

Pharmacist Prescribing Protocol Self-administered Hormonal Contraceptives

(Last updated 12/24/2020)

Background

Minn. Stats. §151.37, subd. 14, states the following:

“A pharmacist is authorized to prescribe self-administered hormonal contraceptives if the intended use is contraception in accordance with this subdivision . . . the board shall develop a standardized protocol for the pharmacist to follow in prescribing self-administrated hormonal contraceptives. In developing the protocol, the board shall consult with the Minnesota Board of Medical Practice; the Minnesota Board of Nursing; the commissioner of health; the Minnesota section of the American Congress of Obstetricians and Gynecologists; professional pharmacy associations; and professional associations of physicians, physician assistants, and advanced practice registered nurses.”

This protocol was developed by Board staff after consulting with the above-mentioned agencies and professional associations. It was approved at the Board’s December 30, 2020 meeting. Pharmacists who *independently* prescribe self-administered hormonal contraceptives **must follow this** protocol. When prescribing per this protocol, the pharmacist is the prescriber-of-record.

Pharmacists can also issue legally valid prescriptions for self-administered hormonal contraceptives through the use of other protocols that they enter into with a physician, advanced practice registered nurse (APRN), or physician assistant (PA) as allowed by [Minn. Stats. §151.01, subd. 27\(6\)](#) and [Minn. Stats. §151.37, subd. 2](#). When working under those protocols, the practitioner, not the pharmacist, is the prescriber-of-record.

Definition

1. **Self-administered hormonal contraceptive or contraceptive.** "Self-administered hormonal contraceptive" or "contraceptive" means a drug composed of a hormone or combination of hormones that is approved by the United States Food and Drug Administration (FDA) to prevent pregnancy and is administered by the user. Only products *approved* by the FDA for self-administration are included.

General considerations

1. Pharmacists who use this protocol must keep a written copy of it at each location at which they issue prescriptions for or dispense a contraceptive. They must make a copy of the protocol available upon the request of a representative of the Board of Pharmacy. This protocol must list the names of each pharmacist who is issuing prescriptions for hormonal contraceptives at the location.
2. Before a pharmacist is authorized to prescribe contraceptives to a patient under this protocol, the pharmacist must successfully complete a training program on *prescribing* contraceptives that is offered by a college of pharmacy or by a continuing education provider that is accredited by the Accreditation Council for Pharmacy Education, or a program approved by the board.

- a. Upon the request of a representative of the Board, pharmacists must provide proof that they have completed the training.
 - b. Pharmacists may request Board approval of a program by downloading the [Continuing Education Program Approval Form for Non-ACPE Program Attendees](#), filling it out, and submitting it to the Board, along with information about the program. This form does *not* need to be submitted for a program offered by a college of pharmacy or by a continuing education provider that is accredited by ACPE.
 - c. Note that the program must be developed for the *prescribing* of contraceptive. For example, a continuing education program that only provides education about the pharmacology of contraceptives would not be sufficient.
3. Pharmacists may prescribe a contraceptive only if the intended use is contraception.
 4. Copies of all documents and templates mentioned in this protocol are available on the Board's Web site for download and printing.
 - a. <https://mn.gov/boards/pharmacy/resourcesfaqs/prescribingprotocols.jsp>

Procedure

1. When an individual requests a self-administered hormonal contraceptive, the pharmacist must complete the following steps:
 - a. Determine the age of the patient:
 - i. If the patient is 18 years of age or older, the pharmacist may prescribe a contraceptive by following this protocol.
 - ii. If the patient is under the age of 18, the pharmacist may issue a prescription only if the pharmacist confirms that the patient has previously been prescribed a contraceptive by a licensed physician, physician assistant, or advanced practice registered nurse. The pharmacist must keep an electronic or written record of the action taken to make this confirmation for a minimum of two years.
 - a) With the patient's permission, the pharmacist may contact the office or clinic where the patient visited a healthcare provider to confirm that a prescription was issued. This can be done by telephone call, facsimile, or by accessing a health record system shared with the provider.
 - b) With the patient's permission, the pharmacist may contact a pharmacy that dispensed a contraceptive prescription to the patient. This can be done by telephone call, facsimile, or by accessing a patient record system shared with the other pharmacy.
 - c) The pharmacist may accept documentation or other evidence from the patient that demonstrates the patient has received a prescription for a contraceptive. (Examples, a visit summary from a clinic that indicates a prescription was issued; or a prescription package or container that bears a label with the patient's name, the name of the pharmacy that dispensed the contraceptive, date of dispensing, and the name of the prescriber).
 - iii. When considering prescribing to someone under the age of 18, the pharmacist should be familiar with Minnesota's Minor Consent Law. Information can be found at: www.health.state.mn.us/people/adolescent/youth/confidential.html
 - b. If the pharmacist will be prescribing a refill for the patient: confirm that the patient has had a clinical visit with a physician, physician assistant, or advanced practice

registered nurse within the preceding three years. The pharmacist must keep an electronic or written record of the action taken to make this confirmation - for a minimum of two years.

