



COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor
Henrico, Virginia 23233

(804) 367-4456 (Tel)
(804) 527-4472 (Fax)

Tentative Agenda of Statewide Protocol Workgroup Meeting

August 4, 2020 Virtual Meeting

9AM - 3PM

*****Refer to the Second Page of Agenda for Meeting Access Information*****

| <u>TOPIC</u> | <u>PAGES</u> |
|---|--------------|
| Call to Order: Ryan Logan, Chairman | |
| • Welcome & Introductions | |
| • Approval of Agenda | 1 |
| Call for Public Comment: The Board will receive public comment at this time from those persons who submitted an email to caroline.juran@dhp.virginia.gov no later than 8am on August 4, 2020 indicating that they wish to offer comment. The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters. | |
| Agenda Items | |
| • Review charge of workgroup as described in the 2 nd enactment clause of HB 1506 | 2-5 |
| • Overview of pharmacist educational/training standards, VCU School of Pharmacy | |
| • Review workforce statistics of pharmacists | |
| • Review recommended components of statewide protocol | 6 |
| • Develop recommended statewide protocols for board consideration for pharmacists to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older: | |
| ○ Naloxone or other opioid antagonist, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone or other opioid antagonist; | 7-25 |
| ○ Epinephrine; | 26-27 |
| ○ Prenatal vitamins for which a prescription is required; | 28-29 |
| ○ Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services; | 30-33 |
| ○ Medications covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug | 34-35 |
| ○ Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use | 36-90 |
| • Develop recommended emergency regulations for board consideration to implement provisions | 91-94 |

Adjourn

****The Board will have a working lunch at approximately 12pm.****

Virginia Board of Pharmacy

Instructions for Accessing August 4, 2020 Virtual Statewide Protocol Workgroup Meeting and Providing Public Comment

- **Access:** Perimeter Center building access remains restricted to the public due to the COVID-19 pandemic. To observe this virtual meeting, use one of the options below. Disregard any reference to the Board of Dentistry as a shared subscription to WebEx is being utilized. Participation capacity is limited and is on a first come, first serve basis due to the capacity of CISCO WebEx technology.
- **Public comment:** Comments will be received during the public hearings and during the full board meeting from those persons who have submitted an email to caroline.juran@dhp.virginia.gov **no later than 8am on August 4, 2020** indicating that they wish to offer comment. Comment may be offered by these individuals when their names are announced by the chairman.
- Public participation connections will be muted following the public comment period.
- Should the Board enter into a closed session, public participants will be blocked from seeing and hearing the discussion. When the Board re-enters into open session, public participation connections to see and hear the discussions will be restored.
- Please call from a location without background noise.
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- FOIA Council *Electronic Meetings Public Comment* form for submitting feedback on this electronic meeting may be accessed at <http://foiacouncil.dls.virginia.gov/sample%20letters/welcome.htm>

JOIN BY AUDIO ONLY

Phone: 1-408-418-9388

Access code: 132 119 6517

Password: 74276200

JOIN THE INTERACTIVE MEETING

<https://virginia-dhp.my.webex.com/virginia-dhp.my/j.php?MTID=m1a6de9b871ee5caf69c65649a7ff1a31>

Meeting number (access code): 132 119 6517

Meeting password: Pharm20!

Statewide Protocols - HB 1506

Second Enactment Clause from HB 1506

2. That the Board of Pharmacy, in collaboration with the Board of Medicine and the Department of Health, shall establish protocols for the initiating of treatment with and dispensing and administering of drugs and devices by pharmacists in accordance with § 54.1-3303.1 of the Code of Virginia, as created by this act, by November 1, 2020, and shall promulgate regulations to implement the provisions of the first enactment of this act to be effective within 280 days of its enactment. Such regulations shall include provisions for ensuring that physical settings in which treatment is provided pursuant to this act shall be in compliance with the Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d et seq.

Workgroup Members:

1. Ryan Logan, RPh, Workgroup Chairman, Board of Pharmacy Member
2. Kris Ratliff, PharmD, Board of Pharmacy Chairman
3. Jake Miller, D.O., Board of Medicine Member
4. Brenda Stokes, M.D., Board of Medicine Member
5. Emily Yeatts, VDH, contraception
6. Tonya Adiches, VDH, fluoride supplement
7. Stephanie Wheawill, PharmD, VDH Pharmacy Services
8. Diana Jordan, VDH, Office of Epidemiology

Staff:

- Caroline Juran, RPh, Executive Director, Board of Pharmacy
- William Harp, M.D., Executive Director Board of Medicine
- Elaine Yeatts, DHP, Senior Policy Analyst
- Jim Rutkowski, Assistant Attorney General
- Sammy Johnson, Pharmacist, Deputy Executive Director, Board of Pharmacy
- Beth O'Halloran, Pharmacist, Deputy Executive Director, Board of Pharmacy
- Ellen Shinaberry, PharmD, Deputy Executive Director, Board of Pharmacy
- Kiara Christian, Executive Assistant, Board of Pharmacy

Scheduled Meeting Dates:

1st virtual meeting: 8/4/20 - 9am-3pm

2nd virtual meeting: 8/17/20 - 9am-3pm

2020 SESSION

CHAPTER 731

An Act to amend and reenact §§ 38.2-3408, 54.1-3300, and 54.1-3300.1 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 54.1-3303.1, relating to pharmacists; initiating treatment with and dispensing and administering of controlled substances.

[H 1506]

Approved April 6, 2020

Be it enacted by the General Assembly of Virginia:

1. That §§ 38.2-3408, 54.1-3300, and 54.1-3300.1 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding a section numbered 54.1-3303.1 as follows:

§ 38.2-3408. Policy providing for reimbursement for services that may be performed by certain practitioners other than physicians.

A. If an accident and sickness insurance policy provides reimbursement for any service that may be legally performed by a person licensed in this Commonwealth as a chiropractor, optometrist, optician, professional counselor, psychologist, clinical social worker, podiatrist, physical therapist, chiropodist, clinical nurse specialist who renders mental health services, audiologist, speech pathologist, certified nurse midwife or other nurse practitioner, marriage and family therapist, or licensed acupuncturist, reimbursement under the policy shall not be denied because the service is rendered by the licensed practitioner.

B. If an accident and sickness insurance policy provides reimbursement for a service that may be legally performed by a licensed pharmacist, reimbursement under the policy shall not be denied because the service is rendered by the licensed pharmacist, provided that (i) the service is performed for an insured for a condition under the terms of a collaborative agreement, as defined in § 54.1-3300, ~~between a pharmacist and the physician with whom the insured is undergoing a course of treatment or~~ (ii) the service is for the administration of vaccines for immunization. ~~Notwithstanding the provisions of § 38.2-3407, the insurer may require the pharmacist, any pharmacy or provider that may employ such pharmacist, or the collaborating physician to enter into a written agreement with the insurer as a condition for reimbursement for such services. In addition, reimbursement to pharmacists acting under the terms of a collaborative agreement under this subsection shall not be subject to the provisions of § 38.2-3407.7, or~~ (iii) the service is provided in accordance with § 54.1-3303.1.

C. This section shall not apply to Medicaid, or any state fund.

§ 54.1-3300. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Board" means the Board of Pharmacy.

"Collaborative agreement" means a voluntary, written, or electronic arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a single physical location where patients receive services and (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative ~~practice~~ agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for delivery.

"Pharmacist" means a person holding a license issued by the Board to practice pharmacy.

"Pharmacy" means every establishment or institution in which drugs, medicines, or medicinal chemicals are dispensed or offered for sale, or a sign is displayed bearing the word or words "pharmacist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "medicine store," "drug sundries," "prescriptions filled," or any similar words intended to indicate that the practice of pharmacy is being conducted.

"Pharmacy intern" means a student currently enrolled in or a graduate of an approved school of pharmacy who is registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

"Pharmacy technician" means a person registered with the Board to assist a pharmacist under the pharmacist's supervision.

"Practice of pharmacy" means the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging, and dispensing of drugs, medicines, and devices used in the diagnosis, treatment, or prevention of disease, whether compounded or dispensed on a prescription or otherwise legally dispensed or distributed, and shall include (i) the proper and safe storage and distribution of drugs; (ii) the maintenance of proper records; (iii) the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; ~~and~~ (iv) the management of patient care under the terms of a collaborative agreement as defined in this section; and (v) *the initiating of treatment with or dispensing or administering of certain drugs in accordance with the provisions of § 54.1-3303.1.*

"Supervision" means the direction and control by a pharmacist of the activities of a pharmacy intern or a pharmacy technician whereby the supervising pharmacist is physically present in the pharmacy or in the facility in which the pharmacy is located when the intern or technician is performing duties restricted to a pharmacy intern or technician, respectively, and is available for immediate oral communication.

Other terms used in the context of this chapter shall be defined as provided in Chapter 34 (§ 54.1-3400 et seq.) unless the context requires a different meaning.

§ 54.1-3300.1. Participation in collaborative agreements; regulations to be promulgated by the Boards of Medicine and Pharmacy.

A. A pharmacist and his designated alternate pharmacists involved directly in patient care may participate with (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative ~~practice~~ agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care in collaborative agreements which authorize cooperative procedures related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes *for patients who meet the criteria set forth in the collaborative agreement.* However, no person licensed to practice medicine, osteopathy, or podiatry shall be required to participate in a collaborative agreement with a pharmacist and his designated alternate pharmacists, regardless of whether a professional business entity on behalf of which the person is authorized to act enters into a collaborative agreement with a pharmacist and his designated alternate pharmacists.

~~No patient shall be required to participate in a collaborative procedure without such patient's consent.~~ B. A patient who *meets the criteria for inclusion in the category of patients whose care is subject to a collaborative agreement and who chooses to not participate in a collaborative procedure shall notify the prescriber of his refusal to participate in such collaborative procedure.* A prescriber may elect to have a patient not participate in a collaborative procedure by contacting the pharmacist or his designated alternative pharmacists or by documenting the same on the patient's prescription.

C. Collaborative agreements may include the implementation, modification, continuation, or discontinuation of drug therapy pursuant to written or electronic protocols, provided implementation of drug therapy occurs following diagnosis by the prescriber; the ordering of laboratory tests; or other patient care management measures related to monitoring or improving the outcomes of drug or device therapy. No such collaborative agreement shall exceed the scope of practice of the respective parties. Any pharmacist who deviates from or practices in a manner inconsistent with the terms of a collaborative agreement shall be in violation of § 54.1-2902; such violation shall constitute grounds for disciplinary action pursuant to §§ 54.1-2400 and

54.1-3316.

D. Collaborative agreements may only be used for conditions which have protocols that are clinically accepted as the standard of care, or are approved by the Boards of Medicine and Pharmacy. The Boards of Medicine and Pharmacy shall jointly develop and promulgate regulations to implement the provisions of this section and to facilitate the development and implementation of safe and effective collaborative agreements between the appropriate practitioners and pharmacists. The regulations shall include guidelines concerning the use of protocols, and a procedure to allow for the approval or disapproval of specific protocols by the Boards of Medicine and Pharmacy if review is requested by a practitioner or pharmacist.

E. Nothing in this section shall be construed to supersede the provisions of § 54.1-3303.

§ 54.1-3303.1. *Initiating of treatment with and dispensing and administering of controlled substances by pharmacists.*

A. Notwithstanding the provisions of § 54.1-3303, a pharmacist may initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older in accordance with a statewide protocol developed by the Board in collaboration with the Board of Medicine and the Department of Health and set forth in regulations of the Board:

1. *Naloxone or other opioid antagonist, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone or other opioid antagonist;*
2. *Epinephrine;*
3. *Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;*
4. *Prenatal vitamins for which a prescription is required;*
5. *Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services; and*
6. *Medications covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug.*

B. A pharmacist who initiates treatment with or dispenses or administers a drug or device pursuant to this section shall notify the patient's primary health care provider that the pharmacist has initiated treatment with such drug or device or that such drug or device has been dispensed or administered to the patient, provided that the patient consents to such notification. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

2. That the Board of Pharmacy, in collaboration with the Board of Medicine and the Department of Health, shall establish protocols for the initiating of treatment with and dispensing and administering of drugs and devices by pharmacists in accordance with § 54.1-3303.1 of the Code of Virginia, as created by this act, by November 1, 2020, and shall promulgate regulations to implement the provisions of the first enactment of this act to be effective within 280 days of its enactment. Such regulations shall include provisions for ensuring that physical settings in which treatment is provided pursuant to this act shall be in compliance with the Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d et seq.

3. That the Board of Pharmacy (the Board) shall establish a work group consisting of representatives of the Board of Medicine, the Department of Health, schools of medicine and pharmacy located in the Commonwealth, and such other stakeholders as the Board may deem appropriate to provide recommendations regarding the development of protocols for the initiating of treatment with and dispensing and administering by pharmacists to persons 18 years of age or older of drugs and devices, including (i) vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention; (ii) drugs approved by the U.S. Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy; (iii) tuberculin purified protein derivative for tuberculosis testing; (iv) controlled substances or devices for the treatment of diseases or conditions for which clinical decision making can be guided by a clinical test that is classified as

waived under the federal Clinical Laboratory Improvement Amendments of 1988, including influenza virus, Helicobacter pylori bacteria, urinary tract infection, and group A Streptococcus bacteria; (v) controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention; and (vi) drugs other than controlled substances, including drugs sold over the counter, for which the patient's health insurance provider requires a prescription. The work group shall report its findings and recommendations to the Governor and the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2020.

COMPONENTS OF THE PROTOCOL

Participants reviewed the components of statewide protocols currently in place, which are inconsistent and variable in the degree of specificity included. The following recommendation was developed to serve as a guide during the protocol development phase. Consistent with the above recommendation that the initial authorizing legislation should not be specific to a medication or medication class, it is not recommended that these elements be included in legislation authorizing statewide protocols generally. Instead, these components should be included in regulation or guidance from the board of pharmacy.

The workgroup recommended that the following core components be included in the design of pharmacist statewide protocols:

- The medications or categories of medications included in the protocol.
- Training or qualifications required for licensed pharmacists to implement the statewide protocol. (Training/qualifications vary based on the clinical application of the protocol and could include further training, such as continuing education, in addition to educational experiences obtained through pharmacy school curricula).
- Procedures:
 - Patient inclusion criteria.
 - Requirements for documentation and maintenance of records.
 - Communication requirements (such as notification to the primary care provider).

The workgroup recommended that product selection decisions, within protocols that apply to categories of medications, should be left to the pharmacist based on their application of clinical judgement and/or available evidenced based guidelines.

Agenda Topic: Naloxone or other opioid antagonist, including such controlled paraphernalia, as defined in § [54.1-3466](#), as may be necessary to administer such naloxone or other opioid antagonist

Included in Agenda Package:

- Draft Virginia Statewide Protocol for Naloxone
- Virginia Statewide Standing Order for Naloxone issued by Health Commissioner Oliver
- Oregon Naloxone Law, Regulations, and Resources
- New Mexico Pharmacist Prescriptive Authority of Naloxone

Action:

Adopt draft statewide protocol for naloxone or other opioid antagonist for overdose reversal for board consideration as presented or as amended.

VIRGINIA BOARD OF PHARMACY

Pharmacist Naloxone Statewide Protocol

Consistent with the naloxone manufacturer's instructions for use approved by the US Food and Drug Administration, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- intranasal naloxone (nasal spray formulation or for administration by mucosal atomization device);
- intramuscular naloxone, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone;
- naloxone auto-injector; or,
- any other opioid antagonist formulation approved by the FDA for overdose reversal, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering naloxone under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use, paraphernalia necessary for administration, and how to properly counsel the patient on recognizing signs of a possible overdose and proper administration of the drug.

PATIENT INCLUSION CRITERIA

Patients eligible for naloxone under this protocol:

- An individual, 18 years of age or older, experiencing or at risk of experiencing an opioid-related overdose;
- A family member, friend, or other person, 18 years of age or older, in a position to assist an individual who is experiencing or at risk of experiencing an opioid-related overdose.

COUNSELING

The pharmacist shall ensure the patient or patient's agent is provided a copy of the REVIVE! Pharmacy dispensing brochure and he or she shall counsel the patient or the patient's agent on how to properly identify signs of a possible overdose and how to properly administer the naloxone or other opioid antagonist for overdose reversal.

RECORDKEEPING

The pharmacist shall maintain records in accordance with board regulation _____.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Statewide Standing Order for Naloxone

Virginia Department of Health
Office of the Commissioner
109 Governor Street, 13th Floor
Richmond, VA 23219

Date Issued: March 19, 2020

The persons identified below are authorized to dispense naloxone pursuant to this standing order and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health. Additionally, this standing order authorizes a licensed pharmacy, wholesale distributor, third party logistics provider or manufacturer to distribute the naloxone formulations specified below via invoice to entities designated by this standing order in accordance with Virginia Board of Pharmacy Guidance Document 110-44.

This order supersedes the order issued by the State Health Commissioner on April 13, 2018.

Authorized Dispensers:

The following individuals may dispense naloxone pursuant to this standing order to a person to administer to another person believed to be experiencing or about to experience a life-threatening opioid overdose and shall follow Board of Pharmacy protocol when dispensing naloxone as authorized in §54.1-3408 (X) and (Y):

- Pharmacists who maintain a current active license practicing in a pharmacy located in Virginia that maintains a current active pharmacy permit, and
- Emergency medical services personnel as defined in § 32.1-111.1

And the following individuals who have completed a training program in accordance with the policies and procedures of their employer or governing entity:

- Law-enforcement officers as defined in § 9.1-101,
- Employees of the Department of Corrections designated as probation and parole officers or as correctional officers as defined in § 53.1-1,
- Employees of regional jails,
- Firefighters,
- Employees of local health departments and contractors or Medical Reserve Corps volunteers acting on behalf of the local health department,
- Employees of local community services boards,
- Persons acting on behalf of a harm reduction site approved by the Department of Health, and
- Individuals acting on behalf of the American Red Cross of Virginia as a Disaster Health Services volunteer.

This order is effective for two (2) years from the date issued, unless otherwise discontinued by the Commissioner or upon his resignation, removal or retirement.

Any individual dispensing naloxone pursuant to this order must maintain a copy of the standing order for two (2) years from the last date of dispensing.

Please call the Office of the Commissioner at (804) 864-7001 with questions about this standing order. Please call the Board of Pharmacy at (804) 367-4456 with questions about the dispensing protocol.

For questions about the REVIVE! training program, please call the Department of Behavioral Health and Developmental Services at (804) 786-0464.

Approved Options for Dispensing:

| Intranasal | Auto-Injector | Intranasal | Injection* (Pharmacists Only) |
|---|---|--|--|
| <p>Naloxone 2mg/2ml prefilled syringe, # 2 syringes</p> <p>SIG: Spray one-half of the syringe into each nostril upon signs of opioid overdose. <u>Call 911</u>. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.</p> <p>Mucosal Atomization Device (MAD) # 2</p> <p>SIG: Use as directed for naloxone administration.</p> <p>Must dispense with 2 prefilled syringes and 2 atomizers and instructions for administration.</p> | <p>Naloxone 2 mg #1 twin pack</p> <p>SIG: Use one auto-injector upon signs of opioid overdose. <u>Call 911</u>. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.</p> | <p>Narcan Nasal Spray 4mg, #1 twin pack</p> <p>SIG: Administer a single spray intranasally into one nostril. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. <u>Call 911</u>. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.</p> | <p>Naloxone 0.4mg/ml #2 single-use 1ml vials</p> <p>SIG: Inject 1ml in shoulder or thigh upon signs of opioid overdose. <u>Call 911</u>. Repeat after 2-3 minutes if no or minimal response.</p> <p>#2 (3ml) syringe with 23-25 gauge 1-1.5 inch IM needles</p> <p>SIG: Use as directed for naloxone administration. Dispenser must dispense 2 single-use 1ml vials, 2 (3ml) syringes and 2 (23-25 gauge) hypodermic needles for administration.</p> |

*** Except for pharmacists, persons authorized to dispense under this standing order shall only dispense formulations for intranasal administration or an auto-injector formulation.**

May refill as long as order remains effective.

| | |
|---|---|
| <p>_____ <i>Signature of Prescriber</i></p> | <p>M. Norman Oliver, MD, MA State Health Commissioner</p> |
| | <p><i>Printed Name of Prescriber</i></p> |

Va. Medical License #:

NPI Number:

Date: March 19, 2020

Caroline Juran

Subject: FW: TIME-SENSITIVE: statewide protocols

From: DAVIS Jen * BOP <Jen.L.DAVIS@oregon.gov>

Sent: Thursday, July 23, 2020 2:20 PM

To: Caroline.Juran@dhp.virginia.gov

Subject: RE: TIME-SENSITIVE: statewide protocols

Caroline,

Oregon utilizes a variety of methods (naloxone/epinephrine by rule only; contraceptives by protocol) that allow pharmacists to provide some of the requested items on your list. Below is a hyperlinked list with applicable resources. Please note the Oregon BOP maintains a website of [Prescribing Resources](#) and many of the items listed below can be found there.

