PHARMACIST PRESCRIBED CONTRACEPTION AND THE PHARMACIST'S ROLE IN REPRODUCTIVE HEALTHCARE

Nicole Cieri-Hutcherson, PharmD, BCPS, MSCP

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Disclosures

No relevant financial relationships to disclose.

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Objectives

1. Describe the process for implementing pharmacist provision of prescribed contraception in the United States
2. Summarize recent New York State Legislation that will allow pharmacists to furnish contraception
3. Briefly describe features of self-administered contraceptives
4. Explain how pharmacists can educate users on the risks and benefits of self-administered contraceptive products
5. Outline pharmacy best practices to combat stigma associated with contraception

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PHARMACIST PROVISION OF CONTRACEPTIVES ACROSS THE COUNTRY

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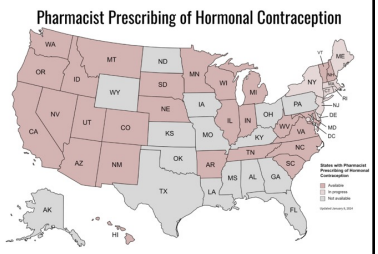
Legislative Updates

- Oregon and California were the first to pass laws allowing pharmacists to furnish (non-collaborative practice agreement) in 2015/2016
- 34 states + Washington D.C. either allow or have legislation in progress

Pharmacist Prescribing of Hormonal Contraception



https://birthcontrolpharmacist.com/policies/

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Implementation

- Some differences in implementation:
  - Pharmacist requirements
  - Patient eligibility
  - Drug formularies
  - Payment for service

Summary of State Policies

State	Available	Authority By	Birth Control Methods	Patient Age Restriction
Arizona	2023	Standing Order	Pill, Patch, Ring	18 and older
Arkansas	2022	Statewide Protocol	Pill	18 and older
California	2016	Statewide Protocol	Pill, Patch, Ring, Shot	All ages
Colorado	2017	Statewide Protocol	Pill, Patch, Ring, Shot	18 and older
Hawaii	2016	Statewide Protocol	Pill, Patch, Ring	All ages
Idaho	2019	Prescriptive Authority	Pill, Patch, Ring, Shot	All ages
Illinois	2025	Standing Order	Pill, Patch, Ring, Shot	All ages
Indiana	2023	Standing Order	Pill, Patch, Ring, Shot	18 and older
Maryland	2019	Statewide Protocol	Pill, Patch, Ring, Shot	All ages
Minnesota	2020	Statewide Protocol	Pill, Patch, Ring	18 and older (under 18 with prior prescription)
Nevada	2021	Statewide Protocol	Pill, Patch, Ring, Shot	All ages
New Hampshire	2022	Standing Order	Pill, Patch, Ring, Shot	All ages
New Mexico	2018	Statewide Protocol	Pill, Patch, Ring, Shot, Hormonal Methods	All ages
North Carolina	2022	Standing Order	Pill, Patch	18 and older (under 18 with parental/legal guardian consent)
Oregon	2016	Statewide Protocol	Pill, Patch, Ring, Shot	All ages
South Carolina	2022	Statewide Protocol	Pill, Patch, Ring, Shot	18 and older (under 18 with prior prescription)
Tennessee	2019	Contraceptive Collaborative Practice Agreement	Pill, Patch, Ring, Shot	18 and older (under 18 if emancipated minor)
Utah	2019	Standing Order	Pill, Patch, Ring	18 and older
Vermont	2021	Statewide Protocol	Pill, Patch, Ring	All ages
Virginia	2021	Statewide Protocol	Pill, Patch, Ring, Shot	18 and older
West Virginia	2020	Standing Order	Pill, Patch, Ring	18 and older
Others Offering via General Collaborative Practice Agreement: Michigan, Montana, Nebraska, South Dakota, Washington, Wisconsin				
Others with Statewide Protocols or Standing Orders in Progress: Connecticut, Delaware, Maine, Massachusetts, New Jersey, New York, Rhode Island, Washington D.C.				

This table reflects states that have implemented their policies for pharmacist prescribing of hormonal contraception, as well as those that have passed legislation and implementation is in progress. Updated January 8, 2024.

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https://birthcontrolpharmacist.com/policies/

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Implementation

Others with Statewide Protocols or Standing Orders in Progress:
Connecticut, Delaware, Maine, Massachusetts, New Jersey, New York, Rhode Island, Washington D.C.

This table reflects states that have implemented their policies for pharmacist prescribing of hormonal contraception, as well as those that have passed legislation and implementation is in progress. Updated January 8, 2024

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https://birthcontrolpharmacist.com/policies/

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Payment for Service

- Product coverage under Affordable Care Act
- Payment for pharmacist consultation varies by state
  - Payment as mid-level provider
  - No specification
  - May charge fee for consulting
- Insurance coverage may depend on provider status in the state

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CONTRACEPTIVE LEGISLATION UPDATES IN NEW YORK STATE

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Comprehensive Contraceptive Coverage Act (A585A/S659A)

- Signed into law: April 12, 2019, Effective: January 1, 2020
- Provide insurance coverage for FDA-approved contraceptive drugs, devices and products.
- Requires coverage without deductible, coinsurance, copayment, or any other cost-sharing requirements for covered contraceptives
  - Federal rules require only one of each of the 18 FDA-approved methods to be covered without cost-sharing
  - This includes emergency contraception, when "provided pursuant to a prescription or order… or when lawfully provided over the counter"
- Requires health insurance plans that offer commercial and Medicaid policies to cover an extended 12-month supply of contraceptives given to a patient during a single encounter.
  - Very little uptake

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NY Birth Control Access Act (A.1060/S1043)

- Signed into law: May 2, 2023
- Authorizes pharmacists to "Execute a non-patient specific order for the dispensing of self-administered hormonal contraceptives prescribed or ordered by the commissioner of health, a physician licensed in this state, or a nurse practitioner certified in this state"
- Procedure and training requirements released March 18, 2024

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NY Birth Control Access Act (A.1060/S1043)

a. Definitions. As used in this section, 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.