- i. With the patient's permission, the pharmacist may contact the office or clinic where the patient visited the healthcare provider to confirm that the visit occurred. This can be done by telephone call, facsimile, or by accessing a health record system shared with the provider.
- ii. The pharmacist may accept documentation the provider gave to the patient that confirms that a visit has occurred. (For example, a visit summary).

Without such confirmation, the pharmacist may not prescribe a refill.

- c. Have the patient complete the ***Minnesota Hormonal Contraceptive Self-Screening Questionnaire*** found near the end of this document (in the primary spoken language of the recipient, upon request and when possible). The Questionnaire is also found on the Board's Web site as a standalone document. If the patient does not complete the questionnaire, a prescription cannot be issued. The completed questionnaire should be kept on file for a minimum of two years. The patient must fill out the questionnaire at least once every 12 months.
- d. Review the self-screening tool answers with the patient and clarify responses if needed.
- e. Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended.
- f. Complete the *Minnesota Board of Pharmacy Standard Procedures Algorithm for Prescribing of Contraceptives*. As part of that process the pharmacist must evaluate the health and history of the patient using the latest version of the *United States Medical Eligibility Criteria (USMEC) for Contraceptive Use* developed by the federal Centers for Disease Control and Prevention. Pharmacists may use the *Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use*, which is color-coded to match the *Minnesota Hormonal Contraceptive Self-Screening Questionnaire*. Pharmacists may also use the *Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use*, that was prepared by the CDC and is available on the Board's Web site.
 - i. If the evaluation indicates that a hormonal contraceptive is indicated for the patient, the pharmacist may prescribe one – as outlined in this protocol.
 - ii. If the evaluation indicates that hormonal contraceptives are contraindicated for the patient, the pharmacist **must not** prescribe one.
 - iii. If the evaluation indicates that patients should be referred to their primary care provider or to a nearby clinic or hospital (if the patient does not have a primary care provider), the pharmacist must not issue a prescription and must make the referral. The *Pharmacist Referral and Visit Summary* template provided below may be used for this purpose.
- g. Before prescribing a contraceptive, the pharmacist shall ensure that the patient is appropriately trained in the administration of the requested or recommended contraceptive medication.
- h. When a contraceptive is prescribed, the pharmacist must provide the patient with appropriate counseling and information for the product prescribed, as required by [Minn. Rules 6800.0910](#). In addition to verbal counseling, the pharmacist must also supply a fact sheet to the patient that is specific to the drug prescribed. The information that must be provided includes the following:
 - i. the name and description of the drug;
 - ii. the dosage form, dose, route of administration, and duration of drug therapy;
 - iii. intended use of the drug and expected action;

- iv. directions and precautions for preparation, administration, and appropriate use by the patient;
 - v. common severe side effects, adverse effects, or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
 - vi. techniques for self-monitoring of drug therapy;
 - vii. proper storage;
 - viii. action to be taken in the event of a missed dose;
 - ix. the importance of receiving recommended preventative health screenings and the need for medical follow-up;
 - x. that self-administered hormonal contraception does not protect against sexually transmitted infections (STIs); and
 - xi. any other information relevant to the patient's drug therapy.
- i. When a contraceptive is prescribed, the pharmacist must provide the patient with a written record of the contraceptive prescribed. The *Pharmacist Referral and Visit Summary* template provided below may be used for this purpose. At a minimum, the record must include:
- i. the patient's name and date-of-birth;
 - ii. the name, practice address, and telephone number for the prescribing pharmacist;
 - iii. the date on which the prescription was issued;
 - iv. the name and strength of the contraceptive that was prescribed; and
 - v. the quantity prescribed and how many refills were authorized (if any)

Delegation prohibited; involvement of pharmacist interns.

A pharmacist who is authorized to prescribe a self-administered hormonal contraceptive is prohibited from delegating the prescribing to any other person. A pharmacist intern registered pursuant to [Minn. Stats. §151.01](#) may prepare a prescription for a self-administered hormonal contraceptive, but before the prescription is processed or dispensed, a pharmacist authorized to prescribe under this protocol must review, approve, and sign the prescription.

Prescription record.

The pharmacist must generate a written or electronic prescription for any self-administered hormonal contraceptive that is prescribed and dispensed. The prescription must include all of the information required by [Minn. Stats. §151.01, subd. 16a](#). The prescription must be processed in the same manner that any other prescription is processed, pursuant to the applicable statutes and rules for the dispensing of prescription drugs. The prescription shall be kept on file and maintained for a minimum of two years. Pharmacists are reminded that prescriptions paid for by Medicare and Medicaid must be kept on file for even longer periods of time.

Names of Pharmacists Who Will Be Prescribing Pursuant to this Protocol

Location at which prescribing will occur

Pharmacy or facility name: _____

Pharmacy or facility address: _____

Names of Prescribing pharmacists:

1) _____

2) _____

3) _____

4) _____

5) _____

6) _____

7) _____

8) _____

9) _____

10) _____

Minnesota Hormonal Contraceptive Self-Screening Questionnaire

Patient Name _____ Health Care Provider's Name _____ Date _____

Date of Birth _____ Age _____ Weight _____ Do you have health insurance? Yes / No

What was the date of your last women's health clinical visit? _____

Any allergies to Medications? Yes / No If yes, list them here _____

Do you have a preferred method of birth control that you would like to use?