Naloxone

Laws & Rules

- [Division 019 \(OAR-855-019-0460\)](#)
- [Division 041 \(OAR 855-041-2340\)](#)
- [ORS 689.682](#)

Naloxone "Tool Kit" Resources

- [Naloxone FAQs](#)
- [Naloxone Access: A Practical Guideline for Pharmacists](#)
- [Instructions for Healthcare Providers: Prescribing Naloxone](#)
- [Good Samaritan Wallet Card](#)
- [Good Samaritan Wallet Card - Spanish](#)
- [OHA Written Training](#)
- [Oregon Board of Pharmacy Position Statement Sterile Syringe Access & Harm Reduction](#)
- [SAMHSA Opioid Overdose Prevention](#)

Epinephrine

Laws & Rules

- [Division 041 \(OAR 855-041-2310 through 855-041-2320\)](#)

Epinephrine "Tool Kit" Resources

- [OHA Written Training / Powerpoint](#)

Injectable or self-administered hormonal contraceptives

Laws & Rules

- [ORS 689.689 \(eff. 1/2016\)](#)
- [Division 019 \(OAR 855-019-0400 through 855-019-0435\)](#)
- [Division 041 \(OAR 855-041-1040\(7\)\)](#)

Contraceptive "Tool Kit" Resources

- [FAQs for Pharmacists Prescribing Hormonal Contraception in Oregon](#)
REQUIRED: [Oregon Standard Procedures Algorithm](#)

- **REQUIRED:** [DPMA Oregon Standard Procedures Algorithm](#)
- **REQUIRED:** [Oregon Self-Screening Risk Assessment Questionnaire](#)
 - [Oregon Self-Screening Risk Assessment Questionnaire - Spanish](#)
- NOTE: Many more resources listed on [Prescribing Resources](#) website

Prenatal Vitamins – Oregon does not have a process/protocol for prescribing of this product

Dietary fluoride supplements– Oregon does not have a process/protocol for prescribing of this product

OTC Equivalents- – Oregon does not have a process/protocol for prescribing of this product

Jennifer L. Davis, PharmD, RPh | she/her/hers

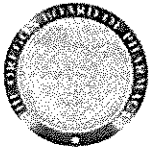
Inspector/Investigator

Oregon Board of Pharmacy

Phone: (971) 673-0001

Jen.L.Davis@oregon.gov

Oregon.Gov/Pharmacy



CONFIDENTIALITY NOTICE

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If you are not the addressee or it appears from the context or otherwise that you have received this e-mail in error, please advise me immediately by reply e-mail, keep the contents confidential, and immediately delete the message and any attachments from your system.

Oregon Laws regarding naloxone

689.682 Prescription of naloxone. (1) In accordance with rules adopted by the State Board of Pharmacy under ORS 689.205, a pharmacist may prescribe naloxone and the necessary medical supplies to administer the naloxone.

(2) If a prescription is presented to a pharmacist for dispensing an opiate or opioid in excess of a morphine equivalent dose established by rule by the board, the pharmacist may offer to prescribe and provide, in addition to the prescribed opiate or opioid, a naloxone kit consisting of a dose of naloxone and the necessary medical supplies to administer the naloxone. [2016 c.100 §4; 2017 c.683 §2; 2019 c.470 §9]

689.683 [2015 c.649 §2; 2015 c.649 §3; 2017 c.289 §§2,3; renumbered 689.689 in 2017]

689.686 Notice of availability of naloxone; rules. (1) A retail or hospital outpatient pharmacy shall provide written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy.

(2) The State Board of Pharmacy may adopt rules to carry out this section. [2019 c.470 §2]

Oregon Regulations regarding naloxone

855-041-2340

Naloxone

Pharmacies providing naloxone services must establish, maintain and enforce written procedures including, but not limited to:

- (1) Providing a workflow process and physical location that maintains confidentiality and is not susceptible to distraction;
- (2) Documentation and recordkeeping; and
- (3) Provide written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy.

BP 7-2015(Temp), f. & cert. ef. 11-6-15 thru 5-3-16

855-019-0460

Naloxone - Delivery of Care and Prescribing

- (1) A pharmacist, having determined that there is an identified medical need, can prescribe naloxone and the necessary medical supplies to administer naloxone for opiate overdose:
 - (a) When dispensing any opiate or opioid prescription in excess of 50 morphine milligram equivalents (MME);
 - (b) To an individual seeking naloxone;
 - (c) To an entity seeking naloxone.
- (2) The pharmacist shall determine that the individual (or the individual on behalf of an entity) seeking naloxone demonstrates understanding of educational materials related to opioid overdose prevention, recognition, response, and the administration of naloxone.
- (3) The pharmacist may prescribe naloxone in any FDA approved dosage form and the necessary medical supplies needed to administer naloxone.
- (4) The pharmacist shall dispense the naloxone product in a properly labeled container.

- (5) Naloxone may not be prescribed without offering to provide oral counseling to the authorized recipient, which may include dose, effectiveness, adverse effects, storage conditions, and safety.
- (6) The pharmacist must document the encounter and the prescription, and maintain records for three years.
- (7) Any person, having once lawfully obtained naloxone may possess, distribute or administer it for the purpose of reversing opiate overdose.

NALOXONE FAQs (OAR 855-019-0450 to 0460 & OAR 855-041-2330 to 2340)

Q: *How does the 2017 law differ from the 2016 and 2013 laws?*

A: The new law, 2017 HB 3440 removes all previous OHA training requirements. In order for a pharmacist to prescribe naloxone he or she must determine that the individual seeking naloxone demonstrates understanding of opioid overdose prevention, recognition, response and the administration of naloxone. Individuals will no longer need to present a naloxone certificate in order for a pharmacist to prescribe naloxone.

The 2016 law gave the pharmacist the authority to prescribe naloxone and supplies to a person who conducts training and to a person who has successfully completed training. OHA developed a written training that was provided for a person coming to a pharmacy seeking naloxone. The pharmacist could prescribe naloxone to the individual upon his or her determination that the individual seeking naloxone demonstrates understanding of the educational material.

The 2013 law allowed a pharmacy to distribute naloxone to a trained person, pursuant to a certificate of training completion. Historically, the training programs were offered 'in-person' by an Oregon Health Authority (OHA) authorized person or organization.

Q: *What qualifications do I need in order to prescribe naloxone?*

A: A pharmacist acting in good faith, exercising reasonable care and who is educated in opiate overdose and naloxone rescue can prescribe naloxone and the necessary medical supplies to administer the naloxone. There is not a Board-required educational training program to prescribe naloxone.

Q: *What does the Board expect for documentation when prescribing naloxone?*

A: The pharmacist must document the encounter and the prescription, and maintain records for three years.

Q: *What are counseling expectations related to prescribing naloxone?*

A: The pharmacist shall determine that the individual seeking naloxone demonstrate understanding of educational materials. The pharmacist shall provide oral counseling to the a person who receives naloxone, which may include dose, effectiveness, adverse effects, storage conditions and safety.

Q: *What naloxone can the pharmacist prescribe?*

A: An FDA approved formulation included in the OHA training (injectable, nasal spray, or nasal kit).

Q: *How many naloxone units can I prescribe per rx?*

A: A: There are no limitations. You can prescribe enough units for a person or organization to provide training, and use professional judgment when prescribing to a single individual. Any person, having lawfully obtained naloxone may possess, distribute or administer it for the purpose of reversing opiate overdose.

Q: *Can I bill insurance for naloxone?*

A: The Oregon Board of Pharmacy does not regulate billing. Please check with your outlet and contracts.

NALOXONE ACCESS: A Practical Guideline for Pharmacists

<http://cpnp.org/guideline/naloxone>

Background

Drug overdoses are occurring at an alarming rate in the United States. Most overdoses have been linked to opioid analgesics, which may have been obtained from community pharmacies. One potential solution is to offer take-home naloxone.

Patient Selection

Naloxone should be considered for all patients exposed to opioids regardless of the source. The risk of a potentially fatal opioid overdose is a hazard of the drug and the drug combinations that are used. This applies to those who take opioids for pain and to those who misuse them.

Additional overdose risk factors include the following:

- Concurrent use of benzodiazepines or alcohol^{1,2}
- History of opioid addiction or other substance use disorder³
- Comorbid mental illness³
- Receiving prescriptions from multiple pharmacies and prescribers⁴
- Daily opioid doses exceeding 100 mg of morphine equivalents³⁻⁶
- Receiving a methadone prescription⁷
- Recent emergency medical care for opioid poisoning/intoxication/overdose⁸
- Recent release from incarceration/prison/jail⁹
- Recent discharge from opioid detox or abstinence-based program¹⁰
- Comorbid renal dysfunction, hepatic disease, or respiratory diagnoses (smoking/COPD/emphysema/asthma/sleep apnea/other)

Naloxone is a bystander-administered drug, and the request for naloxone may come from caregivers.

How It Is Supplied

Naloxone for take-home use can be supplied as an intramuscular (IM) injection or as an intranasal (IN) spray. Both formulations are effective. The nasal spray tends to be preferred by patients and caregivers, while the components of the IM kit are more readily available

in pharmacies. There is also a recently available IM auto-injector, which is convenient to prescribe and dispense but costly.

Intranasal Spray

IN kits should contain: 2 naloxone 2 mg/2 ml prefilled syringes, 2 atomizers, step-by-step instructions for responding to an opioid overdose, and directions for naloxone administration.

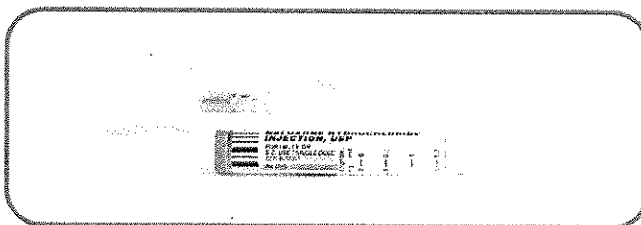


Figure 1. Intranasal kit Used with permission. San Francisco Department of Public Health. *Naloxone for opioid safety: a provider's guide to prescribing naloxone to patients who use opioids.* January 2015.

Intramuscular Injection

IM kits should contain: 2 naloxone 0.4 mg/ml vials, 2 IM syringes, step-by-step instructions for responding to an opioid overdose, and directions for naloxone administration.

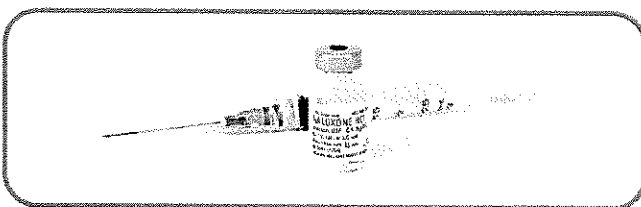


Figure 2. Intramuscular kit Used with permission. San Francisco Department of Public Health. *Naloxone for opioid safety: a provider's guide to prescribing naloxone to patients who use opioids.* January 2015.

IM auto-injector: commercially available as a twin pack with directions for administration included.

Prescribing and Dispensing

Intranasal

Naloxone 2 mg/2 ml prefilled syringe, 2 syringes

NDC No. 76329-3369-01

SIG: Spray one-half of syringe into each nostril upon signs of opioid overdose. Call 911. May repeat $\times 1$.

Atomizer No. 2

SIG: Use as directed for naloxone administration

Intramuscular

Naloxone 0.4 mg/ml single dose vial, 2 vials

NDC No. 00409-1215-01

SIG: Inject 1 ml IM upon signs of opioid overdose. Call 911. May repeat $\times 1$.

Syringe 3 ml 25G $\times 1$ inch No. 2

SIG: Use as directed for naloxone administration

Intramuscular Auto-injector

Naloxone 0.4 mg/0.4 ml

No. 1 twin pack

SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat $\times 1$.

Acquisition and Reimbursement

The single-dose vial, prefilled syringe, and IM syringes are available from pharmacy wholesale distributors. The atomizers for IN administration are available from medical supply vendors, and in some cases, can be purchased directly from the pharmacy wholesaler, or obtained from point persons within the pharmacy corporation.

Table. Nasal Atomizer Vendor Contacts

| Vendor | Item No. | Contact |
|------------------------------|----------|--------------|
| Professional Hospital Supply | 392322 | 707-429-2884 |
| Cardinal | MAD 300 | 800-964-5227 |
| Heathcare Logistics | 17474 | 800-848-1633 |
| Amazon | MAD 300 | Amazon.com |
| American Medical | MAD 300 | 888-988-5350 |
| Teleflex | MAD 300 | 919-544-8000 |

Medicaid, Medicare, and many private insurance companies will pay for naloxone. However, at present, health plans do not have a viable way to pay for the atomizer, which lacks any unique identifier, such as a NDC number.

To cover the cost of the atomizer, some pharmacies are charging patients directly. The cost is about \$10 for 2. In other cases, the atomizers are included with the drug at no additional charge. New Mexico provides a reimbursement code for the entire kit, including the pharmacist's time.

Naloxone Storage Information

- Store naloxone in the original package at room temperature. Avoid light exposure.
- The shelf life of naloxone is generally 12 to 18 months. If stored properly, naloxone should be effective until at least the expiration date on the packaging.
- Do not insert naloxone into the prefilled syringe until ready to use. Once inserted it expires within 2 weeks.
- Monitor the expiration date on naloxone and replace before it expires. When there are no other alternatives, expired naloxone can be administered but may not be as effective.

Supporting Laws and Regulations

State laws to support naloxone access fall under three categories:

- **Good Samaritan:** Protects individuals who call for help at the scene of an overdose from being arrested for drug possession.
- **Liability protection/third party administration:** Protects both the prescriber and the bystander who may be administering the naloxone. It also allows bystanders to be prescribed naloxone for use on opioid overdose victims.
- **Collaborative practice agreement:** Allows pharmacists to prescribe naloxone to at-risk individuals. It may be done with individual physicians or on a statewide basis.

The Network for Public Health Law has an updated [summary of state laws](#) supporting access to naloxone.¹¹

Examples of Successful State and Local Models

New Mexico: In 2001, New Mexico enacted legislation to protect third parties who administer naloxone to an overdose victim. This was followed by a Good Samaritan statute in 2007 and pharmacist prescribing in 2014. To obtain prescribing authority, pharmacists need to complete a 2-hour certification course every 2 years. The State Medicaid program pays for naloxone, the

atomizer, and the consultation time via a specific NDC number for the entire naloxone kit.

California: San Francisco's Department of Public Health expanded naloxone access by making the atomizer and education brochures available in primary care clinics. Naloxone was co-prescribed with opioid analgesics and picked up at community pharmacies. Patients were trained both at the primary care clinic and the community pharmacy. Pharmacist training and outreach was done by the Public Health Department. Pharmacists also make naloxone available to methadone and buprenorphine maintenance patients at a specialty mental health pharmacy run by the Department of Public Health under a collaborative practice agreement.

Rhode Island: All Walgreens and CVS Pharmacies in Rhode Island make IM and IN naloxone available without a prescription under a collaborative practice agreement. The pharmacy chains have secured atomizer access through their supply systems, and the collaborative drug therapy agreement is signed by one physician for the state. The University of Rhode Island offers [continuing education training](#).¹²

Collaborative Practice Agreements

- [New Mexico](#)¹³
- [Washington State](#)¹⁴
- [San Francisco Department of Public Health](#)¹⁵
- [Providers' Clinical Support System for Opioid Therapies \(PCSS-O\): Description of collaborative practice with focus on Rhode Island](#)¹⁶

Frequently Asked Questions

What are signs of opioid overdose?

- Skin is pale and/or clammy to the touch.
- Body is limp.
- Fingernails or lips have a blue or purple cast.
- Patient is vomiting or making gurgling noises.
- Patient is unarousable.
- Breathing is very slow or stopped.

What is rescue breathing?

Rescue breathing involves essentially breathing for someone else. By providing rescue breathing during an opioid overdose, the rescuer can potentially prevent the patient from developing organ damage. See the patient information sheets for details on how to administer rescue breaths.

How quickly does naloxone work?

Naloxone works within 2 to 5 minutes, depending on how naloxone has been administered.

How long should a bystander remain with the overdose victim after naloxone has been administered?

Bystanders should remain with the overdose victim until help arrives. Naloxone only has a 30- to 90-minute duration of action. Patients who have overdosed on a long-acting opioid may initially respond and then succumb to overdose symptoms again. It is important to remain with the patient to continue to provide support and additional doses of naloxone (if required) until help arrives.

Is naloxone effective in treating other types of overdoses?

No, naloxone is only effective in reversing an opioid overdose. At times, it may be difficult to distinguish opioid overdose symptoms from other overdoses or illnesses. Therefore, it is important to immediately seek medical help.

What happens if you administer expired naloxone?

Naloxone's full efficacy cannot be guaranteed beyond the expiration date. However, in urgent situations without alternatives, it will not hurt the patient to administer expired naloxone and may provide some benefit.

Can the intranasal naloxone be assembled in advance?

The shelf life of the assembled prefilled syringe is only 2 weeks; therefore, it is recommended that the atomizer is attached to the syringe but the naloxone is not inserted until ready to administer.

Can naloxone be administered to pregnant women?

Yes, in an opioid overdose, naloxone can and should be administered to a pregnant woman. However, there is risk for opioid withdrawal.

For More Information

- www.prescribetoprevent.org
- [Overdose rescue/naloxone long-format training, August 23, 2012](#)¹⁷
- [SAMHSA Opioid Overdose Prevention Toolkit](#)¹⁸

Intranasal Naloxone Patient Information Sheet

Common brand names: Narcan

Uses: This medication is used to treat an opioid overdose. Naloxone works by reversing the effects of opioids.

Patients should be instructed to tell family/friends where naloxone is stored and how to administer it in case of an overdose.

Signs of an opioid overdose

Slow or shallow breathing, blue or gray lips and fingernails, pale and/or clammy skin, unable to wake up or respond.

How to Use IN Naloxone

If you suspect someone is suffering from an opioid overdose:

Step 1. Call 911.

Step 2. Give naloxone.