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NY Birth Control Access Act (A.1060/S1043)

b. Pursuant to sections 6527, 6801, and 6909 of the Education Law, a pharmacist licensed and located in this state may execute a non-patient specific order to dispense self-administered hormonal contraceptives provided that:
   a. the pharmacist has successfully completed training in the dispensing of self-administered hormonal contraceptives, satisfactory to the commissioner;
   b. the non-patient specific order is prescribed or ordered by the commissioner of health, a physician licensed in this state, or a nurse practitioner certified in this state; and
   c. the self-administered hormonal contraceptive is 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 and is being dispensed to the patient for such purpose.

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NY Birth Control Access Act (A.1060/S1043)

c. Requirements.
   a. A pharmacist licensed and located in this state shall not dispense self-administered hormonal contraceptives to patients pursuant to a non-patient specific order without receiving training satisfactory to the commissioner. Training that is satisfactory to the commissioner shall entail the completion of instruction in the dispensing of self-administered hormonal contraceptives that provides:
      a. knowledge of the menstrual cycle, including the different menstrual cycle phases and hormonal functions;
      b. knowledge of the various contraceptive methods, medications and devices, including both self-administered and non-self-administered contraceptives and devices. Such overview shall also include the pharmacology and mechanisms of actions for the various contraceptives and devices available on the market;
      c. knowledge of the precautions and contraindications in the use of hormonal contraceptives; and
      d. knowledge of the various techniques required to counsel and adequately screen patients for the dispensing of an appropriate self-administered hormonal contraceptive if applicable.

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NY Birth Control Access Act (A.1060/S1043)

c. Requirements.
   a. Pharmacists that dispense self-administered hormonal contraceptives to patients pursuant to a non-patient specific order are required to maintain documentation of their successful completion of the training prescribed in paragraph (1) of this subdivision. Such documentation shall be available for review by the department upon request.

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NY Birth Control Access Act (A.1060/S1043)

d. Standards, procedures and reporting requirements for the dispensing of self-administered hormonal contraceptives pursuant to a non-patient specific order.
   a. Prior to dispensing self-administered hormonal contraceptives to a patient and at a minimum of every twelve months thereafter for each returning patient, the licensed pharmacist shall:
      a. Provide the patient with a self-screening risk assessment questionnaire, developed by the commissioner of health in consultation with the commissioner, to be reviewed by the pharmacist to identify any known risk factors and assist the patient's selection of an appropriate self-administered hormonal contraceptive; and
      b. Provide the patient with a fact sheet, developed by the commissioner of health, that includes, but is not limited to, the clinical considerations and recommendations for use of the self-administered hormonal contraceptive, the appropriate method for using such self-administered hormonal contraceptive, information on the importance of follow-up health care, health care referral information, and the ability of the patient to opt out of practitioner reporting requirements.

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NY Birth Control Access Act (A.1060/S1043)

d. Standards, procedures and reporting requirements for the dispensing of self-administered hormonal contraceptives pursuant to a non-patient specific order.
   b. A licensed pharmacist shall notify the patient's primary health care practitioner, unless the patient opts out of such notification, within 72 hours of dispensing a self-administered hormonal contraceptive, that such self-administered hormonal contraceptive has been dispensed. Such notification may occur via electronic transmission or facsimile. If the patient does not have a primary health care practitioner or is unable to provide contact information for their primary health care practitioner, the pharmacist shall provide the patient with a written record of the self-administered hormonal contraceptives dispensed and advise the patient to consult an appropriate health care practitioner.
   c. A licensed pharmacist shall:
      a. maintain records of the dispensing of the self-administered hormonal contraception, in accordance with section 6810(5) of the Education Law; and
      b. maintain or ensure the maintenance of a copy of the non-patient specific order which authorizes the pharmacist to dispense self-administered hormonal contraception in accordance with the requirements of this section.
   d. Nothing in this section shall prevent a pharmacist from refusing to dispense a non-patient specific order of self-administered hormonal pursuant to this section if, in their professional judgment, potential adverse effects, interactions or other therapeutic complications could endanger the health of the patient

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METHODS
Pill, Patch, Ring

AGES
No restrictions

DURATION
Patient must be evaluated every 12 months

APPOINTMENTS
No restrictions

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Assessment Question 1:

Which of the following methods are pharmacists able to dispense under the New York standing order?

A. Pill
B. IUD
C. Diaphragm
D. Injection

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Reproductive Health

Reproductive Health

Pharmacist Resources

Pharmacist Dispensed Contraception

Governor Hochul signed legislation in May of 2023 to expand access to hormonal contraception – the pill, patch, and ring – by making them available after consulting with a pharmacist. This allows people who may not have a primary care provider, but do have access to a local pharmacy, access to safe and effective contraception.

With the State Education Department adopting an amendment to the Regulations of the Commissioner of Education, and the Department of Health providing a standing order in the coming days, we are one step closer to people being able to access hormonal contraception at the pharmacy.

Resources for Pharmacists

The New York State Education Department and New York State Department of Health have jointly developed resources to support pharmacists. This website will be updated as more resources become available, including translations of materials.

Pursuant to the new law and regulations, the New York State Education Department and New York State Department of Health have jointly developed the following steps and resources to support pharmacists.

