the Protocol. The Boards believe that a graphic tool can be a useful reference for pharmacists. In order to make the algorithms at N.J.A.C. 13:39-14 Appendices B and C less dense, the Boards are changing them upon adoption to remove the pregnancy screen questions in Section 2 and reference the pregnancy screen questions in the Health Screening Questionnaire instead.

With respect to the commenter's assertion that the Legislature intended to expand pharmacists' prescriptive authority, the Boards note that the statute does not confer prescriptive authority on pharmacists. Instead, it [page=909] authorizes pharmacists to furnish self-administered hormonal contraceptives pursuant to a standing order.

The Boards decline the commenter's suggestion to withdraw the notice of proposal.

Summary of Agency-Initiated Changes:

Upon adoption, the Boards are changing the type of care that must be provided by the provider to whom the pharmacist refers the patient from "preventive and contraceptive care" to "primary and contraceptive care" throughout the rulemaking.

The Boards are changing the Background section of the Protocol upon adoption to add the month and date on which each Board approved the Protocol.

The Boards are changing N.J.A.C. 13:39-14 Appendix D to indicate a blood pressure reading of 140/90 or higher, rather than "higher than 140/90," as disqualifying for certain forms of hormonal contraceptives, for consistency with the algorithms at N.J.A.C. 13:39-14 Appendices B and C and the US MEC.

Federal Standards Statement

There are no Federal laws or standards applicable to the adopted new rules, which are governed by N.J.S.A. 45:14-67.9.

Full text of the adopted new rules follows (additions to proposal indicated in boldface with asterisks ***thus***; deletions from proposal indicated in brackets with asterisks *[thus]*):

CHAPTER 35

BOARD OF MEDICAL EXAMINERS

SUBCHAPTER 6. GENERAL RULES OF PRACTICE

13:35-6.28 Furnishing of self-administered hormonal contraceptives by pharmacists

(a) A pharmacist shall be authorized to furnish self-administered hormonal contraceptives to a patient, in accordance with standardized procedures and protocols jointly developed and approved by the Board and the Board of Pharmacy as set forth at N.J.A.C. 13:39-6.28 Appendix (Protocol), a standing order issued by a licensed physician pursuant to the Protocol, and the rules of the Board of Pharmacy. If the licensed physician issuing the standing order is the New Jersey Commissioner of Health or a designee of the New Jersey Commissioner of Health, the standing order may have Statewide effect.

(b) In order to be authorized to furnish self-administered hormonal contraceptives pursuant to the Protocol, a pharmacist must successfully complete a training program meeting the requirements at (c) below that is at least four *[hours]* ***credits*** and that trains the pharmacist to screen patients to determine eligibility for the self-administered

hormonal contraceptives authorized at N.J.A.C. 13:39-14.3, to select a self-administered hormonal contraceptive, and to counsel patients. A training program that provides education only on the pharmacology of contraceptives is not sufficient to satisfy the requirements of this subsection.

(c) The Board shall recognize training programs that meet the requirements at (b) above and are:

1. Offered at a college of pharmacy accredited by the Accreditation Council for Pharmacy Education;

2. Offered by an Accreditation Council for Pharmacy Education-approved provider; and

3. Of comparable scope and rigor to courses accredited by the Accreditation Council for Pharmacy Education and be approved by the Board of Pharmacy pursuant to N.J.A.C. 13:39-3A.6 and by the Board.

(**Agency Note:** The text of N.J.A.C. 13:35-6.28 Appendix below includes text in permanent boldface; language in the appendix indicated in boldface without asterisks is intended to be permanently boldfaced.)

APPENDIX

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 http://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 [page=914] 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;

[page=910] 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 pharmacist shall have a valid certificate of calibration for the device]* ***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 http://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); *[and]*

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, http://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 *[preventive]* ***primary*** and contraceptive care. The Pharmacist Visit Summary and Referral template available at http://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. [page=911] 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 *[preventive]* ***primary*** and contraceptive care. The Pharmacist Visit Summary and Referral template available at http://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 pursuant to 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 in 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 pursuant to 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.