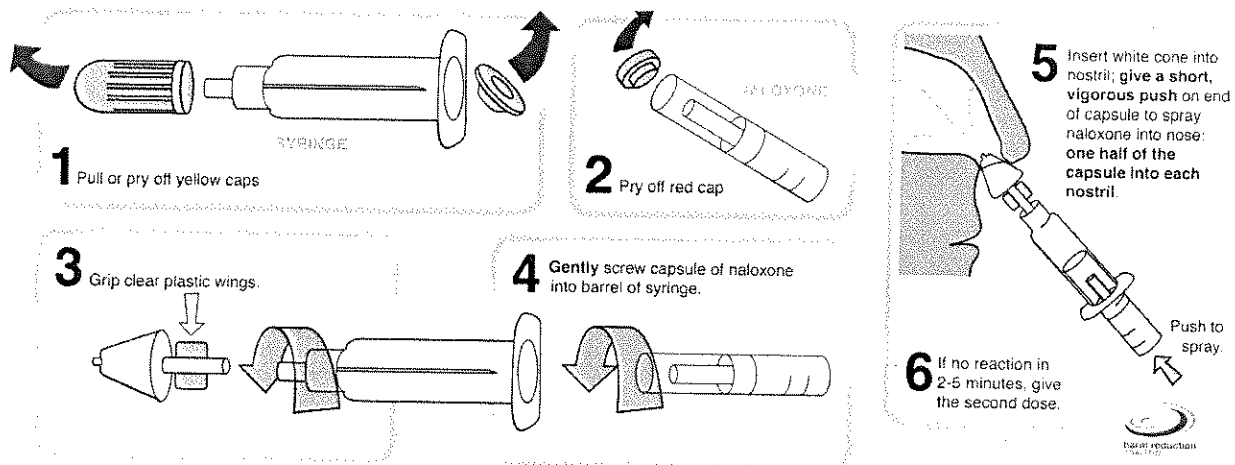


Image by Harm Reduction Coalition. <http://harmreduction.org/issues/overdose-prevention/leois-best-practices/oa-kit-materials/>. Updated October 2014.

Step 3. Give a second dose of naloxone in 2 to 3 minutes if there is no response to the first dose.

Step 4. Follow the 911 dispatcher's instructions or perform rescue breathing if comfortable doing so.

Rescue Breathing

The key components of rescue breathing include the following:

Step 1. Make sure nothing is in the individual's mouth.

Step 2. Tilt the head back, lift chin, and pinch nose shut.

Step 3. Give one slow breath every 5 seconds; chest should rise.

Side effects

Anxiety, sweating, nausea/vomiting, or shaking. This is not a complete list of possible side effects. If you notice other effects not listed, contact your doctor or pharmacist.

Intramuscular Naloxone Patient Information Sheet

Common brand names: Narcan

Uses: This medication is used to treat an opioid overdose. Naloxone works by reversing the effects of opioids.

Patients should be instructed to tell family/friends where naloxone is stored and how to administer it in case of an overdose.

Signs of an opioid overdose

Slow or shallow breathing, blue or gray lips and fingernails, pale and/or clammy skin, unable to wake up or respond.

How to Use IM Naloxone

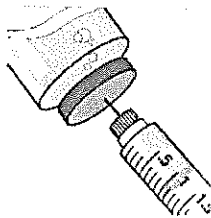
If you suspect someone is suffering from an opioid overdose,

Step 1. Call 911.

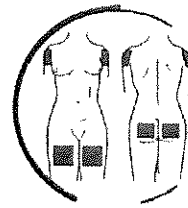
Step 2. Give naloxone.



1 Remove cap from naloxone vial and uncover the needle



2 Insert needle through rubber plug with vial upside down
Pull back on plunger and take up 1 mL



3 Inject 1 mL of naloxone at a 90 degree angle into a large muscle (upper arm/thigh, outer buttocks)

Images in Public Domain. San Francisco Department of Public Health. Naloxone for opioid safety: a provider's guide to prescribing naloxone to patients who use opioids. January 2015.

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**PHARMACIST PRESCRIPTIVE AUTHORITY OF NALOXONE FOR RESCUE USE PROTOCOL
(OUTSIDE OF NM DEPARTMENT OF HEALTH-ISSUED STANDING ORDER)**

A. Title:

New Mexico Pharmacist prescriptive authority of naloxone for rescue use, or naloxone rescue kits (NRKs), as intended to support and pursuant to, New Mexico Board of Pharmacy ("Board") Regulation.

B. Purpose:

This is the protocol by which the Pharmacist will educate, prescribe, and dispense NRKs in order to prevent and/or decrease opioid drug overdose deaths for patients in New Mexico. This tool is intended to ensure safety, efficacy, and provision to meet the needs of the public welfare by decreasing death due to opioid overdose.

C. Definitions:

1. *Opiate*: the natural derivatives of opium, which are morphine and codeine.

2. *Opioid*: includes the opiates and related synthetic and semi-synthetic compounds that act at the opioid receptor.

**for the purposes of this document, opioid will be used exclusively.

3. *Naloxone*: a potent opioid antagonist used in the reversal of opioid overdoses. The primary route of naloxone administration is by injection, but it can also be administered through the nasal spray; this is the preferred method when used by someone other than a medical professional.

D. Introduction:

New Mexico is a leader in the nation for drug overdose deaths (CDC, 2014); however, the current reach of naloxone distribution in New Mexico is limited through the Department of Health (DOH) Harm Reduction Program. The New Mexico Department of Health (NMDOH) Public Health Division supports the distribution of naloxone and overdose prevention training to persons at high risk of opioid overdose and/or friends/family of persons at risk of opioid overdose. Pharmacist prescriptive authority of NRKs allows for increased access for patients throughout the state. Historically, these services have only been provided in syringe exchange venues and, as such, have primarily been directed to illicit drug users. However, prescription drugs, especially opioid medications such as oxycodone, hydrocodone, methadone, and fentanyl are major contributors to the problem of unintentional drug overdose. Prescription drugs can be harmful or fatal when abused, misused, or mixed with other sedative medications (CDC, 2015). In 2007, the prescription drug-associated overdose death rate overtook that of heroin and other illicit drugs that are associated with the increase in overdose deaths in New Mexico. Prescription drug-associated overdose deaths have continued to dominate overdose deaths in this state through 2015. Pharmacist prescriptive authority of NRKs to appropriate patients and to individuals at risk of witnessing an opioid-related overdose allows for increased naloxone for rescue use access, additional educational opportunities for patients and potential witnesses, and a potential for decreased harm due to opioid overdose in New Mexico. Strategies employed make naloxone available when prescribed by a Pharmacist with the appropriate naloxone for rescue use prescriptive authority certification.

E. Guidelines:

Prescribing and dispensing of naloxone for rescue use by a pharmacist exercising prescriptive authority of naloxone will occur as stated below.

a. Pharmacist Education/Training

1. Participating Pharmacists will successfully complete a certification prescriptive authority training approved by the Board and maintain this certification with the Board by completing 2 hours of live continuing education in this area every two years.
2. A primary option of an NRK may include the following contents (the pharmacist will be responsible for the assembly of the NRKs):
 - i. Naloxone 2mg/2ml syringes
 - ii. Intranasal trumpet device
 - iii. Educational handout(s)
3. Other secondary options of naloxone for rescue use as approved by the FDA may be used.

b. Consent/Screening/Prescriber Notification

1. Patient is screened and evaluated by the Pharmacist for the risk of overdose. Potential opioid overdose witnesses do not need to be screened, although the Pharmacist should discuss the person the potential witness believes to be at risk of overdose.
2. Consent form must be completed and signed before the prescribing and dispensing of NRK to the individual at Risk of Experiencing, or Witnessing an Opioid-Related Overdose.
3. Notify the patient's primary care provider with the consent of the patient (if available) within 15 days of the original prescription.

c. Naloxone for rescue use may be prescribed by a pharmacist in accordance with this protocol to all the following:

1. An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose; or
2. A family member, friend, or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

F. Patient Screening Criteria (Individuals at risk of witnessing an opioid-related overdose do not need to be screened)

1. Prescribed long-acting opioid (oxycodone ER, oxymorphone ER, morphine ER, transdermal fentanyl, methadone or buprenorphine).
2. A high daily dose of opioid prescribed.
3. Prescribed opiates or opioid use greater than 30 days.
4. History of or current polyopioid use.
5. Opioid use with certain concurrent diseases such as: renal dysfunction, liver disease, respiratory infection, sleep apnea, COPD, emphysema or other respiratory/airway disease that can lead to potential airway obstruction.
6. Concurrent prescription or OTC medication that could potentiate the CNS and respiratory depressant properties of opioid medications, such as benzodiazepines, antipsychotics, carisoprodol, and/or antihistamine use.
7. Known or suspected substance use, such as alcohol and/or marijuana.
8. Elderly patients (> 65) receiving an opioid prescription.

9. Teens receiving an opioid prescription.
10. Households with people at risk of overdose, such as children and/or someone with a substance abuse disorder.
11. Patients who may have difficulty accessing emergency medical services (distance, remoteness, lack of transportation, homelessness, and/or without phone services).
12. Patients as determined by the Pharmacist using their professional judgment.

G. Mechanism of Action

Naloxone is an opioid antagonist with greatest affinity for the mu receptor. It acts by competing for the mu, kappa, and sigma opioid receptor sites in the CNS.

H. Indication

Naloxone is indicated for known or suspected overdose of an opioid and for the reversal of opioid activity, respiratory depression, with therapeutic opioid use.

I. Contraindications

Hypersensitivity to naloxone.

J. Precautions/Warnings

1. Abrupt reversal of opioid depression may result in nausea, vomiting, sweating, tachycardia, increased blood pressure, tremulousness, seizures, ventricular tachycardia and fibrillation, pulmonary edema, and cardiac arrest which may result in death.
2. Abrupt reversal of opioid effects in persons who are physically dependent on opioids may precipitate an acute withdrawal syndrome which may include, but not limited to the following signs and symptoms: body aches, fever, sweating, runny nose, sneezing, piloerection, yawning, weakness, shivering or trembling, nervousness, restlessness or irritability, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure, and tachycardia.
3. Known or suspected physical dependence on opioids; naloxone will precipitate withdrawal symptoms within minutes after administration and will subside in about 2 hours; observe patients for recurrence of respiratory depression and other narcotic effects for at least 2 hours after the last dose of naloxone and until there is no reasonable risk of recurrent respiratory depression.
4. Acute toxicity caused by levopropoxyphene; naloxone is not effective.
5. Agitation; excessive doses of naloxone may result in significant reversal of analgesia.
6. Liver disease; naloxone is primarily metabolized in the liver; use with caution.
7. Newborns of mothers suspected of long-term opioid use; do not administer naloxone due to risk of seizures and/or acute withdrawal.
8. Partial opioid agonist and mixed opioid agonist/antagonist overdose: Reversal of partial opioid agonists or mixed opioid agonist/antagonists (e.g., buprenorphine, pentazocine) may be incomplete and large doses of naloxone may be required.

K. Adverse Reactions

1. Cardiac Disorders: pulmonary edema, cardiac arrest or failure, tachycardia, ventricular fibrillation, and ventricular tachycardia. Death, coma, and encephalopathy have been reported as sequelae of these events.
2. Gastrointestinal Disorders: vomiting, nausea.
3. Nervous System Disorders: convulsions, paresthesia, grand mal convulsion.

4. Psychiatric Disorders: agitation, hallucination, tremulousness.
5. Respiratory, Thoracic, and Mediastinal Disorders: dyspnea, respiratory depression, hypoxia, pulmonary edema.
6. Skin and Subcutaneous Tissue Disorders: nonspecific injection site reactions, sweating.
7. Vascular Disorders: hypertension, hypotension, hot flashes, or flushing.

L. Patient Education

1. Once the patient is identified to be at high risk, the Pharmacist will provide overdose prevention education and training, which includes proper administration of nasal naloxone and the required immediate medical follow-up after proper use of NRK. Potential overdose witnesses should receive the same education and training.
2. Face-to-face education is required on the proper use of the NRK, including a plan for overdose prevention and adverse effects. A designated rescue person or persons must be identified by the patient.
3. The individual at Risk of Experiencing or Witnessing an Opioid-Related Overdose will be provided with educational materials and a handout describing caregiver medication administration.
4. Family members and/or caregivers are encouraged to attend the appointment to also receive training at the time the patient receives the NRK.
5. Follow-up training and reinforcement is encouraged, the pharmacist will provide their contact information for any questions or concerns.
6. In the event the NRK is used or expired, the patient or potential overdose witness will return to the Pharmacist to request a new prescription; a thorough evaluation will be completed by the Pharmacist regarding the events leading to NRK use and to determine whether appropriate medical follow-up was completed, as required.

M. Records

- a. Consent form.
- b. Primary care provider notification of the prescription, when patient consent is available.
- c. Prescription order.

Agenda Topic: Epinephrine

Included in Agenda Package:

- Draft Virginia Statewide Protocol for Epinephrine

Action:

Adopt draft statewide protocol for epinephrine for board consideration as presented or as amended.

VIRGINIA BOARD OF PHARMACY

Pharmacist Epinephrine Statewide Protocol

Consistent with the epinephrine manufacturer's instructions for use approved by the US Food and Drug Administration, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- Epinephrine auto-injector; or,
- Injectable epinephrine, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such epinephrine.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering epinephrine under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use, paraphernalia necessary for administration, and how to properly counsel the patient on recognition and management of anaphylaxis.

PATIENT INCLUSION CRITERIA

Patients eligible for epinephrine under this protocol:

- Any person, 18 years of age or older, at risk for experiencing anaphylaxis.

COUNSELING

The pharmacist shall counsel the patient or the patient's agent on how to properly recognize and manage anaphylaxis, including proper administration of the epinephrine.

RECORDKEEPING

The pharmacist shall maintain records in accordance with board regulation _____.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Agenda Topic: Prenatal vitamins for which a prescription is required

Included in Agenda Package:

- Draft Pharmacist Statewide Protocol for Prenatal Vitamins

Action:

Adopt draft statewide protocol for prenatal vitamins for board consideration as presented or as amended.

VIRGINIA BOARD OF PHARMACY

Pharmacist Prenatal Vitamin Statewide Protocol

Consistent with the prenatal vitamin manufacturer's instructions for use approved by the US Food and Drug Administration, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs to persons 18 years of age or older:

- Prenatal vitamins for which a prescription is required.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering prenatal vitamins under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use and evidence-based guidelines.

PATIENT INCLUSION CRITERIA

Patients eligible for prenatal vitamins under this protocol:

- An individual, 18 years of age or older, who is considering pregnancy, attempting to become pregnant, or pregnant.

RECORDKEEPING

The pharmacist shall maintain records in accordance with board regulation _____.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Agenda Topic: Dietary fluoride supplements, in accordance with recommendations of the American Dental Association (ADA) for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services

Included in Agenda Package:

- Excerpt from ADA recommending use until 16 years of age
- Draft Pharmacist Statewide Protocol for Dietary fluoride supplements

Action:

- Take no action since ADA does not appear to recommend use of dietary fluoride supplements for persons 18 years of age or older; or,
- Adopt draft statewide protocol for dietary fluoride supplements for board consideration as presented or as amended.

Excerpt from the American Dental Association Website
<https://www.ada.org/en/member-center/oral-health-topics/fluoride-topical-and-systemic-supplements>

- **Dietary Fluoride Supplements**

Fluoride supplements can be prescribed for children ages 6 months to 16 years who are at high risk for tooth decay and whose primary drinking water has a low fluoride concentration.^{2, 25} Tablets and lozenges are manufactured with 1.0, 0.5, or 0.25 mg fluoride.^{2, 3} Most supplements contain sodium fluoride as the active ingredient.² To maximize the topical effect of fluoride, tablets and lozenges are intended to be chewed or sucked for 1–2 minutes before being swallowed;^{2, 3, 5} for infants, supplements are available as a liquid and used with a dropper.³ Dosing is based on the natural fluoride concentration of the child's drinking water and the age of the child (see Table).^{5, 25}

All dietary fluoride supplements must be prescribed by a dentist or physician.² For children aged younger than 6 years, health care providers should weigh the risk for tooth decay without fluoride supplements, the decay prevention offered by supplements, and the potential for dental fluorosis.² Consideration of the child's other sources of fluoride, especially drinking water, is essential in determining this balance.^{3, 5} Parents and caregivers should be informed of both the benefit of protection against tooth decay and the potential risk of dental fluorosis.² The U.S. Preventive Services Task Force recommends the clinical use of oral fluoride supplementation starting at age 6 months through 5 years for children whose water supply is deficient in fluoride.⁹ The recommendation is given a "B" grade, indicating that there is high certainty that the net benefit of the intervention is moderate or there is moderate certainty that the net benefit is moderate to substantial.¹⁰

Table. Fluoride Supplement (Tablets and Drops) Dosage Schedule 2010 (Approved by the American Dental Association Council on Scientific Affairs)²⁵

| Age | Fluoride Ion Level in Drinking Water (ppm)* | | |
|------------------|---|-------------|------|
| | <0.3 | 0.3-0.6 | >0.6 |
| Birth-6 months | None | None | None |
| 6 months-3 years | 0.25 mg/day** | None | None |
| 3-6 years | 0.50 mg/day | 0.25 mg/day | None |
| 6-16 years | 1.0 mg/day | 0.50 mg/day | None |

*1.0 part per million (ppm) = 1 milligram per liter (mg/L)
 **2.2 mg sodium fluoride contains 1 mg fluoride ion

- **Important Considerations When Using Dosage Schedule:²⁵**

- If fluoride level is unknown, drinking water should be tested for fluoride content before supplements are prescribed. For testing of fluoride content, contact the local or state health department.
- All sources of fluoride should be evaluated with a thorough fluoride history.
- Patient exposure to multiple water sources may complicate proper prescribing.
- Ingestion of higher than recommended levels of fluoride by children has been associated with an increased risk of mild dental fluorosis in developing, unerupted teeth.
- To obtain the benefits from fluoride supplements, long-term compliance on a daily basis is required.

It is important to note that fluoridated water may be consumed from sources other than the home water supply, such as the workplace, school and/or day care, bottled water, filtered water and from processed beverages and foods prepared with fluoridated water. For this reason, dietary fluoride supplements

should be prescribed by carefully following the recommended dosage schedule. Dietary fluoride supplements are not recommended for children residing in a community with adequate levels of fluoride in the water supply.

The ADA's dietary fluoride supplement recommendations remain unchanged in light of the new guidelines for community water fluoridation in the U.S. released in April 2015 by the U.S. Public Health Service.²¹ The recommendation for fluoride levels in drinking water was reconsidered in 2015 when it was determined that 0.7 milligrams of fluoride per liter of water (0.7 ppm) was optimal. The new recommendation, which was supported by the ADA, does not change the ADA Council on Scientific Affairs' systematic review, clinical recommendation and chairside guide for the use of dietary fluoride supplements that were released in 2010.

VIRGINIA BOARD OF PHARMACY

Pharmacist Dietary Fluoride Supplement Statewide Protocol

Consistent with the recommendations of the American Dental Association for prescribing dietary fluoride supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services and the dietary fluoride supplement manufacturer's instructions for use approved by the US Food and Drug Administration, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs to persons 18 years of age or older:

- Dietary fluoride supplements.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering dietary fluoride supplements under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use and the recommendations of the American Dental Association for prescribing such supplements.

PATIENT INCLUSION CRITERIA

Patients eligible for prenatal vitamins under this protocol:

- An individual, 18 years of age or older, whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services, and who satisfies the American Dental Association recommendation criteria for taking a dietary fluoride supplement.

RECORDKEEPING

The pharmacist shall maintain records in accordance with board regulation _____.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Agenda Topic: Medications covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter (OTC) equivalent of the same drug

Included in Agenda Package:

- Draft Pharmacist Statewide Protocol for OTC medications

Action:

Adopt draft statewide protocol for OTC medications for board consideration as presented or as amended.

VIRGINIA BOARD OF PHARMACY

Pharmacist Over-the-Counter Drug Statewide Protocol

For the purpose of lowering a patient's out-of-pocket health care costs, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs to persons 18 years of age or older:

- Medications covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering over-the-counter medications under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use and follow any relevant evidence-based guidelines.

PATIENT INCLUSION CRITERIA

Patients eligible for over-the-counter medications under this protocol:

- An individual, 18 years of age or older, whose medications are covered by the patient's health carrier and when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug.

RECORDKEEPING

The pharmacist shall maintain records in accordance with board regulation _____.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Agenda Topic: Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use

Included in Agenda Package:

- Colorado Statewide Protocol for Prescribing Hormonal Contraceptive Patches and Oral Contraceptives - **Pg. 37-44**
- Maryland Contraception Prescribing - **Pg: 45-67**
- Oregon Allowances for Contraceptives - **Pg: 68-77**
- California Self-Administered Hormonal Contraception Protocol for Pharmacists - **Pg: 78-82**
- New Mexico Protocol for Pharmacist Prescription of Hormonal Contraception - **Pg: 83-90**

Action:

Adopt criteria to include in draft statewide protocol for injectable or self-administered hormonal contraceptives for board consideration.