When a patient comes to a pharmacy and asks for the pill, patch, or ring to prevent a pregnancy, the pharmacist shall have them fill out a self-screening risk assessment questionnaire to determine if it is safe for the patient to have one of the approved forms of self-administered hormonal contraception.

After the questionnaire is completed, the pharmacist shall compare the response to the clinical workflow to ensure there are no safety issues with the birth control options. If eligible, a pharmacy referral and patient handout shall be filled out by the pharmacist and given to the person along with a supply (up to 12 months depending upon insurance requirements) of a safe and effective form of birth control and a fact sheet.

Based on the pharmacist's clinical judgement, if there are concerns relating to responses on the questionnaire and a self-administered hormonal contraceptive method cannot be dispensed at the time of the patient's visit, this should be noted on the pharmacy referral and patient handout, which shall include information about how to access a Family Planning Center or access a provider in their insurance network.

Finally, unless the patient opts out, a provider notification form must be sent to the patient's primary health care practitioner with the dispensed drug information.

Available at: health.ny.gov/community/reproductive_health/

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The Commissioner of Health will soon be issuing a statewide standing order that can be utilized by pharmacists and pharmacies as needed.

- Commissioner's Standing Order - Non-Individual Specific Prescription for Self-Administered Hormonal Contraceptives with Pharmacy Dispensing Protocol (PDF)

NEW YORK STATE DEPARTMENT OF HEALTH
CONTRACEPTION: Self-Screening Patient Intake Form

CONFIDENTIAL – PROTECTED HEALTH INFORMATION

- Contraception Fact Sheet - The Pill (#26050) (PDF)
- Contraception Fact Sheet - Progestin-only/Mini-pill (#26070) (PDF)
- Contraception Fact Sheet - The Patch (#26090) (PDF)
- Contraception Fact Sheet - The Ring (#26110) (PDF)

Additional Resources

Available at: health.ny.gov/community/reproductive_health/

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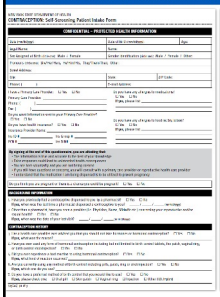

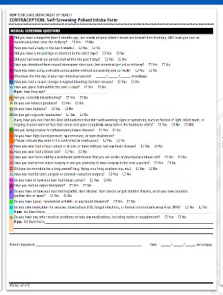

Self-Screening Patient Intake Form

Available at: health.ny.gov/community/reproductive_health/

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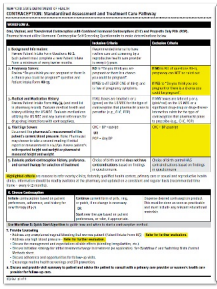
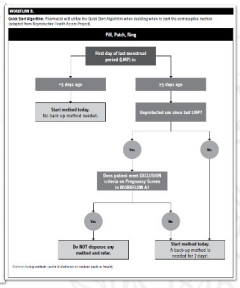
Standard Procedures Algorithm

1. Background
2. Pregnancy screen
3. Medical and medication hx
4. Vital signs screen
5. Evaluate for patient options





Available at: health.ny.gov/community/reproductive_health/

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Pharmacist Requirements and Process

1. Complete training program
2. Review NY self-screening questionnaire
3. Review NY standard procedures algorithm
4. Compare with US Medical Eligibility Criteria (US MEC)
5. If patient is eligible for hormonal contraception, assist patient in selecting the appropriate method
6. If patient is NOT eligible, pharmacist can counsel on other OTC pregnancy prevention options
7. Complete documentation process, provider notice within 72 hours

Curtis KM, Jatlaoui TC, Tepper NK, et al. U.S. Selected Practice Recommendations for Contraceptive Use, 2016. MMWR Recomm Rep 2016;65(No. RR-4):1-66. DOI: http://dx.doi.org/10.15585/mmwr.rr6504a1

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4. Compare with US Medical Eligibility Criteria

Medical Eligibility Criteria (MEC): "Contraindications"

- Category 4 (Unacceptable Health Risks – Method should not be used)
- Category 3 (Risks usually outweigh advantages)
- Category 2 (Advantages usually outweigh risks)
- Category 1 (No Restriction – Method can be used)

Reference: https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/summary.html

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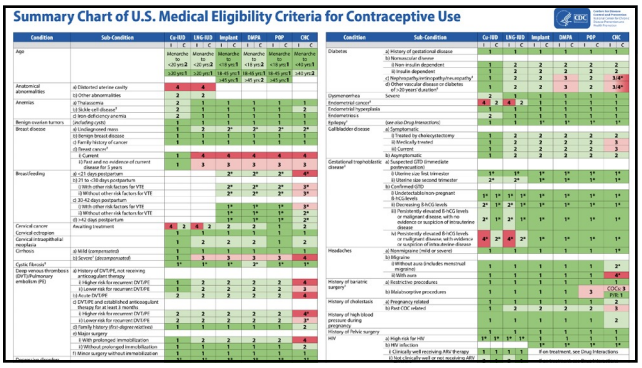
Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use



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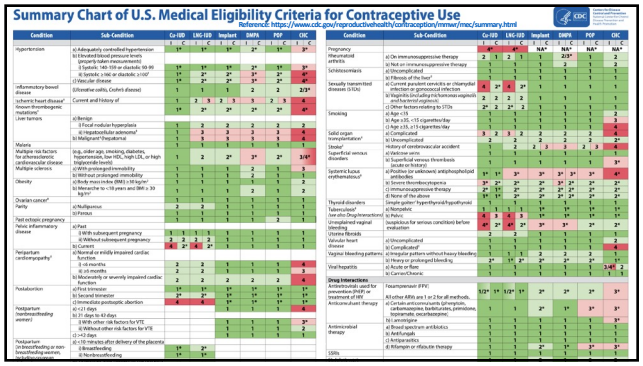
Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use