A daily pill A weekly patch A vaginal ring Injectable (every 3 mo) Other (IUD, implant)

Background Information:

1	Do you think you might be pregnant now?	Yes <input type="checkbox"/> No <input type="checkbox"/>
2	What was the first day of your last menstrual period?	___/___/___
3	Have you ever taken birth control pills, or used a birth control patch, ring, or injection? Have you previously had contraceptives prescribed to you by a pharmacist?	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
	Did you ever experience a bad reaction to using hormonal birth control?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	- If yes, what kind of reaction occurred?	_____
	Are you currently using any method of birth control including pills, or a birth control patch, ring or shot/injection?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	- If yes, which one do you use?	_____
4	Have you ever been told by a medical professional not to take hormones?	Yes <input type="checkbox"/> No <input type="checkbox"/>
5	Do you smoke cigarettes?	Yes <input type="checkbox"/> No <input type="checkbox"/>

Medical History:

6	Have you had a recent change in vaginal bleeding that worries you?	Yes <input type="checkbox"/> No <input type="checkbox"/>
7	Have you given birth within the past 21 days? If yes, how long ago?	Yes <input type="checkbox"/> No <input type="checkbox"/>
8	Are you currently breastfeeding?	Yes <input type="checkbox"/> No <input type="checkbox"/>
9	Do you have diabetes?	Yes <input type="checkbox"/> No <input type="checkbox"/>
10	Do you get migraine headaches?	Yes <input type="checkbox"/> No <input type="checkbox"/>
10a	If so, have you ever had the kind of headaches that start with warning signs or symptoms, such as flashes of light, blind spots, or tingling in your hand or face that comes and goes completely away before the headache starts?	Yes <input type="checkbox"/> No <input type="checkbox"/>
11	Are you being treated for inflammatory bowel disease?	Yes <input type="checkbox"/> No <input type="checkbox"/>
12	Do you have high blood pressure, hypertension, or high cholesterol? (Please indicate yes, even if it is controlled by medication)	Yes <input type="checkbox"/> No <input type="checkbox"/>
13	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes <input type="checkbox"/> No <input type="checkbox"/>
14	Have you ever had a blood clot?	Yes <input type="checkbox"/> No <input type="checkbox"/>
15	Have you ever been told by a medical professional you are at risk of developing a blood clot?	Yes <input type="checkbox"/> No <input type="checkbox"/>
16	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes <input type="checkbox"/> No <input type="checkbox"/>
17	Will you be immobile for a long period? (e.g. flying on a long airplane trip, etc.)	Yes <input type="checkbox"/> No <input type="checkbox"/>
18	Have you had bariatric surgery or stomach reduction surgery?	Yes <input type="checkbox"/> No <input type="checkbox"/>
19	Do you have or have you ever had breast cancer?	Yes <input type="checkbox"/> No <input type="checkbox"/>
20	Have you had a solid organ transplant?	Yes <input type="checkbox"/> No <input type="checkbox"/>
21	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
22	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes <input type="checkbox"/> No <input type="checkbox"/>
23	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	- If yes, list them here:	
24	Do you have any other medical problems or take any medications, including herbs or supplements?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	- If yes, list them here:	

Signature _____ Date _____

Minnesota Hormonal Contraceptive Self-Screening Questionnaire: Optional Side – May be used by the prescribing pharmacist. This side of form may be customized by prescribing pharmacist – Do not make edits to the Questionnaire (front side)

<i>Pregnancy Screen</i>	
a. Did you have a baby less than 6 months ago, are you fully or nearly-fully breast feeding, AND have you had no menstrual period since the delivery?	Yes <input type="checkbox"/> No <input type="checkbox"/>
b. Have you had a baby in the last 4 weeks?	Yes <input type="checkbox"/> No <input type="checkbox"/>
c. Did you have a miscarriage or abortion in the last 7 days?	Yes <input type="checkbox"/> No <input type="checkbox"/>
d. Did your last menstrual period start within the past 7 days?	Yes <input type="checkbox"/> No <input type="checkbox"/>
e. Have you abstained from sexual intercourse since your last menstrual period or delivery?	Yes <input type="checkbox"/> No <input type="checkbox"/>
f. Have you been using a reliable contraceptive method consistently and correctly?	Yes <input type="checkbox"/> No <input type="checkbox"/>

verified DOB with valid photo ID BP Reading _____/_____ *Must be taken by RPH

Note: RPH must refer patient if either systolic or diastolic reading is out of range, per algorithm

Rx

Drug Prescribed _____ Rx _____
 Directions for Use _____
 Pharmacist Name _____ RPH Signature _____
 Pharmacy Address _____ Pharmacy Phone _____