Colorado State Board of Pharmacy Approved Statewide Protocol for Prescribing Hormonal Contraceptive Patches and Oral Contraceptives

(Appendix A)

This collaborative pharmacy practice statewide protocol authorizes qualified Colorado-licensed pharmacists ("Pharmacists") to perform the pertinent physical assessments and prescribe hormonal contraceptive patches and oral contraceptives under the conditions of this protocol and according to and in compliance with all applicable state and federal laws and rules.

Definitions

- (1) "Clinical visit" means a consultation with a healthcare provider, other than a pharmacist, for women's health, which should address contraception and age-appropriate screening.
- (2) "Hormonal contraceptive patch" means a transdermal patch applied to the skin of a patient, by the patient or by a practitioner, that releases a drug composed of a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy.
- (3) "Oral hormonal contraceptive" means a drug composed of a hormone or a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that the patient to whom the drug is prescribed may take orally.

Training Program

Only a Colorado-licensed pharmacist, who has completed an Accreditation Council for Pharmacy Education (ACPE) accredited educational training program related to the prescribing of contraceptives by a pharmacist, may dispense hormonal contraceptive patches and oral hormonal contraceptives to a patient. In addition, pharmacists shall comply with the most current United States Medical Eligibility Criteria (USMEC) for Contraceptive Use as adopted by the U.S. Centers for Disease Control and Prevention (CDC).

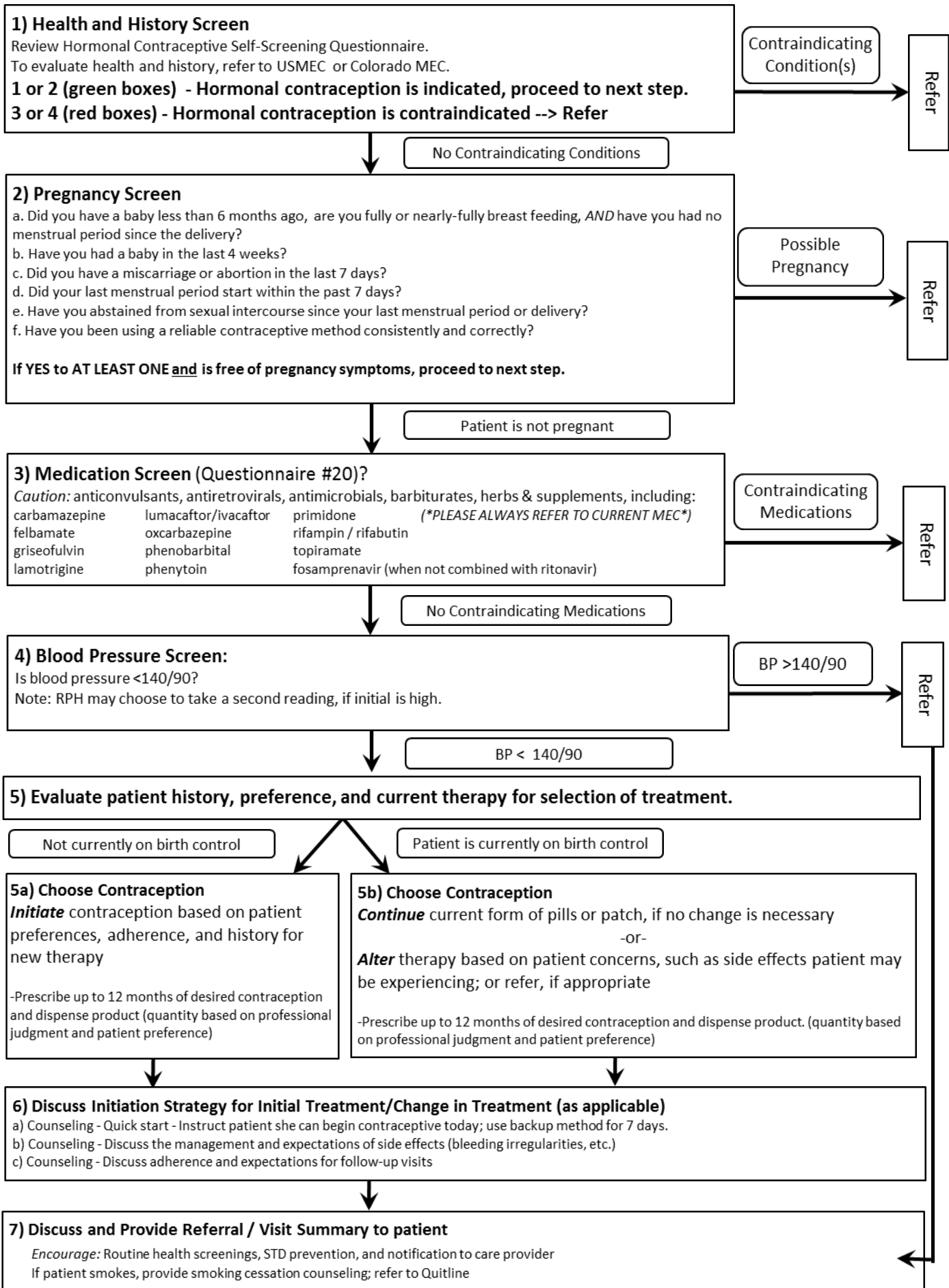
Age Requirements

A pharmacist may prescribe hormonal contraceptive patches and self-administered oral hormonal contraceptives to a person who is at least 18 years of age.

Further Conditions

- (1) For each new patient requesting a contraceptive service and, at a minimum of every twelve months for each returning patient, a participating pharmacist must:
 - (a) Obtain a completed Colorado Self-Screening Risk Assessment Questionnaire;
 - (b) Utilize and follow the Colorado Standard Procedures Algorithm to perform the patient assessment;
 - (c) Prescribe, if clinically appropriate, the hormonal contraceptive patch or self-administered oral hormonal contraceptive, or refer to a healthcare practitioner;
 - (d) Provide the patient with a Visit Summary;
 - (e) Advise the patient to consult with a primary care practitioner or women's health care practitioner;
 - (f) Refer any patient that may be subject to abuse to an appropriate social services agency; and
 - (g) Ensure that the pharmacy provides appropriate space to prevent the spread of infection and ensure confidentiality.
- (2) If the hormonal contraceptive patch or self-administered oral hormonal contraceptive is dispensed, it must be done as soon as practicable after the pharmacist issues the prescription and shall include any relevant educational materials.
- (3) A pharmacist must not:
 - (a) Require a patient to schedule an appointment with the pharmacist for the prescribing or dispensing of a hormonal contraceptive patch or self-administered oral hormonal contraceptive;
 - (b) Continue to prescribe and dispense a hormonal contraceptive to a patient beyond three years from the initial prescription without evidence of a clinical visit; or
 - (c) Prescribe in instances that the Colorado Standard Procedures Algorithm requires referral to a provider.
- (4) Records:
 - (a) Pursuant to Pharmacy Board Rule 17.00.50, a process shall be in place for the pharmacist to communicate with the patient's primary care provider and document changes to the patient's medical record. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult an appropriate health care professional of the patient's choice.
 - (b) Pharmacists shall comply with all aspects of Pharmacy Board Rules 17.01.00 and 17.02.00 with respect to the maintenance of proper records.

STANDARD PROCEDURES ALGORITHM FOR COLORADO RPH PRESCRIBING OF CONTRACEPTIVES



Hormonal Contraceptive Self-Screening Questionnaire (form updated Nov16)

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: _____

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? - If yes, what kind of reaction occurred? | Yes <input type="checkbox"/> No <input type="checkbox"/> _____ |
| | Are you currently using any method of birth control including pills, or a birth control patch, ring or shot/injection? - If yes, which one do you use? | Yes <input type="checkbox"/> No <input type="checkbox"/> _____ |
| 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 given birth within 21 days? If yes, how long ago? | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| 7 | Are you currently breastfeeding? | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| 8 | Do you have diabetes? | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| 9 | Do you get migraine headaches? 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"/> |
| 10 | 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"/> |
| 11 | 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"/> |
| 12 | Have you ever had a blood clot? | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| 13 | Have you ever been told by a medical professional that you are at risk of developing a blood clot? | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| 14 | 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"/> |
| 15 | Have you had bariatric surgery or stomach reduction surgery? | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| 16 | Do you have or have you ever had breast cancer? | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| 17 | 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"/> |
| 18 | Do you have lupus, rheumatoid arthritis, or any blood disorders? | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| 19 | Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)? - If yes, list them here: | Yes <input type="checkbox"/> No <input type="checkbox"/> _____ |
| 20 | Do you have any other medical problems or take any medications, including herbs or supplements? - If yes, list them here: | Yes <input type="checkbox"/> No <input type="checkbox"/> _____ |
| 21 | Will you be immobile for a long period? (e.g. flying on a long airplane trip, etc.) | |

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

A pill you take each day **A patch that you change weekly** **Other (ring, injectable, implant, or IUD)**

Internal use only verified DOB* with valid photo ID BP Reading _____/_____

Pharmacist Name _____ Pharmacist Signature _____

Drug Prescribed _____ Rx# _____ -or- Patient Referred-circle reason(s)

Sig: _____ (Pharmacy Phone _____ Address _____)

Notes: _____



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



Pages 1,2 Color coded in the left column to match the corresponding question of the Oregon Hormonal Contraception Self-Screening Tool Questionnaire.
Pages 3,4 Arranged alphabetically by disease state

Key:

| | |
|---|---|
| 1 | No restriction (method can be used) |
| 2 | Advantages generally outweigh theoretical or proven risks |
| 3 | Theoretical or proven risks usually outweigh the advantages |
| 4 | Unacceptable health risk (method not to be used) |

Updated November 2016. This summary sheet only contains a subset of the recommendations from the US MEC. For complete guidance, see: <http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm>

Corresponding to the order of the Colorado Hormonal Contraception Self Screening Tool Questionnaire:

| Condition | Sub-condition | Combined pill, patch, ring | | Progestin-only pill | | Other Contraception Options Indicated for Patient |
|--|--|----------------------------|------------|---------------------|------------|---|
| | | Initiating | Continuing | Initiating | Continuing | |
| Age | | Menarche to <40=1 | >40=2 | Menarche to <18=1 | >18-45=1 | Yes Yes Yes |
| Smoking | a) Age < 35, < 15 cigarettes/day | 2 | 3 | 1 | 1 | Yes |
| | b) Age ≥ 35, ≤ 15 cigarettes/day | 4 | 4 | 1 | 1 | Yes |
| | c) Age ≥ 35, ≥ 15 cigarettes/day | 4 | 4 | 1 | 1 | Yes |
| Pregnancy | (Not Eligible for contraception) | NA* | NA* | NA* | NA* | NA* |
| Postpartum (see also Breastfeeding) | a) < 21 days | 4 | 4 | 1 | 1 | Yes |
| | b) 21 days to 42 days: | | | | | |
| | (i) with other risk factors for VTE | 3* | 3* | 1 | 1 | Yes |
| | (ii) without other risk factors for VTE | 2 | 2 | 1 | 1 | Yes |
| | c) > 42 days | 1 | 1 | 1 | 1 | Yes |
| Breastfeeding (see also Postpartum) | a) < 1 month postpartum | 3* | 3* | 2* | 2* | Yes |
| | b) 1 month or more postpartum | 2* | 2* | 1* | 1* | Yes |
| Diabetes mellitus (DM) | a) History of gestational DM only | 1 | 1 | 1 | 1 | Yes |
| | b) Non-vascular disease | | | | | |
| | (i) non-insulin dependent | 2 | 2 | 2 | 2 | Yes |
| | (ii) insulin dependent† | 2 | 2 | 2 | 2 | Yes |
| | c) Nephropathy/retinopathy/neuropathy‡ | 3/4* | 3/4* | 2 | 2 | Yes |
| | d) Other vascular disease or diabetes of >20 years' duration‡ | 3/4* | 3/4* | 2 | 2 | Yes |
| Headaches | a) Non-migrainous | 1* | 2* | 1* | 1* | Yes |
| | b) Migraine: | | | | | |
| | (i) without aura, age <35 | 2* | 3* | 1* | 2* | Yes |
| | (ii) without aura, age ≥35 | 3* | 4* | 1* | 2* | Yes |
| | (iii) with aura, any age | 4* | 4* | 2* | 3* | Yes |
| | a) Adequately controlled hypertension | 3* | 3* | 1* | 1* | Yes |
| | b) Elevated blood pressure levels (properly taken measurements): | | | | | |
| | (i) systolic 140-159 or diastolic 90-99 | 3 | 3 | 1 | 1 | Yes |
| | (ii) systolic ≥160 or diastolic ≥100‡ | 4 | 4 | 2 | 2 | Yes |
| | c) Vascular disease | 4 | 4 | 2 | 2 | Yes |
| History of high blood pressure during pregnancy | | 2 | 2 | 1 | 1 | Yes |
| Hypertipidemia | | 2/3* | 2/3* | 2* | 2* | Yes |
| Peripartum cardiomyopathy† | a) Normal or mildly impaired cardiac function: | | | | | |
| | (i) < 6 months | 4 | 4 | 1 | 1 | Yes |
| | (ii) ≥ 6 months | 3 | 3 | 1 | 1 | Yes |

| Condition | Sub-condition | Combined pill, patch, ring | | Progestin-only pill | | Other Contraception Options Indicated for Patient |
|--|--|----------------------------|------------|---------------------|------------|---|
| | | Initiating | Continuing | Initiating | Continuing | |
| Multiple risk factors for arterial cardiovascular disease | b) Moderately or severely impaired cardiac function | 4 | 4 | 2 | 2 | Yes |
| | (such as older age, smoking, diabetes and hypertension) | 3/4* | 3/4* | 2* | 2* | Yes |
| Ischemic heart disease‡ | Current and history of | 4 | 4 | 2 | 3 | Yes |
| Valvular heart disease | a) Uncomplicated | 2 | 2 | 1 | 1 | Yes |
| | b) Complicated‡ | 4 | 4 | 2 | 3 | Yes |
| Stroke‡ | History of cerebrovascular accident | 4 | 4 | 2 | 3 | Yes |
| Thrombogenic mutations‡ | | 4* | 4* | 2* | 2* | Yes |
| Deep venous thrombosis (DVT) / Pulmonary embolism (PE) | a) History of DVT/PE, not on anticoagulant therapy | 4 | 4 | 2 | 2 | Yes |
| | b) Higher risk for recurrent DVT/PE | 3 | 3 | 2 | 2 | Yes |
| | i) lower risk for recurrent DVT/PE | 4 | 4 | 2 | 2 | Yes |
| | b) Acute DVT/PE | 4 | 4 | 2 | 2 | Yes |
| | c) DVT/PE and established on anticoagulant therapy for at least 3 months | | | | | |
| | i) higher risk for recurrent DVT/PE | 4* | 4* | 2 | 2 | Yes |
| | ii) lower risk for recurrent DVT/PE | 3* | 3* | 2 | 2 | Yes |
| | d) Family history (first-degree relatives) | 2 | 2 | 1 | 1 | Yes |
| | e) Major surgery | 4 | 4 | 2 | 2 | Yes |
| | (i) with prolonged immobilization | 2 | 2 | 1 | 1 | Yes |
| | (ii) without prolonged immobilization | 1 | 1 | 1 | 1 | Yes |
| | a) Restrictive procedures | 1 | 1 | 1 | 1 | Yes |
| | b) Malabsorptive procedures | COCs: 3 | COCs: 3 | 3 | 3 | Yes |
| History of bariatric surgery‡ | a) Undiagnosed mass | 2* | 2* | 2* | 2* | Yes |
| | b) Benign breast disease | 1 | 1 | 1 | 1 | Yes |
| | c) Family history of cancer | 1 | 1 | 1 | 1 | Yes |
| | d) Breast cancer:‡ | | | | | |
| | i) current | 4 | 4 | 4 | 4 | Yes |
| | ii) past and no evidence of current disease for 5 years | 3 | 3 | 3 | 3 | Yes |

| Condition | Sub-condition | Combined pill, patch, ring | | Progestin-only pill | | Other Contraception Options Indicated for Patient |
|--|---|----------------------------|------------|---------------------|------------|---|
| | | Initiating | Continuing | Initiating | Continuing | |
| Viral hepatitis | a) Acute or flare | 3/4* | 2 | 1 | 1 | Yes |
| | b) Carrier/Chronic | 1 | 1 | 1 | 1 | Yes |
| Cirrhosis | a) Mild (compensated) | 1 | | 1 | 1 | Yes |
| | b) Severe† (decompensated) | 4 | | 3 | 3 | Yes |
| Liver tumors | a) Benign: | | | | | |
| | i) Focal nodular hyperplasia | 2 | | 2 | 2 | Yes |
| | ii) Hepatocellular adenoma‡ | 4 | | 3 | 3 | Yes |
| | b) Malignant‡ | 4 | | 3 | 3 | Yes |
| Gallbladder disease | a) Symptomatic: | | | | | |
| | (i) treated by cholecystectomy | 2 | | 2 | 2 | Yes |
| | (ii) medically treated | 3 | | 2 | 2 | Yes |
| | (iii) current | 3 | | 2 | 2 | Yes |
| History of Cholelithiasis | b) Asymptomatic | 2 | | 2 | 2 | Yes |
| | a) Pregnancy-related | 2 | | 1 | 1 | Yes |
| | b) Past COC-related | 3 | | 2 | 2 | Yes |
| | a) Positive (or unknown) antiphospholipid antibodies | 4 | | 3 | 3 | Yes |
| Systemic lupus erythematosus‡ | b) Severe thrombocytopenia | 2 | | 2 | 2 | Yes |
| | c) Immunosuppressive treatment | 2 | | 2 | 2 | Yes |
| | d) None of the above | 2 | | 2 | 2 | Yes |
| | a) On immunosuppressive therapy | 2 | | 1 | 1 | Yes |
| Rheumatoid arthritis | b) Not on immunosuppressive therapy | 2 | | 1 | 1 | Yes |
| | | | | | | |
| Blood Conditions? | | | | | | |
| | | | | | | |
| Epilepsy‡ | (see also Drug Interactions) | | | | | |
| | a) Non-pelvic | 1* | | 1* | 1* | Yes |
| Tuberculosis‡ (see also Drug Interactions) | b) Pelvic | 1* | | 1* | 1* | Yes |
| | | | | | | |
| HIV | High risk | 1 | | 1 | 1 | Yes |
| | HIV infected (see also Drug Interactions)‡ | 1* | | 1* | 1* | Yes |
| | AIDS (see also Drug Interactions)‡ | 1* | | 1* | 1* | Yes |
| | Clinically well on therapy (see also Drug Interactions)‡ | | | | | |
| Antiretroviral therapy | a) Nucleoside reverse transcriptase inhibitors | 1* | | 1 | 1 | Yes |
| | b) Non-nucleoside reverse transcriptase inhibitors | 2* | | 2* | 2* | Yes |
| | c) Ritonavir-boosted protease inhibitors | 3* | | 3* | 3* | Yes |
| Anticonvulsant therapy | a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine) | 3* | | 3* | 3* | Yes |
| | b) Lamotrigine | 3* | | 1 | 1 | Yes |
| Antimicrobial therapy | a) Broad spectrum antibiotics | 1 | | 1 | 1 | Yes |
| | b) Antifungals | 1 | | 1 | 1 | Yes |
| | c) Antiparasitics | 1 | | 1 | 1 | Yes |
| | d) Rifampicin or rifabutin therapy | 3* | | 3* | 3* | Yes |