Reference: https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/summary.html



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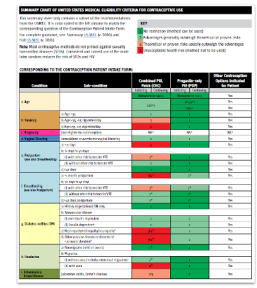

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Available at: health.ny.gov/community/reproductive_health/

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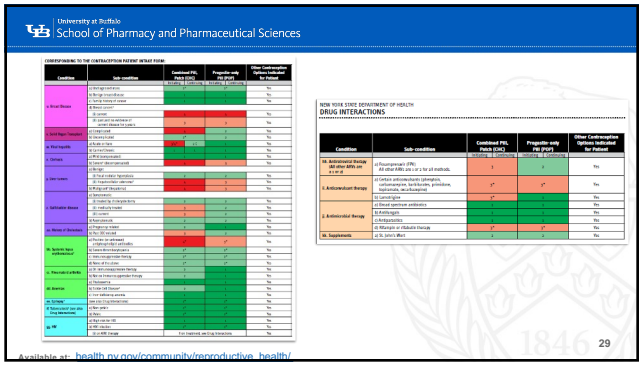

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Available at: health.ny.gov/community/reproductive_health/

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5. Assist Patient in Selecting a Method

Patient Preferences

- How effective are the different methods?
- Can you make contraception part of your daily routine? Would you prefer contraception that you don't have to remember every day?
- Are you comfortable inserting contraceptives into your vagina?
- Do you mind if your periods change?
- Do you smoke?
- What is your age?
- Are you overweight?
- What if you can't use hormonal contraceptives?
- What if you can't use contraceptives that contain estrogen?
- Are you taking medicines for other conditions?
- Do you want to get pregnant in the near future?

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5. Assist Patient in Selecting a Method

Non-contraceptive benefits

- Agents that decrease menstruation related problems (anemia, pain, cramps), improvements in menstrual regularity (PMDD)
- Agents with iron in the formulation for anemia management
- Agents that reduce the risk of ovarian, endometrial cancer or colorectal cancer
- Agents that reduce the risk of ovarian cysts, ectopic pregnancy, pelvic inflammatory disease, endometriosis, uterine fibroids, and benign breast disease
- Agents for acne or migraines

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5. Assist Patient in Selecting a Method

- Has the patient tried the current method for at least 3 months before changing due to minor AE?
- Other patient-specific preferences
  - Does the patient want to skip their period?
  - Have they heard good things about a method from a friend or family member?

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Counsel the Patient on the Method Selected

1. Per the standing order, provide counseling to the patient regarding:
   - How self-administered hormonal contraception works
   - When and how to take
   - Warnings and risks associated with hormonal contraception
   - Risk for HIV and other sexually transmitted diseases
   - When to consult with a health care provider
   - What to do if a dose is missed
2. Provide patient with a fact sheet

FACT SHEET : THE PILL

Remember, the pill **does not protect you from Sexually Transmitted Infections or HIV.** Always use condoms to protect yourself!

HOW DO BIRTH CONTROL PILLS WORK?

- Birth control pills contain hormones like the ones your body makes. These hormones stop your ovaries from releasing eggs. Without an egg, you cannot get pregnant.
- No method of birth control is 100% effective. The pill is 93% effective.

HOW DO I START THE PILL?

- There are 2 ways to start the pill:
  Quick Start: Take your first pill as soon as you get the pack.
  Next period: Take your first pill soon after your next period begins.
- If you take your first pill *up to 5 days after the start of your period*, you are protected against pregnancy **right away.**
- If you take your first pill *more than 5 days after the start of your period*, you should **use condoms as back-up for the first 7 days.**
- You can get a prescription for the pill from your clinician.

HOW DO I USE THE PILL?

- **Once you start using the pill,** take 1 pill each day. Take your pill at the same time each day.
- After you finish a pack of pills, you should start a new pack the next day. You should have NO day without a pill.

WHAT IF I MISS PILLS?

- **I forget ONE pill:** Take your pill as soon as you can.
- **I forget TWO pills or more:** Take your pill as soon as you can. Take your next pill at the usual time. **Use condoms for 7 days. Use emergency contraception (EC) if you have unprotected sex.**

WHAT IF I STOPPED TAKING THE PILL AND HAD UNPROTECTED SEX?

- Take Emergency Contraception (EC) **right away.** EC can prevent pregnancy up to 5 days after sex, and it works better the sooner you take it.

HOW DOES THE PILL HELP ME?

- The pill is safe and effective birth control.
- Your periods may be more regular, lighter, and shorter. You may have clearer skin.
- The pill lowers your risk of getting cancer of the uterus and ovaries.
- The pill has **no effect** on your ability to get pregnant in the future, after you stop taking it.
- Although some people who take testosterone may prefer to avoid estrogen, the pill is safe to use.

HOW WILL I FEEL ON THE PILL?

- You will feel about the same. In the first 2–3 months you may have nausea, bleeding between periods, and/or breast pain. These problems often go away after 2–3 months.

DOES THE PILL HAVE RISKS?

- The pill is very safe. Serious problems are rare. If you have any of the symptoms below, call your clinician.
  - Leg pain, swelling, and redness
  - Weakness or numbness on 1 side of your body
  - Bad headache
  - Vision problems
  - Chest pain
- Your clinician can help you find out if these symptoms are signs of a serious problem.