Name	**Signature**
1) _____	_____
2) _____	_____
3) _____	_____
4) _____	_____
5) _____	_____
6) _____	_____
7) _____	_____
8) _____	_____
9) _____	_____
10) _____	_____

CHAPTER 39

STATE BOARD OF PHARMACY

SUBCHAPTER 14. SELF-ADMINISTERED HORMONAL CONTRACEPTIVES

13:39-14.1 Protocol for pharmacists furnishing self-administered hormonal contraceptives

(a) A pharmacist shall be authorized to furnish self-administered hormonal contraceptives to a patient, in accordance with standardized procedures and protocols jointly developed and approved by the Board and the State Board of Medical Examiners as set forth at N.J.A.C. 13:39 Appendix A (Protocol), a standing order issued by a licensed physician pursuant to the Protocol, and the rules in this chapter. If the licensed physician issuing the standing order is the New Jersey Commissioner of the Department of Health, or a designee, the standing order may have Statewide effect.

(b) A pharmacist must keep a written copy of the 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. The final page of the Protocol must include the names of each pharmacist authorized pursuant to this subchapter to furnish self-administered hormonal contraceptives at the pharmacy practice site. The pharmacist must make a copy of the Protocol and the standing order available upon the request of a representative of the Board.

(c) Nothing in this subchapter or the Protocol shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.

(d) The requirements of this subchapter and the Protocol do not apply to a pharmacist dispensing a self-administered hormonal contraceptive pursuant to an individual prescription issued by a healthcare practitioner authorized to prescribe self-administered hormonal contraceptives in the course of professional practice or to a nonprescription hormonal contraceptive; provided, however, that nothing in this subchapter shall prohibit any person from obtaining a nonprescription hormonal contraceptive pursuant to the Protocol.

13:39-14.2 Authorization of pharmacists to furnish self-administered hormonal contraceptives

(a) In order for a pharmacist to be authorized to furnish self-administered hormonal contraceptives pursuant to the 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 as required at (a)2 above; and

ii. A certificate of completion of the training course required pursuant to (a)1 above.

(b) A pharmacist who is authorized to furnish a self-administered hormonal contraceptive pursuant to the 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) shall be completed by the pharmacist authorized to furnish a hormonal contraceptive pursuant to the Protocol.

(c) A pharmacist authorized to furnish hormonal contraception 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.

[page=912] 13:39-14.3 Hormonal contraceptives authorized pursuant to the Protocol

(a) Pharmacists may furnish the following self-administered hormonal contraceptives pursuant to the Protocol:

1. Combined oral contraceptive pill;

2. Progestin-only oral contraceptive pill;

3. Patch;

4. Ring; and

5. Injectable hormonal contraceptive.

(b) 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 by the patient and cannot be administered by the pharmacist.

(c) In the event the Federal Food and Drug Administration confers nonprescription status to any contraceptive authorized to be furnished pursuant to the Protocol, a consumer shall not be required to obtain

that nonprescription contraceptive through the Protocol, but may obtain it through the Protocol if the consumer chooses to do so.

13:39-14.4 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 measure seated blood pressure, *[the pharmacist shall have a valid certificate of calibration for the device]* ***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 set forth at N.J.A.C. 13:39-14 Appendix B or, if an injectable hormonal contraceptive is under consideration, the Algorithm for Self-Administered Injectable Hormonal Contraceptives set forth at N.J.A.C. 13:39-14 Appendix C. 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 CFR Parts 160 and 164, Subparts A and E, and other applicable law.

(c) The pharmacist must make clinical decisions that are free from any financial influence imposed by insurance providers, contraceptive product manufacturers, and other parties having a financial interest in the disbursement or non-disbursement of self-administered hormonal contraceptives.

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

13:39-14.5 Procedures for patient counseling and furnishing hormonal contraceptives

(a) If the pharmacist concludes, based on N.J.A.C. 13:39-14.4, 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 counseling that includes the following information:

i. An information sheet for the product furnished that includes 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 set forth at N.J.A.C. 13:39-14

Appendix D and available at http://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); *[and]*

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, http://www.nj.gov/health/reproductivehealth/.*

4. Offer to provide counseling to the patient about other forms of contraception, including contraception not included at N.J.A.C. 13:39-14.3(a), 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 *[preventive]* ***primary*** and contraceptive care. The Pharmacist Visit Summary and Referral template set forth at N.J.A.C. 13:39-14 Appendix D and available at http://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 a refill for up to nine months, for a total of 12 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 to verify the patient's continued eligibility for the hormonal contraceptive, provided that measuring seated blood pressure is not necessary if the patient is taking progestin-only oral contraceptive pills.