Alphabetical Listing of USMEC Contraceptive Eligibility By Disease State

| Condition | Sub-condition | Combined pill, patch, ring | | Progestin-only pill | | Other Contraception Options Indicated for Patient |
|--|--|----------------------------|------------|---------------------|------------|---|
| | | Initiating | Continuing | Initiating | Continuing | |
| Breast disease/ Breast Cancer | a) Undiagnosed mass | 2* | 2* | 2* | 2* | Yes |
| | b) Benign breast disease | 1 | 1 | 1 | 1 | Yes |
| | c) Family history of cancer | 1 | 1 | 1 | 1 | Yes |
| | d) Breast cancer# i) current ii) past and no evidence of current disease for 5 years | 4 3 | 4 3 | 4 3 | 4 3 | Yes Yes |
| Breastfeeding (see also Postpartum) | a) < 1 month postpartum | 3* | 3* | 2* | 2* | Yes |
| | b) 1 month or more postpartum | 2* | 2* | 1* | 1* | Yes |
| Cervical cancer | Awaiting treatment | 2 | 2 | 1 | 1 | Yes |
| | Cervical ectropion | 1 | 1 | 1 | 1 | Yes |
| Cervical intraepithelial neoplasia | Cervical intraepithelial neoplasia | 2 | 2 | 1 | 1 | Yes |
| | Cirrhosis | 1 | 1 | 1 | 1 | Yes |
| Cystic Fibrosis | a) Mild (compensated) | 4 | 4 | 3 | 3 | Yes |
| | b) Severe‡ (decompensated) | 1* | 1* | 1* | 1* | Yes |
| Deep venous thrombosis (DVT)/Pulmonary embolism (PE) | a) History of DVT/PE, not on anticoagulant therapy | 4 | 4 | 2 | 2 | Yes |
| | i) higher risk for recurrent DVT/PE | 3 | 3 | 2 | 2 | Yes |
| | ii) lower risk for recurrent DVT/PE | 4 | 4 | 2 | 2 | Yes |
| | b) DVT/PE and established on anticoagulant therapy for at least 3 months | 4* | 4* | 2 | 2 | Yes |
| Depressive disorders | i) higher risk for recurrent DVT/PE | 3* | 3* | 2 | 2 | Yes |
| | ii) lower risk for recurrent DVT/PE | 2 | 2 | 1 | 1 | Yes |
| | d) Family history (first-degree relatives) | 4 | 4 | 2 | 2 | Yes |
| | e) Major surgery (i) with prolonged immobilization (ii) without prolonged immobilization | 2 1 | 2 1 | 1 1 | 1 1 | Yes Yes |
| Diabetes mellitus (DM) | f) Minor surgery without immobilization | 1 | 1 | 1 | 1 | Yes |
| | a) History of gestational DM only | 1* | 1* | 1* | 1* | Yes |
| | b) Non-vascular disease | 1 | 1 | 1 | 1 | Yes |
| | (cont.) (i) non-insulin dependent (ii) insulin dependent‡ | 2 2 | 2 2 | 2 2 | 2 2 | Yes Yes |
| Diabetes mellitus | c) Nephropathy/ retinopathy/ neuropathy‡ | 3/4* | 3/4* | 2 | 2 | Yes |
| | d) Other vascular disease or diabetes of >20 years' duration‡ | 3/4* | 3/4* | 2 | 2 | Yes |
| | Endometrial cancer‡ | 1 | 1 | 1 | 1 | Yes |
| | Endometrial hyperplasia | 1 | 1 | 1 | 1 | Yes |
| Endometriosis | Endometriosis | 1 | 1 | 1* | 1* | Yes |
| | (see also Drug Interactions) | 1 | 1 | 1 | 1 | Yes |
| Epilepsy‡ Gallbladder disease | a) Symptomatic | 2 | 2 | 2 | 2 | Yes |
| | (i) treated by cholecystectomy | 3 | 3 | 2 | 2 | Yes |
| | (ii) medically treated (iii) current | 3 | 3 | 2 | 2 | Yes |

| Sub-condition | Combined pill, patch, ring | | Progestin-only pill | | Other Contraception Options Indicated for Patient | |
|---|---|-------------------|---------------------|------------|---|-----|
| | Initiating | Continuing | Initiating | Continuing | | |
| b) Asymptomatic | 2 | 2 | 2 | 2 | Yes | |
| | 1 | 1 | 1 | 1 | Yes | |
| Gestational trophoblastic disease | a) Decreasing or undetectable β -hCG levels | 1 | 1 | 1 | 1 | Yes |
| | b) Persistently elevated β -hCG levels or malignant disease‡ | 1* | 2* | 1* | 1* | Yes |
| Headaches | a) Non-migrainous | 1* | 2* | 1* | 1* | Yes |
| | b) Migraine i) without aura, age <35 | 2* | 3* | 1* | 2* | Yes |
| | ii) without aura, age \geq 35 | 3* | 4* | 1* | 2* | Yes |
| | iii) with aura, any age | 4* | 4* | 2* | 3* | Yes |
| History of bariatric surgery‡ | a) Restrictive procedures | 1 | 1 | 1 | 1 | Yes |
| | b) Malabsorptive procedures | COCs: 3 P/R: 1 | 3 | 3 | 3 | Yes |
| History of cholestasis | a) Pregnancy-related | 2 | 2 | 1 | 1 | Yes |
| | b) Past COC-related | 3 | 3 | 2 | 2 | Yes |
| History of high blood pressure during pregnancy | 2 | 2 | 1 | 1 | Yes | |
| | History of pelvic surgery | 1 | 1 | 1 | 1 | Yes |
| HIV | High risk | 1 | 1 | 1 | 1 | Yes |
| | HIV infected (see also Drug Interactions)‡ AIDS (see also Drug Interactions) ‡ Clinically well on therapy | 1* | 1* | 1* | 1* | Yes |
| Hyperlipidemias | a) Adequately controlled hypertension | 2/3* | 2/3* | 2* | 2* | Yes |
| | b) Elevated blood pressure levels (properly taken measurements) (i) systolic 140-159 or diastolic 90-99 (ii) systolic \geq 160 or diastolic \geq 100‡ | 3* | 3* | 1* | 1* | Yes |
| | c) Vascular disease (Ulcerative colitis, Crohn's disease) Current and history of disease‡ | 4 | 4 | 2 | 2 | Yes |
| | Liver tumors | 2/3* | 2/3* | 2 | 2 | Yes |
| Hypertension | a) Benign | 4 | 4 | 2 | 2 | Yes |
| | i) Focal nodular hyperplasia | 2 | 2 | 2 | 2 | Yes |
| | ii) Hepatocellular adenoma‡ | 4 | 4 | 3 | 3 | Yes |
| | b) Malignant‡ (such as older age, smoking, diabetes and hypertension) | 4 | 4 | 3 | 3 | Yes |
| Malaria | Multiple risk factors for arterial cardiovascular disease | 3/4* | 3/4* | 2* | 2* | Yes |
| | Obesity a) \geq 30 kg/m ² body mass index (BMI) b) Menarche to < 18 years and \geq 30 kg/m ² BMI | 2 | 2 | 1 | 1 | Yes |
| Ovarian cancer‡ | Obesity | 2 | 2 | 1 | 1 | Yes |
| | Parity | 1 | 1 | 1 | 1 | Yes |
| Past ectopic pregnancy | a) Nulliparous | 1 | 1 | 1 | 1 | Yes |
| | b) Parous | 1 | 1 | 1 | 1 | Yes |

Alphabetical Listing of USMEC Contraceptive Eligibility By Disease State

| Condition | Sub-condition | Combined pill, patch, ring | | Progestin-only pill | | Other Contraception Options Indicated for Patient |
|---|--|----------------------------|------------|---------------------|------------|---|
| | | Initiating | Continuing | Initiating | Continuing | |
| Pelvic inflammatory disease | a) Past, (assuming no current risk factors of STIs) | | | | | |
| | (i) with subsequent pregnancy | 1 | | 1 | | Yes |
| | (ii) without subsequent pregnancy | 1 | | 1 | | Yes |
| Peripartum cardiomyopathy‡ | b) Current | 1 | | 1 | | Yes |
| | a) Normal or mildly impaired cardiac function | | | | | |
| | (i) < 6 months | 4 | | 1 | | Yes |
| Postabortion | (ii) ≥ 6 months | 3 | | 1 | | Yes |
| | b) Moderately or severely impaired cardiac function | 4 | | 2 | | Yes |
| | a) First trimester | 1* | | 1* | | Yes |
| Postpartum (see also Breastfeeding) | b) Second trimester | 1* | | 1* | | Yes |
| | c) Immediately post-septic abortion | 1* | | 1* | | Yes |
| | a) < 21 days | 4 | | 1 | | Yes |
| Postpartum (in breastfeeding or non-breastfeeding women, including post-cesarean section) | b) 21 days to 42 days | | | | | |
| | (i) with other risk factors for VTE | 3* | | 1 | | Yes |
| | (ii) without other risk factors for VTE | 2 | | 1 | | Yes |
| Pregnancy | c) ≥ 42 days | 1 | | 1 | | Yes |
| | a) < 10 minutes after delivery of the placenta | | | | | |
| | b) 10 minutes after delivery of the placenta to < 4 weeks | | | | | |
| Rheumatoid arthritis | d) Puerperal sepsis | | | | | |
| Schistosomiasis | | NA* | | NA* | | NA* |
| | a) On immunosuppressive therapy | 2 | | 1 | | Yes |
| Severe dysmenorrhea | b) Not on immunosuppressive therapy | 2 | | 1 | | Yes |
| | a) Uncomplicated | 1 | | 1 | | Yes |
| Sexually transmitted infections (STIs) | b) Fibrosis of the liver‡ | 1 | | 1 | | Yes |
| | a) Current purulent cervicitis or chlamydial infection or gonorrhea | 1 | | 1 | | Yes |
| Sexually transmitted infections (cont.) | b) Other STIs (excluding HIV and hepatitis) | 1 | | 1 | | Yes |
| | c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis) | 1 | | 1 | | Yes |
| Smoking | d) Increased risk of STIs | 1 | | 1 | | Yes |
| | a) Age < 35 | 2 | | 1 | | Yes |
| Solid organ transplantation‡ | b) Age ≥ 35, < 15 cigarettes/day | 3 | | 1 | | Yes |
| | c) Age ≥ 35, ≥ 15 cigarettes/day | 4 | | 1 | | Yes |
| Stroke‡ | a) Complicated | 4 | | 2 | | Yes |
| | b) Uncomplicated | 2* | | 2 | | Yes |
| Superficial venous thrombosis | History of cerebrovascular accident | 4 | | 2 | 3 | Yes |
| | a) Varicose veins | 1 | | 1 | | Yes |
| Systemic lupus erythematosus‡ | b) Superficial thrombophlebitis | 2 | | 1 | | Yes |
| | a) Positive (or unknown) antiphospholipid antibodies | 4 | | 3 | | Yes |
| Thromboembolic mutations‡ | b) Severe thrombocytopenia | 2 | | 2 | | Yes |
| | c) Immunosuppressive treatment | 2 | | 2 | | Yes |
| | d) None of the above | 2 | | 2 | | Yes |
| | | 4* | | 2* | | Yes |

| Condition | Sub-condition | Combined pill, patch, ring | | Progestin-only pill | | Other Contraception Options Indicated for Patient | |
|--|---|----------------------------|------------|---------------------|------------|---|-----|
| | | Initiating | Continuing | Initiating | Continuing | | |
| Thyroid disorders | Simple goiter/hypothyroid/hypothyroid. | | | 1 | | 1 | Yes |
| | a) Non-pelvic (see also Drug Interactions) | | | 1* | | 1* | Yes |
| Unexplained vaginal bleeding before evaluation | b) Pelvic | | | 1* | | 1* | Yes |
| | (suspicious for serious condition) | | | 2* | | 2* | Yes |
| Uterine fibroids | a) Uncomplicated disease | | | 1 | | 1 | Yes |
| | b) Complicated‡ | | | 4 | | 1 | Yes |
| Vaginal bleeding patterns | a) Irregular pattern without heavy bleeding | | | 1 | | 2 | Yes |
| | b) Heavy or prolonged bleeding | | | 1* | | 2* | Yes |
| Viral hepatitis | a) Acute or flare | | | 3/4* | 2 | 1 | Yes |
| | b) Carrier/Chronic | | | 1 | 1 | 1 | Yes |
| Antiretroviral therapy (All other ARVs are 1 or 2 for all methods) | Fosamprenavir (FPV) | | | 3* | | 2* | Yes |
| | a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine) | | | 3* | | 3* | Yes |
| Antimicrobial therapy | b) Lamotrigine | | | 3* | | 1 | Yes |
| | a) Broad spectrum antibiotics | | | 1 | | 1 | Yes |
| SSRIs | b) Antifungals | | | 1 | | 1 | Yes |
| | c) Antiparasitics | | | 1 | | 1 | Yes |
| | d) Rifampicin or rifabutin therapy | | | 3* | | 3* | Yes |
| St. John's Wort | | | | 1 | | 1 | Yes |
| | | | | 2 | | 2 | Yes |

1 = initiation of contraceptive method; C = continuation of contraceptive method; NA = Not applicable
 * Please see the complete guidance for a clarification to this classification: www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm
 ‡ Condition that exposes a woman to increased risk as a result of unintended pregnancy.

Maryland

, 2020: GOVERNOR HOGAN AUTHORIZES COVID-19 TESTING BY LICENSED PHARMACISTS--SEE GOVERNOR:

Contraception Prescribing

Contraception Training Programs

Please click on the individual program to access the training curriculum

1. OREGON STATE UNIVERSITY COLLEGE OF PHARMACY
COMPREHENSIVE CONTRACEPTIVE EDUCATION &
CERTIFICATION FOR THE MARYLAND PHARMACIST
2. MARYLAND PHARMACISTS ASSOCIATION
3. WEGMAN'S
4. THE UNIVERSITY OF MARYLAND SCHOOL OF PHARMACY DEPARTMENT OF PHARMACY PRACTICE
5. AMERICAN PHARMACISTS ASSOCIATION
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7. TRC HEALTHCARE, HORMONAL CONTRACEPTI

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Contraception Training Program Submission

All training program submissions must be submitted for approval by email or UPS to:

Deena Speights-Napata
Executive Director, Maryland Board of Pharmacy
4201 Patterson Avenue
Baltimore, MD 21215
deena.speights-napata@maryland.gov

Maryland Medicaid Contraception Prescriber Enrollment

Maryland Medicaid Enrollment: Pharmacist Contraception Prescriber Protocol

Effective January 1, 2019, qualified pharmacists and pharmacies may enroll with Maryland Medicaid as a Pharmacist Prescriber provider type. In order for Medicaid to reimburse providers for these services, a pharmacy must take three steps:

- 1) The pharmacy must obtain a new type 2 National Provider Identifier (NPI) through the National Plan and Provider Enumeration System (NPPES) for the location it intends to enroll as a Pharmacist Prescriber. The NPPES website is <https://nppes.cms.hhs.gov>.
- 2) The pharmacy will enroll as a group pharmacist prescriber and need to affiliate with at least one qualified pharmacist in order to submit the application.
- 3) The individual qualified pharmacist must enroll as a Pharmacist Prescriber renderer. Please note: Any individual pharmacist who does not have a type 1 NPI will need to obtain one in order to apply as a Pharmacist Prescriber.

Once enrolled, Pharmacist Prescribers may bill for the patient assessment rendered in order to determine whether to prescribe contraceptives and which contraceptive to prescribe. To be reimbursed for the patient assessment, the Pharmacist Prescriber provider type must bill via a CMS-1500 form. Pharmacies should NOT bill Conduent for the patient assessment.

Pharmacy providers who intend to participate as Pharmacist Prescribers should visit health.maryland.gov/providerinfo for more information about how to enroll and bill for these services.

Please direct any specific questions you may have regarding your participation in Maryland Medicaid as a pharmacist prescriber to MDH.pharmacistenrollment@maryland.gov

Maryland Insurance Administration

To become credentialed as a participating provider for health care services, the pharmacist should contact the carrier and complete the [Uniform Credentialing Form](#), which can be used for any carrier.

Carriers will have their own claims processes, but are required to complete the CMS 1500. The claims submitter must provide a copy of the member's identification card.

For provider complaints or questions relating to credentialing or Chief, L&H Complaints, Maryland Insurance Administration, 200 468-2224.

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PharmacyCE@oregonstate.edu.

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Contraception Prescribing Credentialing for Maryland Pharmacists

[Description](#)[Learning Objectives](#)[Your Instructors](#)[Technology Requirements](#)[Disclosures](#)[Refund Policy](#)

Contraception Prescribing Credentialing for Maryland Pharmacists

THIS EDUCATIONAL ACTIVITY HAS BEEN APPROVED BY THE MARYLAND BOARD OF PHARMACY

In the United States, it is estimated that 49% of pregnancies are unintended¹. Prevention of unwanted pregnancy has been identified as a public health goal in U.S. Department of Health and Human Services' Healthy People 2020 Initiative². The use of oral contraception is a safe and effective strategy for avoiding unwanted pregnancy. However, there are barriers that prevent women desiring contraception from obtaining it, such as knowledge deficits among health care providers and the lack of affordable access³. In 2017 the state of Maryland passed legislation that broadens the scope of pharmacist practice to include hormonal contraceptive prescribing. This regulation broadens access to contraceptive therapy, which in turn will lead to the prevention of unwanted pregnancies.

The University of Maryland School of Pharmacy's Office of Continuing Education has developed a comprehensive pharmacist training program focused on providing pharmacists with the knowledge and skills necessary to provide contraceptive care to women. This educational program will prepare pharmacists to serve as direct providers of contraceptive treatment pursuant to COMAR 10.34.40 and is catered to the specific processes adopted by the Board of Pharmacy and will enable Maryland's pharmacists to prescribe contraceptive treatment according to Maryland's law.

The training program will include modules covering patient assessment, drug selection, and ongoing therapeutic management of patients. The program is designed to provide the knowledge and skills needed to successfully

implement this expansion. This four hour, interactive program is presented as a series of four (4) modules. Each module provides one hour of continuing education credit for a total of 4.0 contact hours of continuing education for pharmacists. At the completion of the full series,



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pharmacists will be eligible to apply to the Board of Pharmacy for a credential to prescribe contraceptive drugs in their practice.

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¹ Finer LB, Zolna MR. Unintended pregnancy in the United States: Incidence and disparities, 2006. *Contraception*. 2011;84:478-485.

² Healthy People 2020 [Internet]. Washington, DC: U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion [cited 7/25/2018]. Available from: [\[https://www.healthypeople.gov/2020/topics-objectives/topic/family-planning\]](https://www.healthypeople.gov/2020/topics-objectives/topic/family-planning)

³ Leeman L. Medical barriers to effective contraception. *Obstet Gynecol Clin North Am* 2007;34:19-29.

Modules (UAN, Contact Hours)

- Hormonal Contraceptive Products (0025-0000-19-002-H01-P, 1.0 CE Contact Hours)
- Assessing Women for Hormonal Contraception (0025-0000-19-003-H01-P, 1.0 CE Contact Hours)
- Communicating About Hormonal Contraceptives (0025-00000-19-004-H01-P, 1.0 CE Contact Hours)
- Pharmacy Practice Operations (0025-0000-19-005-H03-P, 1.0 CE Contact Hours)

Launch Date: 1/1/2019

Expiration Date: 1/1/2021

Course Number: CN#CPCS01

Target Audience: Pharmacists

Instructors:

- Kristine Parbuoni, PharmD, BCPPS, Associate Professor, Department of Pharmacy, Practice and Science and Director of OSCE Programs, University of Maryland School of Pharmacy
- Charmaine Rochester-Eyeguokan, PharmD, CDE, BCPS, BCACP, Professor, Department of Pharmacy, Practice and Science and Associate Director, Clinical Services, P³ eHealth Services, University of Maryland School of Pharmacy
- Katherine Sánchez Vega, PharmD, Clinical Pharmacy Specialist, Women's Health, Veteran Affairs Maryland Health Care System

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More Information

Series Details

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The University of Maryland School of Pharmacy's Office of Continuing Education disseminates educational programming developed by pharmacists and other health care professionals.