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How to Start?

How to Be Reasonably Certain That a Woman is Not Pregnant

A health-care provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:

- is ≤7 days after the start of normal menses
- has not had sexual intercourse since the start of last normal menses
- has been correctly and consistently using a reliable method of contraception
- is ≤7 days after spontaneous or induced abortion
- is within 4 weeks postpartum
- is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrheic, and <6 months postpartum

CHCs and POP for NY Pharmacists

When to Start Using Specific Contraceptive Methods

Contraceptive method	When to start (if the provider is reasonably certain that the woman is not pregnant)	Additional contraception (i.e., back up) needed	Examinations or tests needed before initiation[a]
Copper-containing IUD	Anytime	Not needed	Bimanual examination and cervical inspection[c]
Levonorgestrel-releasing IUD	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	Bimanual examination and cervical inspection[c]
Implant	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	None
Injectable	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	None
Combined hormonal contraceptive	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	Blood pressure measurement
Progestin-only pill	Anytime	If >5 days after menses started, use back-up method or abstain for 2 days.	None

Abbreviations: BMI = body mass index; IUD = intrauterine device; STD = sexually transmitted disease; U.S. MEC = U.S. Medical Eligibility Criteria for Contraceptive Use

[a] Weight (kilo) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women. However, measuring weight and calculating BMI (weight [kg]/height [m²]) at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight changes perceived to be associated with their contraceptive method.

[b] Most women do not require additional STD screening at the time of IUD insertion. If a woman with risk factors for STDs has not been screened for gonorrhea and chlamydia according to CDC's STD Treatment Guidelines (http://www.cdc.gov/std/treatment), screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with current purulent cervicitis or chlamydial infection or gonococcal infection should not undergo IUD insertion (U.S. MEC 4).

References: US Selected Practice Recommendations for Contraception Use, CDC
https://www.cdc.gov/reproductivehealth/contraception/pdf/WhenToStart_508Tagged.pdf

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Examinations and Tests Needed Before Initiation of Contraceptive Methods

CHCs, POP, barrier contraceptives for NY Pharmacists

Class A: essential and mandatory in all circumstances for safe and effective use of the contraceptive method.
Class B: contributes substantially to safe and effective use, but implementation may be considered within the public health and/or service context; risk of not performing an examination or test should be balanced against the benefits of making the contraceptive method available.
Class C: does not contribute substantially to safe and effective use of the contraceptive method

Examination or test	Contraceptive method and class								
	Cu-IUD, LNG-IUD	Implant	Injectable	CHC	POP	Condom	Diaphragm, cervical cap	Spermicide (all forms)	Contra-ceptive gel
Examination									
Blood pressure	C	C	C	A[a]	C	C	C	C	C
Weight (BMI)	—[b]	—[b]	—[b]	—[b]	—[b]	C	C	C	C
Clinical breast examination	C	C	C	C	C	C	C	C	C
Bimanual examination and cervical inspection	A	C	C	C	C	C	A[a]	C	C
Laboratory test									
Glucose	C	C	C	C	C	C	C	C	C
Lipids	C	C	C	C	C	C	C	C	C
Liver enzymes	C	C	C	C	C	C	C	C	C
Hemoglobin	C	C	C	C	C	C	C	C	C
Thrombogenic mutations	C	C	C	C	C	C	C	C	C
Cervical cytology (Papanicolaou smear)	C	C	C	C	C	C	C	C	C
STD screening with lab tests	—[b]	C	C	C	C	C	C	C	C
HIV screening with lab tests	C	C	C	C	C	C	C	C	C

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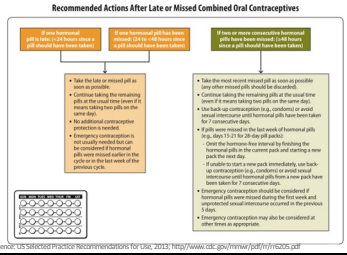
How to Manage Missed Doses?

Recommended Actions After Late or Missed Combined Oral Contraceptives



Reference: US Selected Practice Recommendations for Use, 2013; http://www.cdc.gov/mmwr/pdf/rr/rr6205.pdf

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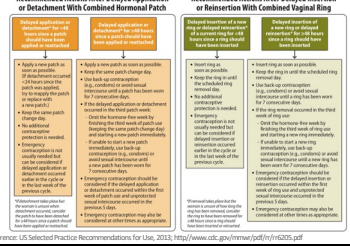
How to Manage Missed Doses?

Recommended Actions After Delayed Application or Detachment With Combined Hormonal Patch



Recommended Actions After Delayed Insertion or Reinsertion With Combined Vaginal Ring

Reference: US Selected Practice Recommendations for Use, 2013; http://www.cdc.gov/mmwr/pdf/rr/rr6205.pdf

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What to Expect? Adverse Effects

- Common AE's with CHCs: Nausea, bloating and breakthrough bleeding
  - These symptoms often improve spontaneously after the 3rd cycle of therapy
  - Counsel women to maintain therapy for ~3 months before changing regimens
- Serious AE's can be remembered using the **ACHES** acronym
  - **A:** abdominal pain
  - **C:** chest pain
  - **H:** headaches
  - **E:** eye problems
  - **S:** severe leg pain

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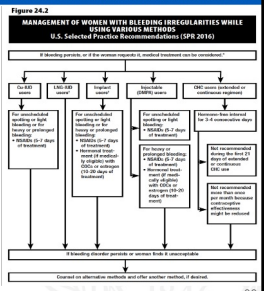
What to Expect? Adverse Effects

