

Governor

JAMES V. McDONALD, M.D., M.P.H. Commissioner JOHANNE E. MORNE, M.S. Executive Deputy Commissioner

Non-Individual Specific Prescription for Self-Administered Hormonal Contraceptives with Pharmacy Dispensing Protocol

This non-individual specific prescription (standing order) for self-administered hormonal contraceptives by pharmacists in New York state is issued contingent upon compliance with the protocol and terms below. It is effective January 1, 2024, until such time that it is rescinded or revised, whichever comes first. Questions regarding the scope or applicability of this standing order should be directed to **Pharm_Contraception@health.ny.gov**

Section 1: Purpose

Self-administered hormonal contraceptives means self-administered contraceptive medications or devices approved by the federal Food and Drug Administration to prevent pregnancy by using hormones to regulate or prevent ovulation, and includes oral hormonal contraceptives, hormonal contraceptive vaginal rings, and hormonal contraceptive patches. When used correctly, it is 99% effective at preventing pregnancy.

Section 2: Authority

This Commissioner of Health is authorized by Public Health Law § 267-a to establish a non-individual specific order for pharmacists dispensing of "self-administered hormonal contraception". Non-individual specific prescribing and dispensing of self-administered hormonal contraception is explicitly authorized in Education Law § 6527, 6801, 6802, and 6909.

Section 3: Scope

This standing order pertains to self-administered hormonal contraceptives that are approved by the federal Food and Drug Administration to prevent pregnancy, and include a) an oral hormonal contraceptive, b) a hormonal contraceptive vaginal ring, and c) a hormonal contraceptive patch.

This standing order does not override a valid individual-specific prescription for a hormonal contraceptive that is issued by an authorized prescriber and dispensed by a pharmacist pursuant to that valid prescription unless individual wishes to change birth control method.

This standing order is not intended to be used by organizations who employ or contract with medical staff who are authorized to write standing orders and prescriptions. Such medical staff may create their own standing orders for their individuals.

Section 4: Warnings/Risks

Self -administered hormonal contraception is not a good option for person(s) who have:

- History of blood clots.
- High blood pressure.
- Diabetes.
- Other medical conditions that could be affected by hormonal contraception.

- Are taking medications that could interact with hormonal contraception.
- Are pregnant or breastfeeding.

Risks associated with using self-administered hormonal contraception include:

- Increased risk of blood clots, especially in women who are at high risk for blood clots.
- Increased risk of stroke
- Increased risk of heart attack.
- Increased risk of depression.
- Weight gain.
- Mood Swings.
- Irregular periods.

Section 5: Authorized Dispensers

Registered pharmacists in good standing that have successfully completed training deemed appropriate to the New York State Education Department (NYSED) may utilize this order to dispense self-administered hormonal contraceptives to patients.

Section 6: Eligible Individuals

Persons who may become pregnant, who request hormonal contraception under this standing order, and deemed medically appropriate. Medical appropriateness will be based on individual completion and pharmacist review of the NYS Hormonal Contraception Questionnaire, the standard procedures algorithm, and <a href="Center for Disease Control and Prevention's (CDC) U.S. Medical Eligibility Criteria quidelines.

If the pharmacist's evaluation deems the individual eligible, the pharmacist can assist the individual with selecting the appropriate method of hormonal contraception.

If the pharmacist's review of the individual's completed Hormonal Contraceptive Self-Screening Questionnaire indicates the individual's preferred method is unsafe or inappropriate without medical supervision, they should not dispense the contraceptive method and refer the individual to a physician or other applicable health provider.

Pharmacists reserve the right to refuse to dispense self-administered hormonal contraception if in their professional judgement the potential for adverse effects, interactions, or other therapeutic complications could endanger the health of the individual.