[page=913] (d) If, after 12 months, the patient requests a refill, the pharmacist shall repeat the procedures at N.J.A.C. 13:39-14.4. The patient shall complete the Health Screening Questionnaire at least once every 12 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 12 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 12 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 health care 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 shall not furnish one.

1. The pharmacist shall offer to provide counseling to the patient about other forms of contraception, including contraception not included at N.J.A.C. 13:39-14.3(a), 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 *[preventive]* ***primary*** and contraceptive care. The Pharmacist Visit Summary and Referral template set forth at N.J.A.C. 13:39-14 Appendix D and available at http://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 pursuant to the Protocol, the name and National Provider Identifier number of the licensed physician issuing the standing order is entered in the patient profile as the prescriber.

13:39-14.6 Recordkeeping

(a) The pharmacist must keep the following records:

1. A written or electronic record for any patient screened and for any self-administered hormonal contraceptive that is furnished pursuant to 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 pursuant to the standing order at the pharmacy practice site, as required at N.J.A.C. 13:39-14.2(b).

(b) All records required pursuant to the Protocol shall be maintained in either hard copy or electronic form for a period of not less than seven years and shall be supplied to the Board upon request.

(c) All records shall be made available to persons authorized to inspect them pursuant to State and Federal statutes and regulations. The oldest six years of information shall be maintained in such a manner, so as to be retrievable and readable within two weeks. The most recent one year of information shall be retrievable and readable within one business day.

(d) Records not currently in use need not be stored in the pharmacy, but the storage facilities shall be secure.

(e) Patient records shall be kept confidential.

13:39-14.7 Hormonal contraceptive training

(a) In order to be authorized to furnish self-administered hormonal contraceptives pursuant to the Protocol, a pharmacist must successfully complete a training program recognized pursuant to (c) below that is at least four *[hours]* ***credits*** and trains the pharmacist to:

1. Screen patients to determine eligibility for the self-administered hormonal contraceptives authorized at N.J.A.C. 13:39-14.3;

2. Select a self-administered hormonal contraceptive; and

3. Counsel patients.

(b) A training program that provides education only on the pharmacology of contraceptives is not sufficient to satisfy the requirements of this section.

(c) The Board shall recognize training programs that meet the requirements at (a) above and are:

1. Offered at a college of pharmacy accredited by the Accreditation Council for Pharmacy Education;

2. Offered by an Accreditation Council for Pharmacy Education-approved provider; and

3. Of comparable scope and rigor to courses accredited by the Accreditation Council for Pharmacy Education and be approved by the Board pursuant to N.J.A.C. 13:39-3A.6 and by the State Board of Medical Examiners.

(**Agency Note:** The text of N.J.A.C. 13:39-14 Appendices A through D below include text in permanent boldface; language in the appendices indicated in boldface without asterisks is intended to be permanently boldfaced.)

APPENDIX A

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 http://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 pharmacist shall have a valid certificate of calibration for the device]* ***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 http://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); *[and]*

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, http://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.

[page=915] 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 *[preventive]* ***primary*** and contraceptive care. The Pharmacist Visit Summary and Referral template available at http://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 *[preventive]* ***primary*** and contraceptive care. The Pharmacist Visit Summary and Referral template available at http://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.