- Bleeding irregularities
  - Breakthrough bleeding on CHC
    - Early cycle (days 1-9) increase estrogen content
    - Late cycle (days 10-21) increase progestin content



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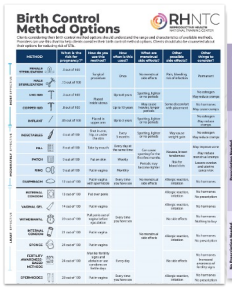
Additional Education Tools

- NY Provided fact sheets
- Birth Control Pharmacist methods guide and fact sheets
- Bedsider.org
- Reproductiveaccess.org



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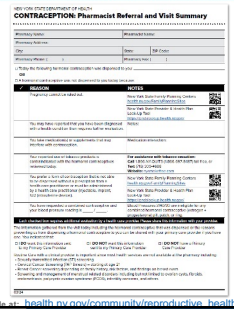

Referral Form and Visit Summary

Available at: health.ny.gov/community/reproductive_health/

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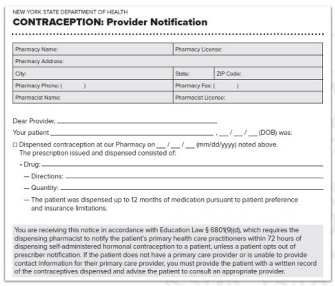
Provider Notification Form



Available at: health.ny.gov/community/reproductive_health/

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Assessment Question 2:

Which of the following is **NOT** required by the New York State hormonal contraception protocol?

A. Measure patient's blood pressure
B. Provide patient with counseling
C. Provide patient with visit summary
D. Notify patient's PCP even if the patient opts out
E. Review patient self-screening form

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Assessment Question 3:

The purpose of the CDC MEC is to:

A. Screen for unacceptable health risks or contraindications
B. Be reasonably certain the patient is not pregnant
C. Determine if the patient has an indication for self-administered contraception
D. Provide an education and counseling information about contraceptives

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SELF-ADMINISTERED HORMONAL CONTRACEPTIVE OPTIONS

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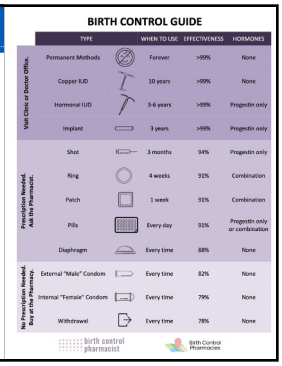
Distinctions

- Hormonal vs. Non-hormonal
- Estrogen + Progestin (CHC) vs. Progestin only
- Historically Prescription vs. Non-prescription
- Self-administered vs. Provider-administered



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Hormonal Products

Combined Hormonal Contraceptives (CHC)

- Combined oral contraceptive pill (COC)
- Transdermal patch
- Vaginal ring

Progestin only products

- Oral pill (POP or minipill)
- Depot medroxyprogesterone acetate (DMPA)
- Intrauterine device (IUD)
- Implant

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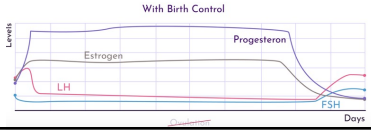
Menstrual Cycle

https://www.pearl-fertility.com/blog/entry/how-does-the-pill-work



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Combined Hormonal Contraceptives - Overview

Includes: Pill, patch, vaginal ring

- **Advantages:**
  - Menstrual: regulates blood loss, good for anemia, endometriosis, fibroids, decreased cramps
  - Sexual/psychological: increased spontaneity, sexual enjoyment, easy to use
  - Cancers: dec chance ovarian, endometrial, colorectal cancer, benign breast mass
  - Others: improved acne, effective, improved hirsutism, inc BMD (osteoporosis protection)
- **Disadvantages:**
  - Menstrual: spotting (usually goes away within 3 months), post pill amenorrhea (when go off pill permanently)
  - Sexual/psychological: mood changes, daily administration, can be expensive, adherence, decreased libido and anorgasmia
  - Cancers: cervical and possibly breast cancer
  - Others: no STD protection, side effects, drug interactions

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Combined Hormonal Contraceptives - Adverse Events

- Common AE's: Nausea, bloating and breakthrough bleeding
  - These symptoms often improve spontaneously after the 3rd cycle of therapy
  - Counsel women to maintain therapy for 2-3 months before changing regimens
- Serious AE's can be remembered using the ACHES acronym
  - A: abdominal pain
  - C: chest pain
  - H: headaches
  - E: eye problems
  - S: severe leg pain

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Combined Oral Contraceptives (COC)

- Administration: Orally, daily
- Estrogen doses of 20 – 50mcg ethinyl estradiol equivalent, generally start with medium dose
  - Low Dose: 20-25mcg
  - Medium Dose: 30-35mcg
  - High Dose: 50mcg
- Various progestin products, choose based on generation
  - 1st generation: norethindrone, ethynodiol
  - 2nd generation: levonorgestrel, norgestrel
  - 3rd generation: desogestrel, norgestimate
  - 4th generation: drospirenone

Progestin	Androgenicity	Thrombophilicity
1st generation (earliest)	Higher	Lower
2nd generation (early)	↑	↑
3rd generation (late)	↓	↓
4th generation (latest)	Lower	Higher

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Combined Oral Contraceptives (COC)

Estrogen Choice:

- When to choose a low dose formulation or decrease from a medium or high dose: If estrogenic AE occur or when a patient's baseline history indicates she may be susceptible to estrogenic AE OR to reduce the risk of VTE
- When to increase the dose of estrogen from low dose formulation to a medium or high dose: If there is significant breakthrough bleeding (BTB) early in the cycle or a bleeding pattern that is irregular and frequent