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Increasing Access to Hormonal Contraceptive Products

Many states are allowing pharmacists to prescribe hormonal contraceptives to increase and ensure access. This 4-hour online interactive training program will prepare pharmacists to discuss the hormonal contraceptive options available to prescribe, furnish or dispense, in accordance with state laws. This training meets the requirements for most states that currently allow pharmacist-furnished contraception.

Activity Type: Knowledge-based (Module 1); Application-based (Modules 2-4)

Target Audience: Pharmacists in all practice settings

[Learn more and register](#)

Learning objectives

Module 1: Hormonal Contraceptive Products

At the completion of this knowledge-based activity, participants will be able to:

- Describe how hormonal contraceptive products affect phases of the menstrual cycle to inhibit ovulation.
- Differentiate among types of hormonal contraceptive products.
- List non-contraceptive uses of various forms of hormonal contraceptive products.

Module 2: Assessing Women for Hormonal Contraception

At the completion of this application-based activity, participants will be able to:

- Assess whether a woman is an appropriate candidate for hormonal contraceptives.
- Describe features of the currently available forms of hormonal contraception.
- Determine if a woman meets the eligibility criteria for specific methods of hormonal contraception.

Module 3: Communicating About Hormonal Contraceptives

At the completion of this application-based activity, participants will be able to:

- Formulate a plan to educate women on proper use of hormonal contraceptive products.

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- Formulate a plan to educate women on the risks and benefits of hormonal contraceptive products.
- List counseling strategies to reduce risk of sexually transmitted diseases.
- List strategies on how to communicate information with other members of a patient's care team.

Module 4: Pharmacy Practice Operations

At the completion of this application-based activity, participants will be able to:

- Discuss laws and regulations that allow pharmacists to furnish hormonal contraceptives.
- Describe a process to furnish patients with hormonal contraceptives in pharmacy practice.
- Explain how to write a prescription for contraceptive products.
- Document patient care visits related to hormonal contraceptive products.

Accreditation



The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. *Increasing Access to Hormonal Contraceptive Products* is approved for 4 contact hours (0.4 CEUs) of continuing pharmacy education (CPE) credit. The ACPE Universal Activity Numbers (UAN) for this activity are listed below.

- Module 1: Hormonal Contraceptive Products is approved for 1 hour (0.1 CEU) of CPE credit. *ACPE UAN 0202-0000-17-233-H01-P*
- Module 2: Assessing Women for Hormonal Contraception is approved for 1 hours (0.1 CEUs) of CPE credit. *ACPE UAN 0202-0000-17-234-H01-P*
- Module 3: Communicating About Hormonal Contraceptives is approved for 1 hour (0.1 CEUs) of CPE credit. *ACPE UAN 0202-0000-17-235-H04-P*
- Module 4: Pharmacy Practice Operations is approved for 1 hours (0.1 CEUs) of CPE credit. *ACPE UAN 0202-0000-17-236-H04-P*

Program completion requirements

To earn continuing pharmacy education (CPE) credit and/or a Certificate of Completion, participants must meet all the following requirements:

- Complete four self-study modules, each of which consists of a presentation, an assessment, and a module evaluation.
- Achieve a passing grade of 70% or higher on each module assessment.
- Credit must be *claimed* for each module in order to obtain credit.
 - Participants will need to have a valid APhA (pharmacist.com) username and password, as well as a CPE Monitor account to claim credit. After credit has been claimed, please

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OK, I agree

- The Certificate of Completion will be available online upon successful completion of the necessary activity requirements on the participant's **My Training** page.

APhA continuing pharmacy education policy provides you with two opportunities to successfully complete a continuing pharmacy education assessment. Please note that you will not be permitted to submit an assessment a third time. The current policy of the APhA Education Department is not to release the correct answers to any of our CPE tests. This is intended to maintain the integrity of the CPE activity and the assessment.

Release Date: September 1, 2017

Expiration Date: September 1, 2020 - PLEASE NOTE: NO Home Study credit granted after this date

Development and support

Increasing Access to Hormonal Contraceptive Products was developed by the American Pharmacists Association. Copyright © 2017 by the American Pharmacists Association. This activity is supported by an unrestricted educational grant by Merck & Co.

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OK, I agree

Please view the forms we have available for prescribing contraceptions below:

| Maryland Contraception Prescribing Forms | |
|---|-----|
| Maryland Self-Assessment Form | PDF |
| Maryland Summary Form | PDF |
| Maryland Summary Form – Optional Supplement | PDF |
| Algorithm | PDF |
| Contraception Training Notification Form | PDF |
| FY20 Family Planning Sites | PDF |

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Office Location: 4201 Patterson Avenue, Baltimore, Maryland 21215

(410) 764-4755 or (800) 542-4964 (Maryland Only)

(800) 735-2258 TTY for the Deaf

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[No thanks](#)

MARYLAND SELF-SCREENING RISK ASSESSMENT FOR BIRTH CONTROL

THIS FORM SHOULD BE FILLED OUT BY THE PATIENT

Patient Name _____ Date ____/____/____

Patient Address _____ Date of Birth ____/____/____

Name of your Primary Care Provider (PCP) or Reproductive Health Care Provider
 _____ Address _____

When did you last visit a PCP or Reproductive Health Care Provider: Date ____/____/____

Please answer the following questions about your medical history:

| PREGNANCY SCREEN | | | |
|-------------------------|--|------------------------------|-----------------------------|
| 1 | Do you think you might be pregnant now? If you answered YES , please STOP here. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 2 | Did you have a baby in the past 4 weeks? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 3a | Did you have a baby less than 6 months ago? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 3b | Are you fully or nearly-fully breast feeding? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 3c | Have you had a menstrual period since the delivery? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 4 | Did your last menstrual period start within the last 7 days? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 5 | Have you been using a reliable birth control method consistently and correctly? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 6 | Have you abstained from sexual intercourse since your last menstrual period or delivery? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| MEDICAL HISTORY | | | |
| 7 | Did you have a baby in the past 21 days? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 8 | Did you have a baby in the past 6 weeks? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 9 | Have you ever had surgery? If so, list the date of your most recent procedure? | ____/____/____ | |
| 10 | Have you ever had a blood clot in the arms, legs, lungs or other parts of the body? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 11 | Have you ever been told by your PCP that you are at risk of having a blood clot? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 12 | Do you have high blood pressure? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 13a | Do you have diabetes? If you answered NO , skip to question 14. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 13b | Have you had diabetes for more than 20 years? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 13c | Are you using insulin? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 13d | Do you have damage to your eyes, nerves of the feet, hands, kidneys or any other organ from diabetes? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 14 | Do you have high cholesterol? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 15 | Have you ever had a heart attack or stroke, or been told you had heart disease? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 16a | Do you use any form of tobacco, e.g. vape e-cigarette, e-hookah, or e-liquid; chew tobacco, dip snuff, or smoke cigarettes? If you answered NO , skip to question 17. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 16b | If you answered YES , how often do you use any form of tobacco? | _____ | |
| 16c | How much tobacco do you use in a day? | _____ | |
| 17 | Do you ever have headaches that start with flashes of light, blind spots, or tingling in your hands or face, that comes and goes away before the headache starts? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

PLEASE TURN OVER

| | | | |
|---------------------------|---|------------------------------|-----------------------------|
| 18 | Have you had a recent change in vaginal bleeding that worries you? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 19 | Have you had stomach reduction or weight loss surgery? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 20 | Do you have, or have you ever had breast cancer? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 21 | Have you had a heart, liver, kidney, lung, or other organ transplant? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 22 | Do you have lupus? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 23 | Have you ever had hepatitis, liver disease, liver cancer, gall bladder disease, or jaundice (yellow skin/eyes)? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 24 | Do you have or have you ever had any other medical conditions that we have not discussed? Please list them here: _____ | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| MEDICATION HISTORY | | | |
| 25 | Do you take any medications or supplements? Please list them here: _____ | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 26 | Have you had any allergies or bad reactions to any medication you have taken? Please list them here: _____ | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 27 | Have you ever been told by a health care provider not to take birth control pills, patch, vaginal ring, injection, implant, diaphragm, intrauterine device (IUD) or coil or any other? _____ | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 28 | Have you ever used birth control in the past? If YES, circle the type you have used: birth control pills, patch, vaginal ring, injection, implant, diaphragm, IUD or coil, or any other? _____ | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 29 | When did you last use birth control pills, patch, vaginal ring, injection, implant, diaphragm, IUD or coil, or any other? _____ | ___/___/___ | |
| 30 | Is there a type of birth control that you would like to use? If YES, circle your response: birth control pills, patch, vaginal ring, injection, implant, diaphragm, IUD or coil, or any other? _____ | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 31 | Have you taken emergency contraception in the last 5 days? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

| | | | |
|-------------------------------------|------------|-------|-------------|
| Pharmacist Internal Use Only | | | |
| Blood Pressure Reading | _____ mmHg | Pulse | _____ b/min |
| Weight | _____ lbs | | |
| Pharmacist Name | _____ | | |
| Phone | _____ | | |
| Pharmacy Name | _____ | | |
| Address | _____ | | |
| Notes | _____ | | |
| | _____ | | |

MARYLAND VISIT SUMMARY FORM

This side must be completed if birth control is prescribed

Patient Name _____ Date ____/____/____

Today you were prescribed the following birth control:

Medication Name _____

Dosage _____ Number of Refills _____

- **Your Pharmacist can answer questions about this birth control. Your Pharmacist is:**

Pharmacist Name _____

Phone _____

Pharmacy Name and Address _____

- **Review this information with your Primary Care Provider (PCP) or Reproductive Health Care Provider. A visit with a Primary Care Provider or Reproductive Health Care Provider is recommended to obtain the recommended tests and screening.**
- **If you do not have a Primary Care Provider or Reproductive Health Care Provider, please consult your Pharmacist for a referral.**
- **Patient: please sign below to indicate that**
 - You understand the information provided.
 - You have received a copy of this visit summary.

Patient Signature

Pharmacist Signature

MARYLAND VISIT SUMMARY FORM

This side must be completed if birth control is not prescribed

Patient Name _____ Date ____/____/____

Today the Pharmacist could not prescribe birth control due to one or more health concerns.

- Your blood pressure was above 140/90 mmHg. Today ____/____ mmHg
- You take medications or supplements that may interfere with birth control.
- You have a condition that may interfere with the safe use of birth control.
- You may be pregnant.
- Other: _____

• **Your Pharmacist can answer questions about this visit. Your Pharmacist is:**

Pharmacist Name _____

Phone _____

Pharmacy Name and Address _____

- **You may still be eligible for prescription birth control.**
- **Review this information with your Primary Care Provider (PCP) or Reproductive Health Care Provider. A visit with a Primary Care Provider or Reproductive Health Care Provider is recommended to obtain the recommended tests and screenings.**
- **If you do not have a Primary Care Provider or Reproductive Health Provider, please consult your Pharmacist for a referral.**
 - Most women should have a reproductive health review each year.
- **Patient: please sign below to indicate that**
 - You understand the information provided.
 - You have received a copy of this visit summary.

Patient Signature

Pharmacist Signature

OPTIONAL SUPPLEMENT TO MARYLAND VISIT SUMMARY FORM

ATTENTION PATIENT: PLEASE REFER TO THIS SIDE IF YOU WERE PRESCRIBED BIRTH CONTROL. PLEASE ASK YOUR PHARMACIST IF YOU HAVE ANY QUESTIONS ABOUT THE INFORMATION CONTAINED ON THIS FORM OR YOUR VISIT SUMMARY FORM.

Your Prescribing Pharmacist is:

Name: _____

Phone: _____

- **A visit with your Primary Care Provider or Reproductive Healthcare Provider is recommended to review this prescription and to obtain any recommended tests and screenings. Most women should have a reproductive health review once a year.**

- **If you do NOT have a Primary Care or Reproductive Health Provider, please consult your pharmacist for a referral. A visit with a Primary Care Provider or Reproductive Health Care Provider is recommended to obtain the recommended tests and screenings.**
 - Your pharmacist can provide you with a list of Reproductive Healthcare Providers in your area.

- **Your Pharmacist may have counseled you on the following:**
 - When to start and continue birth control
 - Why it is important for you to take the medication as prescribed
 - What to do if you miss a dose, such as using a backup protection method
 - When to follow up with your health care providers
 - What to do if you experience side effects of the medication
 - Warning signs to look out for, such as shortness of breath, chest pain, or blood clots
 - When to call 911, call your doctor, or go to the emergency room
 - How to practice safe sex to protect yourself from getting a sexually transmitted disease
 - Which health screenings are important for you
 - Other _____
 - **PLEASE CONSULT YOUR PHARMACIST IF YOU HAVE ANY QUESTIONS REGARDING THESE ISSUES.**

- **Patient Checklist:**
 - I understand the information provided.
 - I have received a visit summary.

OPTIONAL SUPPLEMENT TO MARYLAND VISIT SUMMARY FORM

ATTENTION PATIENT: PLEASE REFER TO THIS SIDE IF YOU WERE NOT PRESCRIBED BIRTH CONTROL. PLEASE ASK YOUR PHARMACIST IF YOU HAVE ANY QUESTIONS ABOUT THE INFORMATION CONTAINED ON THIS FORM OR YOUR VISIT SUMMARY FORM.

Your Prescribing Pharmacist is:

Name: _____

Phone: _____

- **Prescription birth control may still be an option for you.**
 - The pharmacist is referring you to a healthcare provider.
 - Your healthcare provider will discuss your options with you.

- **A visit with your Primary Care Provider or Reproductive Healthcare Provider is recommended to review the information that has been provided to you today and to obtain any recommended tests and screenings.**

- **If you do NOT have a Primary Care Provider, please tell your pharmacist. It is recommended that you schedule a visit to discuss your prescription and obtain any recommended tests and screenings.**
 - Your pharmacist can provide you with a list of Reproductive Healthcare Providers in your area.

- **Most women should have a reproductive health review once a year.**

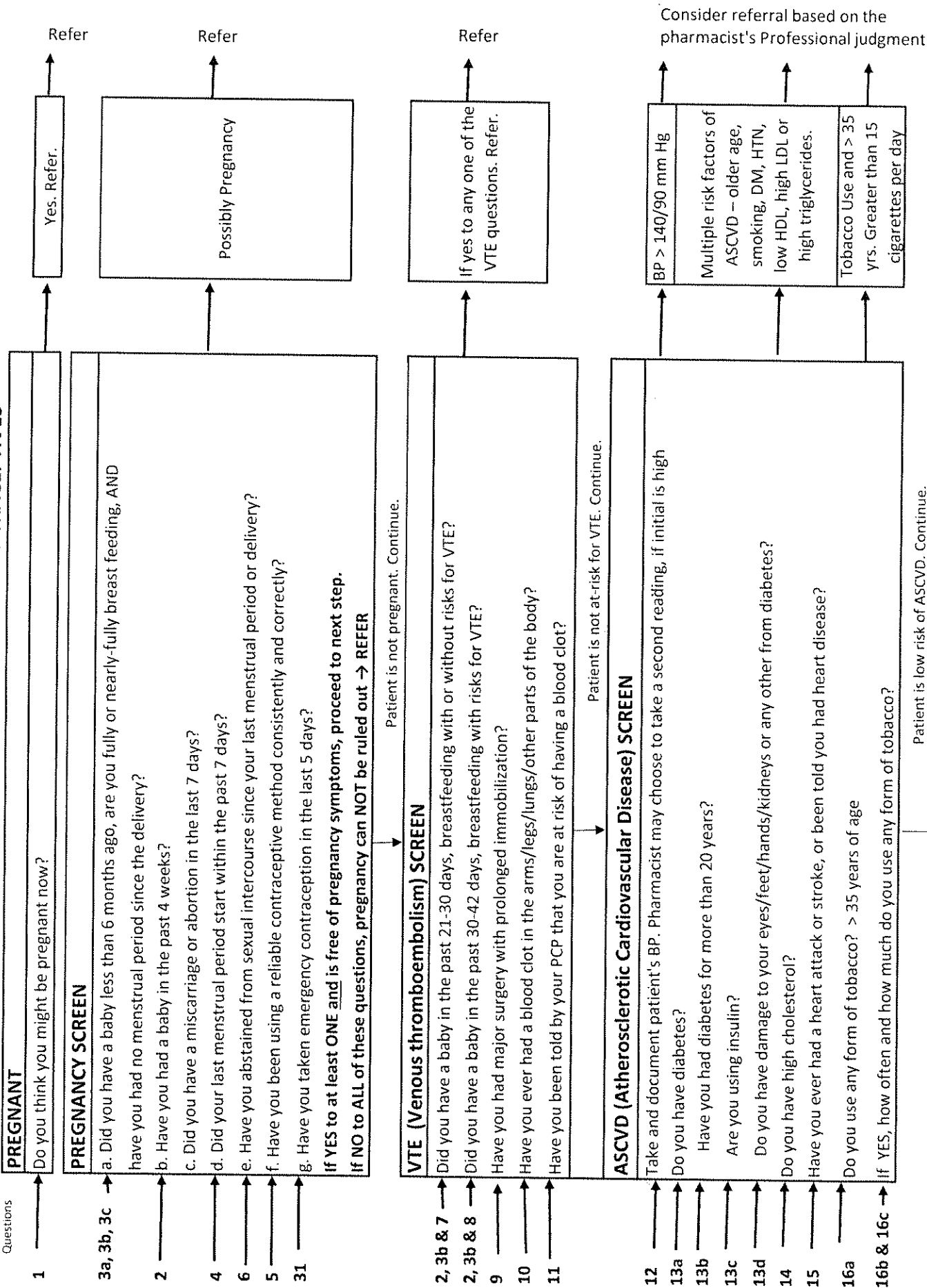
- **Over-the-counter birth control methods are available to you.**
 - Condoms (male or female)
 - Spermicide (gel, foam, cream, films, or suppository)
 - Contraceptive Sponge
 - Other _____

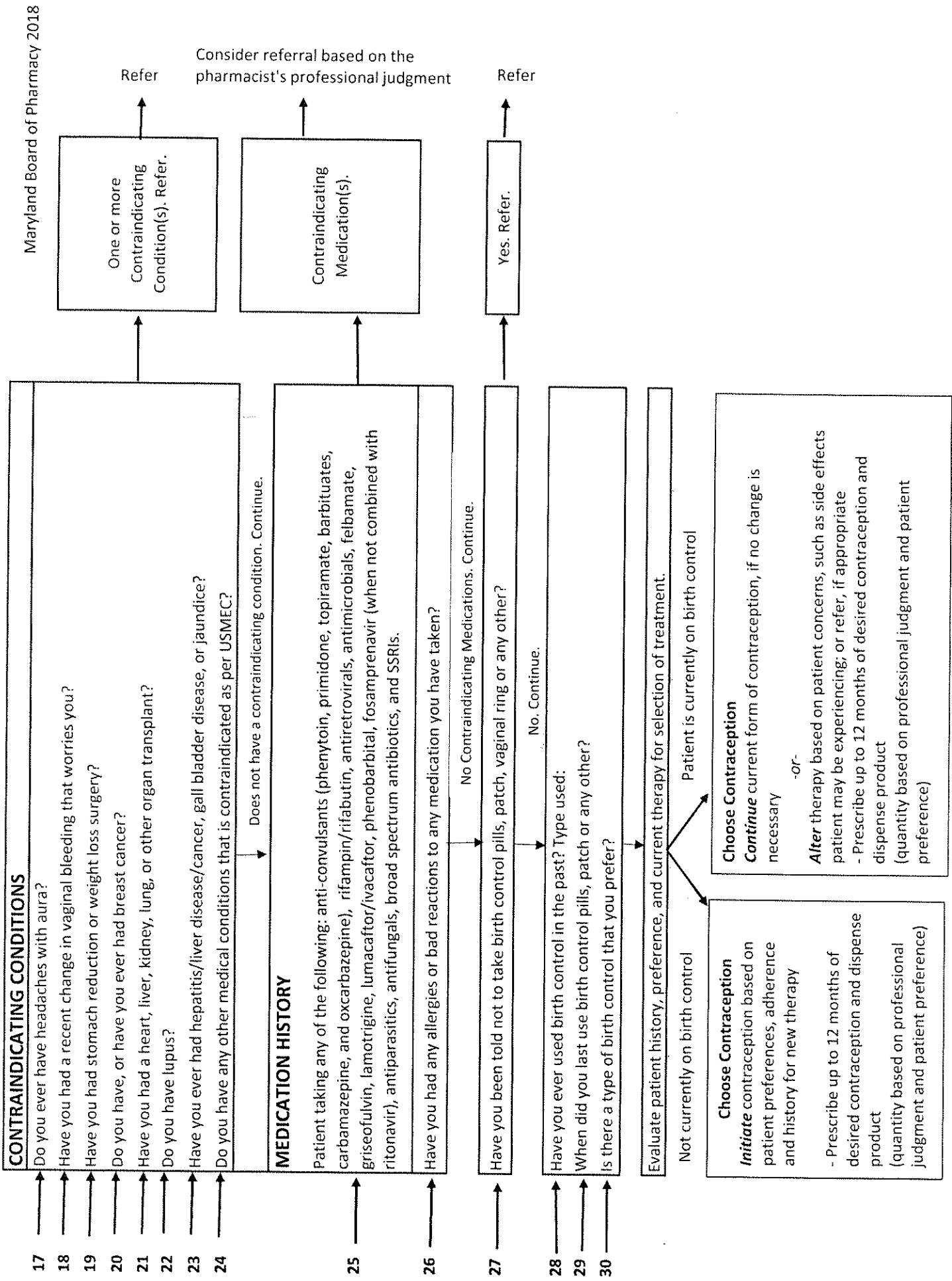
- **The Pharmacist may have counseled you on the following:**
 - How to practice safe sex to protect yourself from getting a sexually transmitted disease
 - Which health screenings are important to you
 - Other _____
 - **PLEASE CONSULT YOUR PHARMACIST IF YOU HAVE ANY QUESTIONS REGARDING THESE ISSUES.**

- **Patient Checklist:**
 - I understand the information provided.
 - I have received a visit summary.