Name	**Signature**
1) _____	_____
2) _____	_____
3) _____	_____

4) _____ _____

5) _____ _____

6) _____ _____

7) _____ _____

8) _____ _____

9) _____ _____

10) _____ _____

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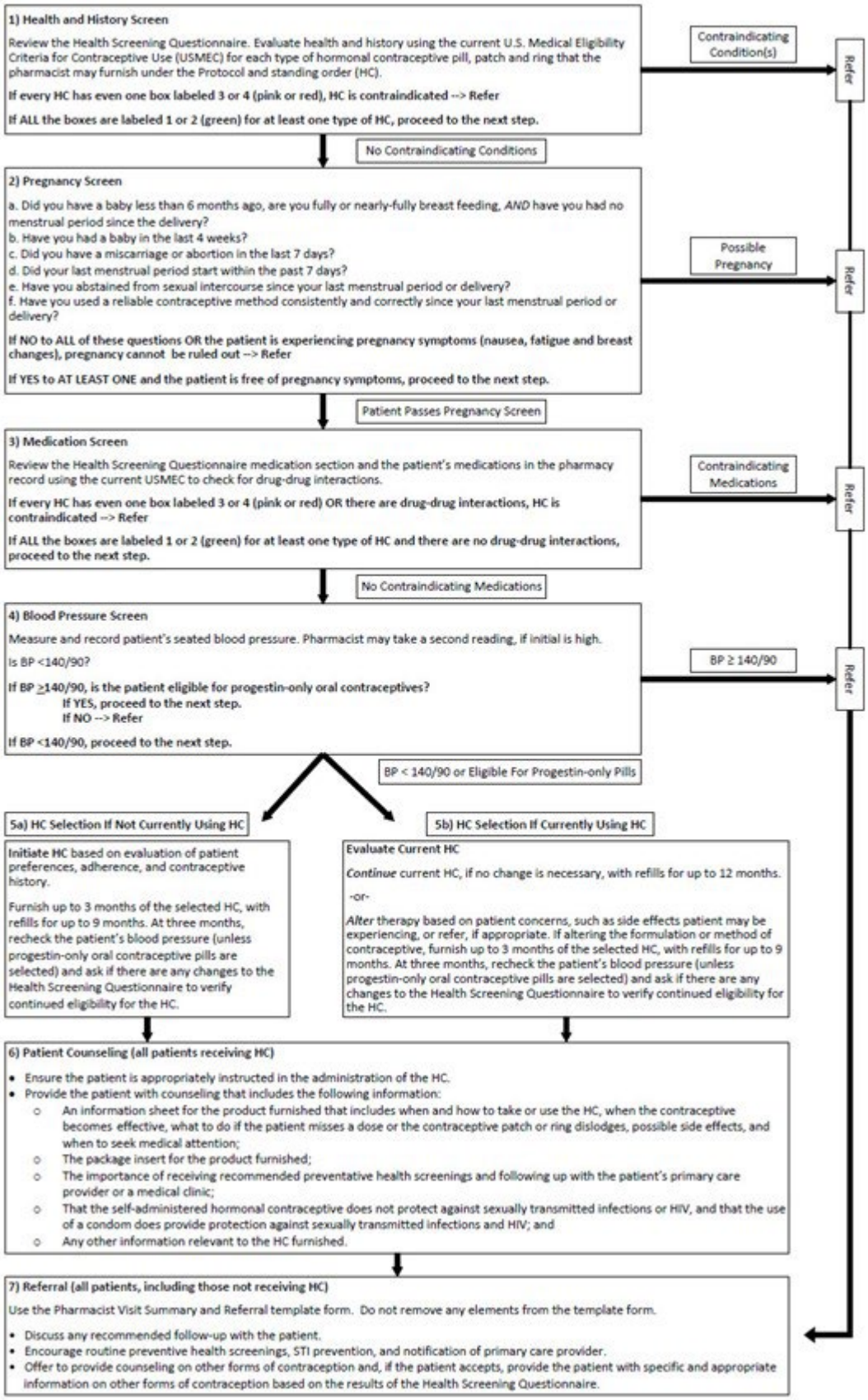
Appendix B
Algorithm for Self-administered Hormonal Contraceptive Pills, Patches, and Rings