Section 7: Dispense Self-Administered Hormonal Contraception

If the Hormonal Contraceptive <u>Self-Screening Questionnaire</u> has been completed and the method is deemed <u>medically appropriate</u> by the Standardized Assessment and Treatment Care Pathway and the <u>Centers for Disease Control and Prevention's (CDC) U.S. Medical Eligibility Criteria guidelines</u>, pharmacists have the authority under this standing order to provide it. Self-administered hormonal contraceptive methods that can be dispensed under this standing order must be approved by the federal Food and Drug Administration (FDA) to prevent pregnancy and include only the following:

- Oral hormonal pill;
- Hormonal vaginal ring;
- Hormonal contraceptive patch

Pharmacists may dispense up to 12-months of a self-administered hormonal contraceptive, pursuant to patient preference and insurance limitations.

Section 8: Individual Education

Prior to dispensing self-administered hormonal contraception to an individual, and at a minimum of every 12 months for each returning individual, the pharmacist shall:

- Provide the individual with a self-screening risk assessment questionnaire to be utilized and assessed by the pharmacist to assist the individual in selecting an appropriate selfadministered hormonal contraceptive.
- If the selected self-administered hormonal contraception is deemed safe and appropriate based on a pharmacist's clinical judgment, assessment of individual's questionnaire and according to CDC's U.S. Medical Eligibility Criteria guidelines, pharmacist will provide counseling on dispensed self-administered hormonal contraceptive.
- If self-administered hormonal contraceptives are not eligible to be dispensed, pharmacist can counsel on other over-the-counter (OTC) pregnancy prevention.
- Counseling provided based on state requirement 8 NYCRR 63.6(b)(8) and any additional federal requirements, including but is not limited to:
 - How self-administered hormonal contraception works.
 - When and how to take.
 - Warnings and risks associated with taking a self-administered hormonal contraceptive.
 - o Risk for HIV and other sexually transmitted diseases.
 - When to consult with a health care practitioner.
 - What to do if a dose is missed.
- Provide the individual with a fact sheet that includes the clinical considerations and recommendations for use, the appropriate method of use, importance of follow-up health care, health care referral information and the ability of individual to opt out of practitioner reporting requirements.
 - Fact Sheets
 - These informational documents were adapted under a <u>Creative</u>
 <u>Commons license</u> granted by the Reproductive Health Access Project:
 - Combined Oral Pill
 - Progestin Only/Mini Pill
 - The Patch
 - The Ring
- A pharmacist shall <u>notify the individual's primary health care practitioner</u> within 72 hours
 of dispensing unless the individual opts out of this notification. If the individual does not
 have a primary care health care practitioner, the pharmacist will provide the individual
 with written documentation of the self-administered hormonal contraceptive dispensed
 and advise the individual to follow up with an appropriate healthcare provider.
- Additional information to be provided to the individual includes:

- o The importance of follow-up health care
- Health care referral information
- o The ability of the individual to opt out of practitioner reporting requirements

Section 9: Referrals

If the requested self-administered hormonal contraceptive is not eligible to be dispensed, individual should be referred to an appropriate health care practitioner. Resources for Referral:

- New York State Department of Health (NYSDOH) funded sites can be located at <u>Family Planning Program Sites</u>
 (https://www.health.ny.gov/community/pregnancy/family_planning/program_sites.htm)
- New York State Provider and Health Plan Look-Up Tool (https://pndslookup.health.ny.gov/)

Section 10: Record Keeping

All hormonal contraceptive dispensing must be documented consistent with applicable federal and state laws and regulations and with standard pharmacy practice.

Section 11: Review

This standing order will be reviewed and may be updated if there is relevant new evidence, data, reporting requirement or legal language that would impact the process or utilization.

This standing order may be revised or withdrawn at any time by the signee or a higher-ranking physician at the Department with prescribing ability. This Standing order will be reviewed as needed on an annual basis, by the first of January.

Section 12: Order

I am hereby prescribing this non patient-specific order to dispense hormonal contraception as defined by state chapter 128 of the Law of 2023 (Chapter 128), as amended by Chapter 90 of the Laws of 2024 has made Chapter 128 retroactively to January 2024. Specifically, pharmacists who are employees, volunteers, or contractors of the pharmacy licensed in New York State may dispense hormonal contraception.

This standing order is issued by Dr. James V. McDonald, M.D., M.P.H., New York State Commissioner of Health.

Signature:		Date: March 19, 2024

National Provider Identification Number: 1619966959

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