ALGORITHM FOR MARYLAND PHARMACIST PRESCRIBING OF CONTRACEPTIVES

Correlates to the Self-Assessment Questions





Maryland Board of Pharmacy
 4201 Patterson Avenue
 Baltimore MD 21215-2299
 Phone: 410-764-4755
 Fax: 410-358-6207
 www.health.maryland.gov/pharmacy



Pharmacist Contraceptive Training Notification Form

Notification is required for pharmacists who wish to prescribe and dispense contraceptives as set forth under COMAR 10.34.40.

Mail to Maryland Board of Pharmacy, P.O. Box 1991, Baltimore, MD 21203-1991; email to mdh.mdbop@maryland.gov, or fax to 410-358-6207.
 PRINT OR TYPE ONLY

ATTENTION: THIS FORM MUST BE COMPLETED AND RETURNED TO THE BOARD AT LEAST FIFTEEN (15) DAYS BEFORE PRESCRIBING CONTRACEPTIVES (COMAR 10.34.40.03B). APPLICANTS MAY NOT PRESCRIBE CONTRACEPTIVES UNTIL THEY HAVE RECEIVED WRITTEN CONFIRMATION FROM THE BOARD THAT THIS APPLICATION HAS BEEN ACCEPTED (COMAR 10.34.40.03B(3)).

| SECTION 1 – PHARMACIST INFORMATION | | | | |
|------------------------------------|--------|--------------------------|------|--|
| Name: | | | | |
| Maryland License #: | | License Expiration Date: | | |
| Street Address: | | | | |
| City: | State: | | Zip: | |
| Home Phone: | | | | |
| Work Phone: | | | | |
| Email Address: | | | | |

| BOARD-APPROVED TRAINING PROGRAM | DATE OF COMPLETION |
|--|--------------------|
| Board-Approved Training Program Completed: | |

(PLEASE ATTACH A COPY OF PROGRAM COMPLETION NOTIFICATION)

OR

- I have undergone training for prescribing contraceptives as part of my formal pharmacy educational program and am thus exempt from the training program requirement pursuant to COMAR 10.34.40.03B(2)(a).

| | |
|--|--|
| I certify that the above information is true, correct, and complete; and if such approval is granted, I agree to abide by the laws surrounding pharmacists prescribing contraceptives in the State of Maryland, all civil and criminal laws, as well as the rules and regulations promulgated by the Maryland Board of Pharmacy. By signing this notification form, I understand that any violation of these laws, rules or regulations may constitute grounds for revoking this approval to prescribe and dispense contraceptives in the State of Maryland. | |
| Signature: | |
| Date: | |

Popular Links

Adopted Regulations

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Regulation Forms (MDH Employees Only)

PROPOSAL

Maryland Register

Issue Date: February 16, 2018

Volume 45 • Issue 4 • Pages 212—213

Title 10 MARYLAND DEPARTMENT OF HEALTH Subtitle 34 BOARD OF PHARMACY

10.34.40 Pharmacists Prescribing Contraceptives

Authority: Health Occupations Article, §§12-101, 12-102(b), 12-205(a), and 12-511, Annotated Code of Maryland

Notice of Proposed Action

[18-042-P]

The Secretary of Health proposes to adopt new Regulations .01—.06 under a new chapter, **COMAR 10.34.40 Pharmacists Prescribing Contraceptives**. This action was considered by the Board of Pharmacy at an open meeting held on October 18, 2017, notice of which was given by publication on the Board's website, <http://health.maryland.gov/pharmacy/Pages/index.aspx>, from September 21, 2017 — October 18, 2017, pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to authorize a pharmacist who meets the requirements of State Board of Pharmacy regulations to prescribe and dispense specified contraceptives.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Maryland Department of Health, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499 (TTY 800-735-2258), or email to mdh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through March 19, 2018. A public hearing has not been scheduled.

.01 Scope.

This chapter does not limit or otherwise affect the right of an individual to practice pharmacy or any other health occupation that the individual is authorized to practice.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

- (1) "Board" means the Maryland Board of Pharmacy.
- (2) "Contraceptives" means contraceptive medications and self-administered contraceptive devices approved by the U.S. Food and Drug Administration.
- (3) "Pharmacist" means an individual who practices pharmacy under the Health Occupations Article, §12-101, Annotated Code of Maryland.
- (4) "Pharmacy" means an establishment holding a permit under Health Occupations Article, §12-401, Annotated Code of Maryland.
- (5) "Practicing pharmacy" has the same meaning stated in Health Occupations Article, §12-101(x), Annotated Code of Maryland.
- (6) "Primary care practitioner" means a licensed health care practitioner who:
 - (a) Provides an individual's primary care services; and
 - (b) Is the primary coordinator of health care services for the individual.
- (7) "Reproductive health care practitioner" means a licensed health care practitioner who provides an individual's reproductive health services.
- (8) "Visit summary" means:
 - (a) A written record of either the contraceptives dispensed or a brief explanation as to why contraceptives were not prescribed;
 - (b) Written information about the importance of seeing the patient's primary care practitioner or reproductive health care practitioner to obtain recommended tests and screenings; and
 - (c) A copy of the patient's completed Self-Screening Risk Assessment Questionnaire.

.03 Requirements to Prescribe Contraceptives.

A. Board Responsibilities. The Board shall develop and adopt the following items, in consultation with stakeholders to be determined by the Board:

- (1) A self-screening risk assessment questionnaire that a patient shall complete before a pharmacist may prescribe contraceptives for a patient;
- (2) A standard procedure contraceptive algorithm which the pharmacist shall use to perform a patient assessment for purposes of determining:
 - (a) Whether to prescribe contraceptives; and
 - (b) Which contraceptive options to prescribe;
- (3) A notification form to be submitted by a pharmacist before prescribing contraceptives; and
- (4) Other forms and procedures for:
 - (a) The prescription of contraceptives; and
 - (b) Referral to a primary care or reproductive health care practitioner for treatment.

B. Notification.

- (1) Except as provided in §B(2) of this regulation, at least 15 days before prescribing contraceptives, a pharmacist shall submit to the Board a notification form, which includes an attestation of completion of a Board-approved training program.
- (2) A pharmacist who has undergone training for prescribing contraceptives as part of the pharmacist's formal educational program:
 - (a) Is exempt from completing a Board-approved training program; and

(b) At least 15 days before prescribing contraceptives, shall submit to the Board a notification form, which includes an attestation of the pharmacist's formal education program.

(3) A pharmacist may not prescribe contraceptives until the pharmacist receives a written confirmation from the Board accepting the pharmacist's notification form.

C. Pharmacist Responsibilities.

(1) For each new patient requesting contraceptive services, and at a minimum of every 12 months for each returning patient, a participating pharmacist shall:

(a) Obtain the completed Board-approved self-screening risk assessment questionnaire from the patient; and

(b) Utilize and follow the Board-approved standard procedure contraceptive algorithm to:

(i) Perform the patient assessment;

(ii) Determine whether to prescribe contraceptives; and

(iii) Determine which contraceptive options to prescribe.

(2) Upon completion of all requirements established by the Board and after review of all relevant information, a pharmacist may prescribe contraceptives, if deemed clinically appropriate.

(3) If contraceptives are prescribed, the pharmacist shall:

(a) Refer the patient:

(i) For additional care to their primary care practitioner or reproductive health care practitioner; or

(ii) If the patient does not have a primary care practitioner or a reproductive health care practitioner, to a family planning provider or a licensed clinician who provides reproductive health care services;

(b) Provide the patient with a visit summary; and

(c) Document the encounter and maintain records pursuant to Regulation .05 of this chapter.

(4) Upon completion of all requirements established by the Board and after review of all relevant information, if the pharmacist does not prescribe contraceptives, the pharmacist will provide a visit summary to the patient which provides the basis for the decision not to prescribe contraceptives.

(5) A pharmacist may not prescribe contraceptives before January 1, 2019.

.04 Training Program Requirements.

At a minimum, a Board-approved training program shall contain the following elements:

A. An overview of contraceptive medications and self-administered contraceptive devices;

B. An overview of the self-screening risk assessment questionnaire;

C. An overview of the standard procedure contraceptive algorithm; and

D. An overview of the U.S. Medical Eligibility Criteria for Contraceptive Use and other Center for Disease Control guidance on contraception.

.05 Record Keeping.

For a minimum of 5 years, a pharmacy whose pharmacists prescribe contraceptives shall maintain documentation, in electronic or other form, which includes:

A. The type of contraceptive prescribed, and dosage, if applicable, or the basis for not prescribing a contraceptive;

B. The name, address, and date of birth of the patient;

C. The name of the pharmacist who prescribed the contraceptive or determined a contraceptive would not be prescribed;

D. The date the contraceptive was prescribed or that the patient was advised that a contraceptive would not be prescribed;

E. A copy of the patient's visit summary;

F. A copy of the patient's self screening risk assessment questionnaire; and

G. The name and address of the:

(1) Patient's primary care practitioner or reproductive health care practitioner, if provided by the patient; or

(2) Family planning provider or licensed clinician who provides reproductive health care services referred by the pharmacist, if the patient does not have a primary care practitioner or reproductive health care practitioner.

.06 Continuing Education Requirement.

A pharmacist who prescribes contraceptives in Maryland shall earn 1 hour of Board-approved continuing pharmaceutical education related to contraception before the pharmacist's license renewal date.

ROBERT R. NEALL
Secretary of Health

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Oregon Board of Pharmacy

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The Oregon Board of Pharmacy serves to promote and protect public health, safety, and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs.

[\(/pharmacy/\)](#) [\(/pharmacy/\)](#)

[home \(/pharmacy/Pages/index.aspx\)](#) [Contraceptive Prescribing](#)

notifications **Protect our Community. MASK UP.**

Contraceptive Prescribing

Oregon Pharmacists Prescribing of Contraceptive Therapy

During the 2015 Legislative Session, House Bill (HB) 2879 passed into law and was signed by Oregon Governor Kate Brown on July 6, 2015. The law was intended to develop standard procedures for the prescribing of hormonal contraceptive patches and oral contraceptives by an Oregon licensed pharmacist, providing timely access to care. To ensure public safety and provide a consistent level of care, a pharmacist may participate upon completion of a Board approved training program. Under the rules, OAR 855-019-0400 through 855-019-0435, a qualified pharmacist may prescribe hormonal contraceptives to a patient pursuant to The Oregon Self-Screening Risk Assessment Questionnaire and Standard Procedures Algorithm.

The Oregon Board of Pharmacy convened a consultative workgroup consisting of representatives from the Oregon Medical Board, the Oregon State Board of Nursing, the Oregon Health Authority and subject matter experts. The workgroup's primary function is to provide advice to the Board related to standard procedures for pharmacist prescribing of hormonal contraceptives, in consideration of guidelines established by the American Congress of Obstetricians and Gynecologists and other evidence-based practice standards. The Board will prepare and provide the forms and materials related to the developed standards.

The Board would like to extend appreciation to all parties involved, who both directly and indirectly worked to develop this program. The Board would like to extend special recognition to the following individuals: Members of the consultative workgroup, subject matter clinicians including but not limited to Dr. Pete Palacio, Dr. Carrie Miles, and Drs. Maria Rodriguez and Alison Edelman as well as the other clinicians of the OHSU Obstetrics and Gynecology Department. Additionally, the Board recognizes the American Congress of Obstetricians and Gynecologists, the US Center for Disease Control, the World Health Organization and Family Health International, FHI360.

Laws & Rules

- ORS 689.689 (https://www.oregonlegislature.gov/bills_laws/ors/ors689.html)(eff. 1/2016)
- Division 019 (OAR 855-019-0400 through 855-019-0435) (https://secure.sos.state.or.us/oard/displayDivisionRules.action;JSESSIONID_OARD=fYcoTN30KnMGbPf9xZb5vZInE_8-NI5kV11n0zI479495115?selectedDivision=3967)
- Division 041 (OAR 855-041-1040(7)) (<https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=250955>)

Contraceptive "Tool Kit" Resources

The Oregon Board of Pharmacy has approved one educational training program related to the prescribing of contraceptives by a pharmacist.

[\(/pharmacy/Documents/FrequentlyAskedQuestions-ContraceptivePrescribing12.2017.pdf\)](#)

[\(/pharmacy/Documents/FrequentlyAskedQuestions-ContraceptivePrescribing12.2017.pdf\)](#)

- (<http://www.oregon.gov>) • [ACPE Educational Training Program \(https://oregon-state-pharmacy-boards.com/\)](https://oregon-state-pharmacy-boards.com/) • [COVID-19 \(/pharmacy/Pages/COVID-19.aspx\)](https://oregon-state-pharmacy-boards.com/COVID-19/) • [ce.catalog.instructure.com/browse/oregon/courses/oregon-contraceptive-education-and-certification](https://oregon-state-pharmacy-boards.com/ce.catalog.instructure.com/browse/oregon/courses/oregon-contraceptive-education-and-certification))
- [Find a Family Planning & County Health Department Clinic \(/pharmacy/Pages/Laws-Rules.aspx\)](https://oregon-state-pharmacy-boards.com/Find-a-Family-Planning-County-Health-Department-Clinic/) • [Laws & Rules \(/pharmacy/Pages/Laws-Rules.aspx\)](https://oregon-state-pharmacy-boards.com/Laws-Rules/) • [Frequently Asked Questions - Contraceptive Prescribing 12.2017.pdf \(/pharmacy/Documents/FrequentlyAskedQuestions-ContraceptivePrescribing12.2017.pdf\)](https://oregon-state-pharmacy-boards.com/Frequently-Asked-Questions-Contraceptive-Prescribing-12-2017.pdf) • [Online REQUIRED Documentation Procedures Algorithm \(/pharmacy/Documents/OregonStandardProceduresAlgorithmforRPhPrescribing12.17.pdf\)](https://oregon-state-pharmacy-boards.com/Online-Required-Documentation-Procedures-Algorithm/) • [Contact Us \(/pharmacy/Pages/Contact-Us.aspx\)](https://oregon-state-pharmacy-boards.com/Contact-Us.aspx)
- **REQUIRED:** Oregon Standard Procedures Algorithm for RPh Prescribing 12.17.pdf (/pharmacy/Documents/OregonStandardProceduresAlgorithmforRPhPrescribing12.17.pdf)
 - **REQUIRED:** DPMA Oregon Standard Procedures Algorithm (/pharmacy/Documents/DMPAOregonStandardProceduresAlgorithmforRPhPrescribing12.17.pdf)
 - **REQUIRED:** Oregon Self-Screening Risk Assessment Questionnaire (/pharmacy/Documents/ORSelf-ScreeningRiskAssessmentQuestionnaire12.17.pdf)
 - Oregon Self-Screening Risk Assessment Questionnaire - Spanish (/pharmacy/Documents/ORSelf-ScreeningRiskAssessmentQuestionnaire_Spanish.pdf)
 - MEC Corresponding to Oregon Questionnaire (/pharmacy/Documents/MECCorrespondingToORQuestionnaire1.18.pdf)
 - MMWR - US Medical Eligibility Criteria for Contraceptive Use - 2016 (/pharmacy/Documents/MMWRr2016.pdf)
 - Visit Summary Template (/pharmacy/Documents/VisitSummaryTemplate.pdf)
 - Visit Summary Template - Spanish (/pharmacy/Documents/VisitSummaryTemplate_Spanish.pdf)
 - Find a Family Planning & County Health Department Clinic (/oha/PH/HEALTHYPEOPLEFAMILIES/REPRODUCTIVEXUALHEALTH/OREGONCONTRACEPTIVECARE/Pages/wheredoig)
 - OHA Reproductive Health Education Materials (/oha/ph/HealthyPeopleFamilies/ReproductiveSexualHealth/HealthEducation/Pages/Provider-Health-Education-Materials-to-Order-for-Clients.aspx)
 - CDC Preconception (<https://www.cdc.gov/preconception/index.html>)
 - CDC U.S. Selected Practice Recommendations (<https://www.cdc.gov/preconception/index.html>)
 - ACOG Well-Woman Recommendations (<https://www.acog.org/About-ACOG/ACOG-Departments/Annual-Womens-Health-Care/Well-Woman-Recommendations>)
 - Contraceptive Choice Center (<https://contraceptivechoice.wustl.edu/>)
 - Birth Control Pharmacies.com (<https://www.birthcontrolpharmacies.com/>)
 - Effectiveness of Family Planning Methods (/pharmacy/Documents/family-planning-methods-2014.pdf)
 - JCCP Pharmacist's Patient Care Process (/pharmacy/Documents/JCCP_Pharmacists_Patient_Care_Process.pdf)
 - Empathy & Emotional Intelligence (<https://www.6seconds.org/>)
 - Successful Implementation of Patient Assessment and Proper Billing - Education Course (<https://oregon-state-pharmacy-boards.com/ce.catalog.instructure.com/browse/oregon/courses/patient-assessment-and-proper-billing>)
 - OSPA Informational - NPI/Taxonomy (/pharmacy/Documents/OSPACountdown_January%202.pdf)
- (/pharmacy/Documents/OSPACountdown_January%202.pdf)

Additional Resources

- Expedited Partner Therapy for STDs - Protocol for Healthcare Providers in Oregon (/pharmacy/Documents/EPTProtocolSTD.pdf)
- Workgroup Committee Meeting Agendas & Minutes (/pharmacy/Documents/ContraceptiveRACAgendas_Minutes.pdf)

Questions?

Email all prescribing related inquiries to pharmacy.board@oregon.gov (<mailto:pharmacy.board@oregon.gov>)
(/pharmacy/Documents/EPTProtocolSTD.pdf)

Help us improve! Was this page helpful?

| | |
|-----|----|
| Yes | No |
|-----|----|

Oregon law regarding contraception

689.689 Prescription and administration or dispensation of certain contraceptives; rules; insurance coverage.

(1) In accordance with rules adopted by the State Board of Pharmacy under ORS 689.205, a pharmacist may prescribe and administer injectable hormonal contraceptives and prescribe and dispense self-administered hormonal contraceptives.