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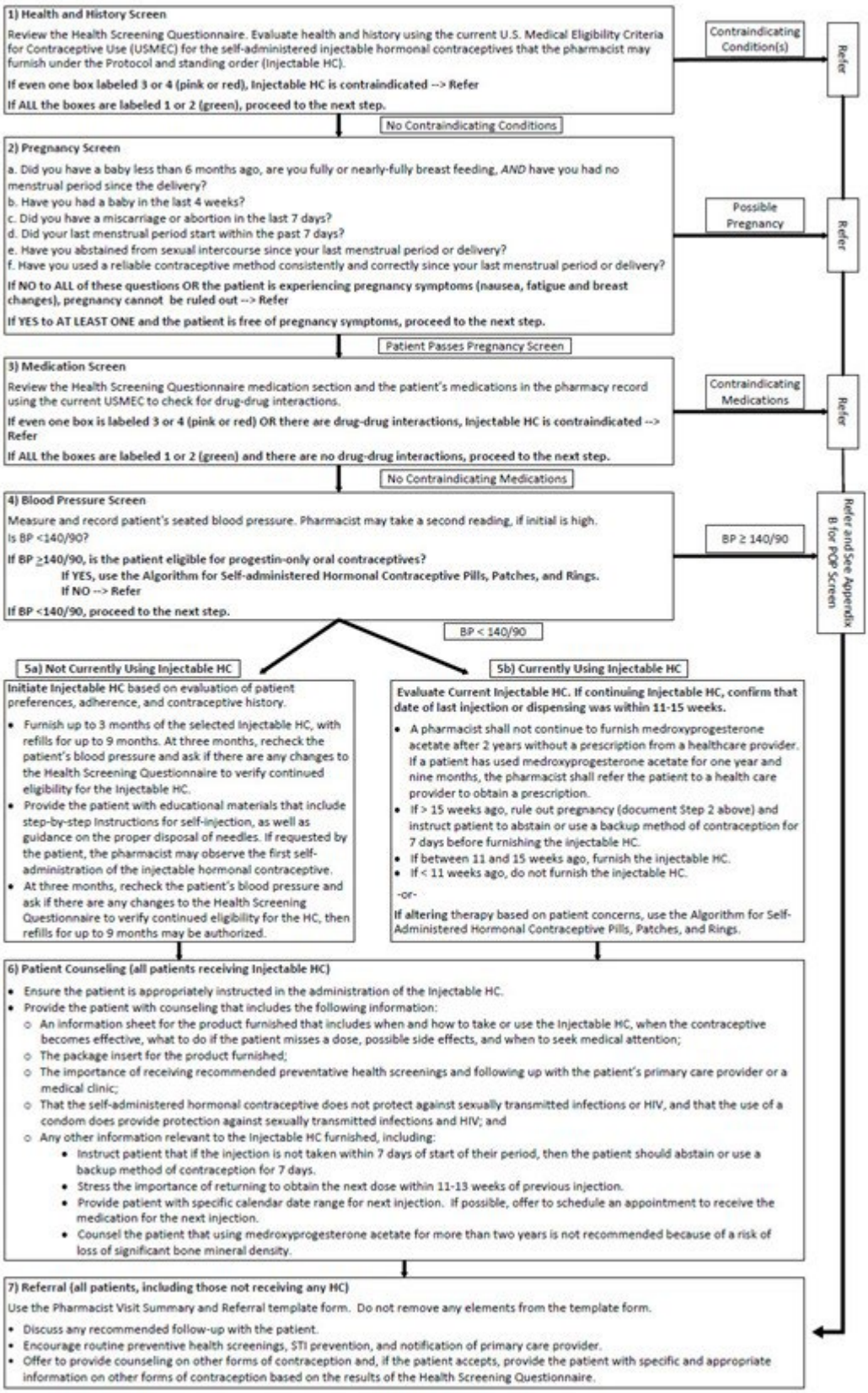
Appendix C
Algorithm for Self-administered Injectable Hormonal Contraceptives



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APPENDIX D

Pharmacist Visit Summary and Referral Template

Attention: You may customize this template by adding to it; however, you must retain all elements in this template.

Patient Name:_____ Date of birth:____/____/_____

Date of visit: ___/___/___

Date hormonal contraceptive furnished (if applicable): ___/___/____

Please review this form with your primary care provider. If you do not have a primary care provider, you may follow up at _____ (insert name, address, and phone number of an appropriate and nearby medical clinic that provides *[preventive]* ***primary*** and contraceptive care).

Recommended follow-up:

_____

Self-administered hormonal contraceptive furnished:

_____

Strength (if applicable): _____ Quantity furnished: _____ Refills authorized: _____

OR

_____ Pharmacist is not able to furnish a self-administered hormonal contraceptive to you because:

☐ Pregnancy cannot be ruled out.

[(Notes:_____)]

☐ You may have a health condition than requires further evaluation.

[(Notes:_____)]

☐ You take medication(s) or supplements that may interfere with contraceptives.

[(Notes:_____)]

☐ Your blood pressure reading is _____/_____ (*[higher than]* 140/90 ***or higher***) and you are not eligible for progestin-only pills because _____.

☐ Other (e.g., intended use is not contraception)

[(Notes:_____)]

Notes:_____

Each requires additional evaluation by another healthcare provider. Please share this information with your provider.

Pharmacist Name _____

Pharmacist Signature _____

Pharmacist License Number _____

Pharmacy Name _____

Pharmacy Practice Site Permit Number _____

Pharmacy Practice Site Address _____

Pharmacy Practice Site Phone Number _____

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

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