Progestin Choice

- When to choose a late generation progestin pill or move from an earlier to later generation progestin: if androgen AE are predominant or patient's baseline history indicates that they may be susceptible to androgen AE
- When to choose an earlier generation progestin pill or move from a later to earlier generation progestin: to reduce the risk of VTE
- Increase progestin dose: if the patient experiences BTB later in the cycle

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COC: Phasic Preparations

- Phasic preparations
  - Monophasic/fixed dose: Same hormone amount x21 days, placebo pills x7 days
  - Biphasic: Hormone levels change 2 times per cycle
  - Triphasic: Hormone levels change 3 times per cycle
  - Quadriphasic: Hormone levels change 4 times per cycle
- Marketed as more accurately mimicking the "natural cycle"
- Studies have found no difference between monophasic and multiphasic regimens in effectiveness, side effects, cycle control and VTE risk

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COC: Extended Cycle Preparations

- Lower ratio of active:placebo pills → can help maintain steadier hormone levels
- Prepared products
  - Active pill x24 days, placebo pill x3 days
  - Active pill x84 days, placebo pill x7 days
- "Manual" extended cycle
  - Traditional pill pack, skip placebo pills, start active tablets in next pack immediately
- Skipping the placebo pills leads to amenorrhea in many women
- Withdrawal bleed ≠ true menstrual period so it is safe to skip
- *Clinical pearl: spotting is more likely to occur with extended cycle dosing, and may last for up to one year*

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CHC – Transdermal patch

ORTHO EVRA [DSC], XULANE, ZAFEMY, TWIRLA

- Administration: Apply one patch weekly for 3 weeks, remove for 4th week
  - Apply to the upper arm, stomach, back and buttock; rotate location to avoid irritation
- First dose: use backup method for one month
- Clinical pearls:
  - Higher daily exposure to estrogen than average COC dose
  - Xulane/Zafemy is considered less effective in women >198lb/90kg (should not be used)
  - Twirla is contraindicated in BMI >30 kg/m^2 and has a lower estrogen exposure (30mcg EE) than Xulane/Zafemy

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CHC - Vaginal Rings

NUVARING/ELURING, ANNOVERA

- Administration: Insert vaginal ring into vagina and leave in for 3 weeks; remove the ring for week 4 and menses will occur.
  - *Annovera: reinsert same ring every 4 weeks (3 weeks in, 1 week out) for up to 1 year*
- Clinical pearls:
  - NuvaRing must be refrigerated in the pharmacy but can be kept at room temperature for up to 4 months; Annovera does not require refrigeration
  - May be kept in or removed during intercourse
  - May be worn with tampon, if there is breakthrough bleeding
  - Systemic absorption (not just local effects)

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Progestin Only Pill: POP, Minipill, Opill

NORGESTREL, NORETHINDRONE OR DROSPIRENONE (SLYND)

- Administration: 1 tablet at the same time each day
  - Norethindrone ust be within the same 3 hour window
  - Drospirenone has a larger 'missed dose' window
- Not as effective at preventing ovulation
  - Risk of ectopic pregnancy is higher than with other HCs

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POP: Clinical Pearls

- Advantages/Benefits
  - No estrogenic side effects
  - Good choice for women where estrogen is contraindicated
  - Does not disrupt breast milk production
  - Decreased menstrual pain
- Disadvantages/Risks
  - Less efficacy than combined pills
  - MUST be taken at same time every day
  - Benefits of COC's may not apply to mini-pill
  - Irregular menses and breakthrough bleeding – most common complaint and reason for discontinuing

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POP - Also an OTC Option

- On July 13th, 2023 the FDA approved the first OTC birth control pill, Opill (norgestrel 0.075mg)
- Once daily pill for purchase without a prescription
- Available on shelves March 2024

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DMPA Injection (Self-administered)

- Several states allow pharmacists to administer DMPA injections.
- The standing order in New York does not including DMPA injections.
- But, could a case be made that DMPA is a self-administered contraceptive?
  - Self-administered subcutaneous depot medroxyprogesterone acetate (DMPA) improves contraception continuation rates without notable increases in pregnancy or adverse effects
  - Successful pharmacist programs in California implementing this service

Kennedy CE, Yeh PT, Gatfield ML, et al. Self-administration of injectable contraception: a systematic review and meta-analysis. *BMJ Glob Health*. 2019;4:e001350. doi: 10.1136/bmjgh-2018-001350
Nalaishi, L., & Castelli, G. (2023). Is self-administered DMPA an answer to contraception access in the post-Roe era?. The Journal of family practice, 72(2), 84–86.
Katz, M., Newmark, B. L., Aronstam, A., O'Grady, N., Strome, S., Rafie, S., & Karlin, J. (2020). An implementation project to expand access to self-administered depot medroxyprogesterone acetate (DMPA). *Contraception*, *102*(6), 392–395.

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Assessment Question 4:

Which of the following scenarios would require a referral instead of dispensing hormonal contraception according to the NY standing order?

A. 16-year-old with no past medical history requesting the CHC ring
B. 17-year-old with a past medical history of asthma requesting CHC pills
C. 18-year-old with a blood pressure of 162/92 mmHg requesting the patch
D. 19-year-old with no past medical history requesting the Opill

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IMPLEMENTING BEST PRACTICES TO COMBAT STIGMA

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Barriers to Access

- Lack of knowledge, misperception, exaggerated or misrepresented concerns regarding safety
- Ineffective abstinence only education
- Healthcare provider knowledge deficits
- Legal restrictions
- Cost and insurance reimbursement
- Healthcare provider refusal
- Unnecessary medical practices prior to dispensing

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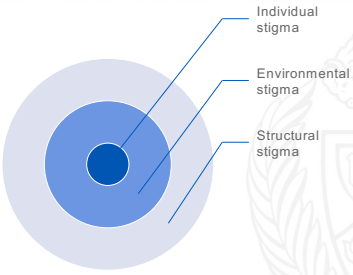
Stigma



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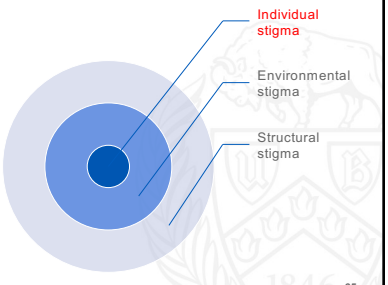
Individual Stigma

- 1 to 1 interactions
  - Implied or overt
  - Referral making



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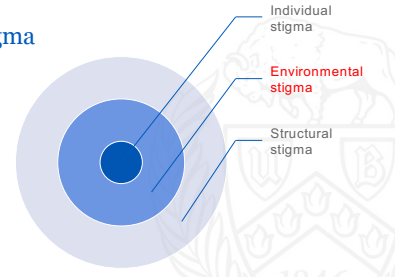
Environmental Stigma

- Physical space of the pharmacy
  - Prompts and signage to advertise product availability
    - Pharmacy website
  - Confidential and safe spaces
  - Stock
  - Online ordering
  - Delivery
  - Telepharmacy services



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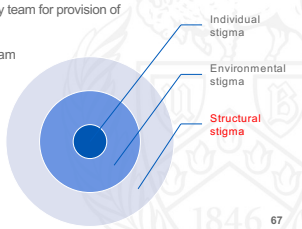
Structural Stigma

- Policies and procedures that support the pharmacy team for provision of equitable services
- Job expectations of pharmacists and pharmacy team
- Training for prescribing and referrals



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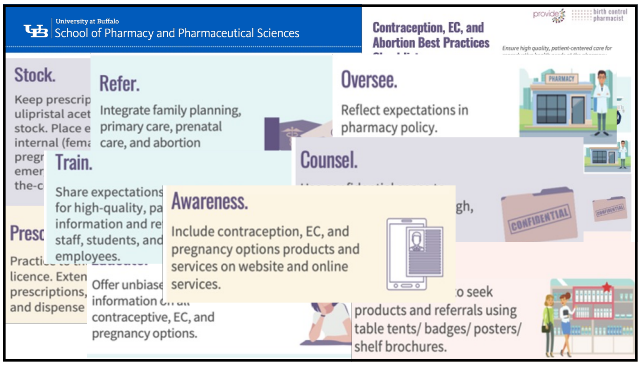

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Refusing to Provide Health Services

- State dependent, company dependent
  - 12 states allow some health care providers to refuse to provide services related to contraception.
  - 9 states allow individual health care providers to refuse to provide services related to contraception.
  - 6 states explicitly permit pharmacists to refuse to dispense contraceptives. (6 additional states have broad refusal clauses that do not specifically include pharmacists, but may apply to them.)
  - 8 states allow health care institutions to refuse to provide services related to contraception; 5 states limit the exemption to private entities.

https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services

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Refusing to Provide Health Services

- CAVEAT: Policy from the NYBOP that **allows refusal** but ***prohibits obstructing the patient access to medication***

Policies Allowing Providers to Refuse

State	Refusal						
	Abortion		Contraception			Sterilization	
	Individual Provider	Institution	Individual Provider	Pharmacist	Institution	Individual Provider	Institution
Federal Policy	X	X				X	X
New York	X	X					

  - Cannot "abandon" the patient
  - Company policy may or may not be in line with this
  - Balance with HHS Guidance on access to comprehensive reproductive health care services. Refusal to fill might be considered discrimination on the basis of sex.

https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services
https://www.hhs.gov/about/news/2022/07/13/hhs-issues-guidance-nations-retail-pharmacies-clarifying-their-obligations-ensure-access-comprehensive-reproductive-health-care-services.html

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Contraceptive Deserts

- 1.2 million women in New York currently live in a contraceptive desert-county in which there is no reasonable access to a health center offering the full range of contraceptive methods
  - Contraceptive desert: defined as less than one health center for every 1000 women in need of publicly funded contraception
  - NY Counties: Orleans, Herkimer, Schuyler, Rensselaer, Washington, Madison, and Hamilton

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Summary

- Under a standing order, pharmacists in New York can dispense self-administered hormonal contraceptives: CHC pill, CHC patch, CHC ring, POP
- Individuals should be informed of all options to prevent pregnancy (barrier vs. hormonal options, short vs. long acting, OTC vs. prescribed, etc.) and the strengths and weaknesses of each to help advise them in their decision
- Pharmacists can take steps to reduce stigma and improve access to reproductive health products in the pharmacy setting

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Resources

FDA Birth Control Chart
https://www.fda.gov/media/150299/download
Birth Control Pharmacies – find a birth control pharmacy near you
https://www.birthcontrolpharmacies.com
Bedsider – find a health center for birth control, get birth control online
https://www.bedsider.org/find-health-care
US Department of Health and Human Services Office on Women's Health Birth Control Methods
https://www.womenshealth.gov/a-z-topics/birth-control-methods
US Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2016
https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/summary.html
American Society for Emergency Contraception Guidelines and Fact Sheets
https://www.americansocietyforec.org/projects
Birth Control Pharmacist – get trained
https://birthcontrolpharmacist.com/training/

US MEC
US SPR
CDC
US MEC available as a Mobile app

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QUESTIONS?

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