(2)(a) The board shall adopt rules to establish, in consultation with the Oregon Medical Board, the Oregon State Board of Nursing and the Oregon Health Authority, and in consideration of guidelines established by the American College of Obstetricians and Gynecologists or its successor organization, standard procedures for the prescribing of injectable hormonal contraceptives and self-administered hormonal contraceptives by pharmacists.

(b) The rules adopted under this subsection must require a pharmacist to:

(A) Complete a training program approved by the State Board of Pharmacy that is related to prescribing injectable hormonal contraceptives and self-administered hormonal contraceptives;

(B) Provide a self-screening risk assessment tool that the patient must use prior to the pharmacist's prescribing the injectable hormonal contraceptive or self-administered hormonal contraceptive;

(C) Refer the patient to the patient's primary care practitioner or women's health care practitioner upon prescribing and administering the injectable hormonal contraceptive or prescribing and dispensing the self-administered hormonal contraceptive;

(D) Provide the patient with a written record of the injectable hormonal contraceptive prescribed and administered or the self-administered hormonal contraceptive prescribed and dispensed and advise the patient to consult with a primary care practitioner or women's health care practitioner; and

(E) Administer the injectable hormonal contraceptive or dispense the self-administered hormonal contraceptive to the patient as soon as practicable after the pharmacist issues the prescription.

(c) The rules adopted under this subsection must prohibit a pharmacist from:

(A) Requiring a patient to schedule an appointment with the pharmacist for the prescribing or administering of an injectable hormonal contraceptive or the prescribing or dispensing of a self-administered hormonal contraceptive; and

(B) Prescribing and administering an injectable hormonal contraceptive or prescribing and dispensing a self-administered hormonal contraceptive to a patient who does not have evidence of a clinical visit for women's health within the three years immediately following the initial prescription and administration of an injectable hormonal contraceptive or the initial prescription and dispensation of a self-administered hormonal contraceptive by a pharmacist to the patient.

(3) All state and federal laws governing insurance coverage of contraceptive drugs, devices, products and services apply to injectable hormonal contraceptives and self-administered hormonal contraceptives prescribed by a pharmacist under this section. [Formerly 689.683; 2019 c.13 §§65,66]

689.690 [1975 c.686 §6; repealed by 1979 c.777 §59]

Oregon Regulations on Contraceptives

855-019-0400

Contraceptives - Purpose

The purpose of rules OAR 855-019-0400 through 855-019-0435, is to develop standard procedures for the prescribing of injectable hormonal contraceptives and self-administered hormonal contraceptives by an Oregon licensed pharmacist, providing timely access to care. To ensure public safety and provide a consistent level of care, a pharmacist may participate upon completion of a Board approved training program. Under the rules of this section, a qualified pharmacist may prescribe hormonal contraceptives to a patient pursuant to a self-screening risk assessment questionnaire and standard procedural algorithm.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.005 & 689.683

History:

BP 9-2017, amend filed 12/22/2017, effective 01/01/2018

BP 1-2016, f. 4-28-16, cert. ef. 5-1-16

BP 7-2015(Temp), f. & cert. ef. 11-6-15 thru 5-3-16

855-019-0405

Contraceptives - Definitions

In OAR 855-019-0400 through 855-019-0435:

- (1) "Clinical visit" means a consultation with a healthcare provider, other than a pharmacist, for women's health, which should address contraception and age-appropriate screening.
- (2) "Injectable hormonal contraceptive" means a drug composed of a hormone or a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that a health care practitioner administers to the patient by injection.
- (3) "Self-administered hormonal contraceptive" means a drug composed of a hormone or a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that the patient to whom the drug is prescribed may administer to oneself.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.005 & 689.683

History:

BP 9-2017, amend filed 12/22/2017, effective 01/01/2018

BP 1-2016, f. 4-28-16, cert. ef. 5-1-16

BP 7-2015(Temp), f. & cert. ef. 11-6-15 thru 5-3-16

855-019-0410

Prescriptive Practice Consultation

In an effort to clarify, improve, and support appropriate pharmacist prescribing, the Board shall periodically review prescribing standards, practices, and scope in consultation with designated representatives from the Oregon Medical Board, Oregon State Board of Nursing, and Oregon Health Authority. The Board will seek recommendations from these representatives to be considered in conjunction with American Congress of Obstetricians and Gynecologists (ACOG) guidelines and other evidence-based standards, as it seeks to evaluate and improve prescribing practices within pharmacy. To

the extent that developed standards are incorporated into practice, the forms, screening tools, or requisite training materials shall be prepared by the Board in consultation with these designated representatives.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.005 & 689.683

History:

BP 1-2016, f. 4-28-16, cert. ef. 5-1-16

BP 7-2015(Temp), f. & cert. ef. 11-6-15 thru 5-3-16

855-019-0415

Contraceptive - Training Program

(1) Only a pharmacist, who has completed a Board approved Accreditation Council for Pharmacy Education (ACPE) accredited educational training program related to the prescribing of contraceptives by a pharmacist, may prescribe injectable hormonal contraceptives and self-administered hormonal contraceptives for a patient.

(2) A pharmacist must submit a copy of the certificate of completion of training to the Board within 15 days of completion.

(3) A pharmacist must maintain the certificate of completion and make available upon request.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.005 & 689.683

History:

BP 9-2017, amend filed 12/22/2017, effective 01/01/2018

BP 1-2016, f. 4-28-16, cert. ef. 5-1-16

BP 7-2015(Temp), f. & cert. ef. 11-6-15 thru 5-3-16

855-019-0425

Contraceptive - Procedural Mandates

(1) For each new patient requesting contraceptive services and, at a minimum of every twelve months for each returning patient, a participating pharmacist must:

(a) Obtain a completed Oregon Self-Screening Risk Assessment Questionnaire; and

(b) Utilize and follow the Oregon Standard Procedures Algorithm to perform the patient assessment; and

(c) Prescribe, if clinically appropriate, the self-administered or injectable hormonal contraceptive, or refer to a healthcare practitioner; and

(d) Provide the patient with a Visit Summary; and

(e) Advise the patient to consult with a primary care practitioner or women's health care practitioner; and

(f) Document the encounter and maintain records pursuant to OAR 855-019-0435.

(2) If the self-administered hormonal contraceptive is dispensed or the injectable hormonal contraceptive is administered, it must be done as soon as practicable after the pharmacist issues the prescription and shall include any relevant educational materials.

(3) Nothing in this rule shall prohibit the partial filling or transferring of a drug prescribed pursuant to this process, per the request of the patient.

(4) A pharmacy must:

(a) Keep records of the encounter, including but not limited to, the Oregon Self-Screening Risk Assessment Questionnaire for a minimum of five years; and

(b) Keep records of the medication dispensed for a minimum of three years; and

(c) Establish, maintain and enforce written procedures for the provision of care under this section, including, but not limited to:

(A) Providing a workflow process and physical location that maintains confidentiality and is not susceptible to distraction; and

(B) Documentation and recordkeeping.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.005 & 689.683

History:

BP 9-2017, amend filed 12/22/2017, effective 01/01/2018

BP 1-2016, f. 4-28-16, cert. ef. 5-1-16

BP 7-2015(Temp), f. & cert. ef. 11-6-15 thru 5-3-16

855-019-0430

Contraceptive - Prohibited Practices

A pharmacist must not:

(1) Require a patient to schedule an appointment with the pharmacist for the prescribing, administering or dispensing of a hormonal contraceptive;

(2) Continue to prescribe a hormonal contraceptive to a patient beyond three years from the initial prescription without evidence of a clinical visit;

(3) Prescribe in instances that the Oregon Standard Procedures Algorithm requires referral to a provider; and

(4) Prescribe to self or immediate family members.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.005 & 689.683

History:

BP 9-2017, amend filed 12/22/2017, effective 01/01/2018

BP 1-2016, f. 4-28-16, cert. ef. 5-1-16

BP 7-2015(Temp), f. & cert. ef. 11-6-15 thru 5-3-16

855-019-0435

Contraceptive - Records

(1) A pharmacist must document the encounter and the prescription, and maintain records.

(2) A pharmacy must maintain records of the encounter, including but not limited to, the Oregon Self-Screening Risk Assessment Questionnaire for a minimum of five years and maintain records of the medication administered or dispensed for a minimum of three years.

(3) Prescriptions are valid for one year pursuant to OAR 855-041-1125.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.005 & 689.683

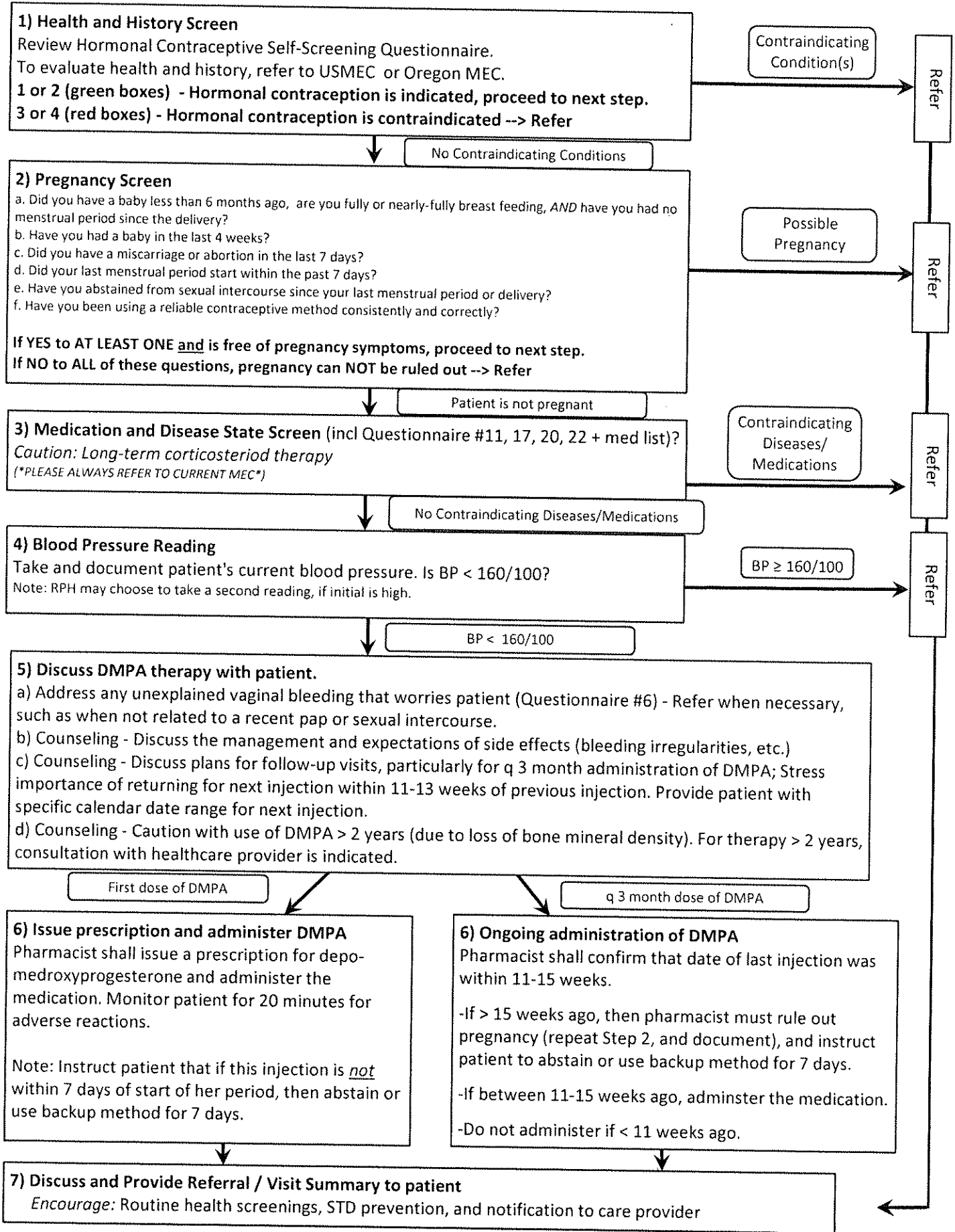
History:

BP 9-2017, amend filed 12/22/2017, effective 01/01/2018

BP 1-2016, f. 4-28-16, cert. ef. 5-1-16

BP 7-2015(Temp), f. & cert. ef. 11-6-15 thru 5-3-16

STANDARD PROCEDURES ALGORITHM FOR PRESCRIBING & ADMINISTERING DEPOT MEDROXYPROGESTERONE ACETATE



Hormonal Contraceptive Self-Screening Questionnaire

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 monthly 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? - If yes, what kind of reaction occurred? | Yes <input type="checkbox"/> No <input type="checkbox"/> _____ |
| | Are you currently using any method of birth control including pills, or a birth control patch, ring or shot/injection? - If yes, which one do you use? | Yes <input type="checkbox"/> No <input type="checkbox"/> _____ |
| 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? 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"/> 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)? - If yes, list them here: | Yes <input type="checkbox"/> No <input type="checkbox"/> _____ |
| 24 | Do you have any other medical problems or take any medications, including herbs or supplements? - If yes, list them here: | Yes <input type="checkbox"/> No <input type="checkbox"/> _____ |

Signature _____ Date _____

Optional Side – May be used by pharmacy

This side of form may be customized by pharmacy –Do not make edits to the Questionnaire (front side)

| Pregnancy Screen | | |
|---|------------------------------|-----------------------------|
| 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 _____

-or-

Patient Referred

Notes:

BOARD OF PHARMACY

**Self-Administered Hormonal Contraception Protocol
for Pharmacists**

Adopt §1746.1 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1746.1 Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception.

(a) A pharmacist furnishing self-administered hormonal contraception pursuant to Section 4052.3 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception

(1) Authority: Section 4052.3(a)(1) of the California Business and Professions Code authorizes a pharmacist to furnish self-administered hormonal contraceptives in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to self-administered hormonal contraception medication and to ensure that the patient receives adequate information to successfully comply with therapy.

(3) Definition of Self-Administered Hormonal Contraception: Hormonal contraception products with the following routes of administration are considered self-administered:

- (A) Oral;
- (B) Transdermal;
- (C) Vaginal;
- (D) Depot Injection.

(4) Procedure: When a patient requests self-administered hormonal contraception, the pharmacist shall complete the following steps:

- (A) Ask the patient to use and complete the self-screening tool;
- (B) Review the self-screening answers and clarify responses if needed;
- (C) Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended;
- (D) Before furnishing self-administered hormonal contraception, the pharmacist shall ensure that the patient is appropriately trained in

administration of the requested or recommended contraceptive medication.

(E) When a self-administered hormonal contraceptive is furnished, the patient shall be provided with appropriate counseling and information on the product furnished, including:

1. Dosage;
2. Effectiveness;
3. Potential side effects;
4. Safety;
5. The importance of receiving recommended preventative health screenings;
6. That self-administered hormonal contraception does not protect against sexually transmitted infections (STIs).

(5) Self-Screening Tool: The pharmacist shall provide the patient with a self-screening tool containing the list of questions specified in this protocol. The patient shall complete the self-screening tool, and the pharmacist shall use the answers to screen for all Category 3 and 4 conditions and characteristics for self-administered hormonal contraception from the current United States Medical Eligibility Criteria for Contraceptive Use (USMEC) developed by the federal Centers for Disease Control and Prevention (CDC). The patient shall complete the self-screening tool annually, or whenever the patient indicates a major health change.

A copy of the most recently completed self-screening tool shall be securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense.

This self-screening tool should be made available in alternate languages for patients whose primary language is not English.

(6) Fact Sheets:

(A) The pharmacist should provide the patient with a copy of a current, consumer-friendly, comprehensive birth control guide such as that created by the Food and Drug Administration (FDA). Examples of appropriate guides are available on the Board of Pharmacy's website.

(B) The pharmacist shall provide the patient with the FDA-required patient product information leaflet included in all self-administered hormonal contraception products, as required by Business and Professions Code Section 4052.3(c). The pharmacist shall answer any questions the patient may have regarding self-administered hormonal contraception.

(C) The pharmacist should provide the patient with a copy of an administration-specific factsheet. Examples of appropriate factsheets are available on the Board of Pharmacy's website.

(7) Follow-Up Care: Upon furnishing a self-administered hormonal contraceptive, or if it is determined that use of a self-administered hormonal contraceptive is not recommended, the pharmacist shall refer the patient for appropriate follow-up care to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics. A patient who is determined not to be an appropriate candidate for self-administered hormonal contraception shall be advised of the potential risk and referred to an appropriate health care provider for further evaluation.

(8) Notifications: The pharmacist shall notify the patient's primary care provider of any drug(s) or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drug(s) or device(s) furnished and advise the patient to consult an appropriate health care professional of the patient's choice.

(9) Referrals and Supplies: If self-administered hormonal contraception services are not immediately available or the pharmacist declines to furnish pursuant to a conscience clause, the pharmacist shall refer the patient to another appropriate health care provider.

The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(10) Product Selection: The pharmacist, in consultation with the patient, may select any hormonal contraceptive listed in the current version of the USMEC for individuals identified as Category 1 or 2, based on the information reported in the self-screening tool and the blood pressure (if recorded by the pharmacist). The USMEC shall be kept current and maintained in the pharmacy or health care facility, and shall be available on the Board of Pharmacy's website.

Generic equivalent products may be furnished.

(11) Documentation: Each self-administered hormonal contraceptive furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. A patient medication record shall be maintained in an automated data processing or manual record mode

such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(12) Training: Prior to furnishing self-administered hormonal contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of a board-approved continuing education program specific to self-administered hormonal contraception, application of the USMEC, and other CDC guidance on contraception. An equivalent, curriculum-based training program completed on or after the year 2014 in an accredited California school of pharmacy is also sufficient training to participate in this protocol.

(13) Patient Privacy: All pharmacists furnishing self-administered hormonal contraception in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that patient confidentiality and privacy are maintained.

(14) Self-Screening Tool Questions

HORMONAL CONTRACEPTION SELF-SCREENING TOOL QUESTIONS

| | | | |
|----|---|------------------------------|-----------------------------|
| 1 | What was the first date of your last menstrual period? | / / | |
| 2a | Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection? (If no, go to question 3) | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 2b | Did you ever experience a bad reaction to using hormonal birth control? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 2c | Are you currently using birth control pills, or a birth control patch, ring, or shot/injection? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 3 | Have you ever been told by a medical professional not to take hormones? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 4 | Do you smoke cigarettes? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 5 | Do you think you might be pregnant now? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 6 | Have you given birth within the past 6 weeks? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 7 | Are you currently breastfeeding an infant who is less than 1 month of age? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 8 | Do you have diabetes? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 9 | Do you get migraine headaches, or headaches so bad that you feel sick to your stomach, you lose the ability to see, it makes it hard to be in light, or it involves numbness? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 10 | Do you have high blood pressure, hypertension, or high cholesterol? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 11 | 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"/> |
| 12 | Have you ever had a blood clot in your leg or in your lung? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 13 | Have you ever been told by a medical professional that you are at a high risk of developing a blood clot in your leg or in your lung? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 14 | Have you had bariatric surgery or stomach reduction surgery? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

| | | | |
|-----|--|------------------------------|-----------------------------|
| 15 | 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"/> |
| 16 | Do you have or have you ever had breast cancer? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 17 | 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"/> |
| 18 | Do you have lupus, rheumatoid arthritis, or any blood disorders? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 19a | Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 19b | If yes, list them here: | | |
| 20a | Do you have any other medical problems or take regular medication? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 20b | If yes, list them here: | | |

Authority: Sections 4005 and 4052.3, Business and Professions Code.

Reference: Sections 733, 4052, 4052.3 and 4103, Business & Professions Code.



New Mexico Regulation and Licensing Department
BOARDS AND COMMISSIONS DIVISION
Board of Pharmacy

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PROTOCOL FOR PHARMACIST PRESCRIPTION OF HORMONAL CONTRACEPTION

I. TITLE

New Mexico Pharmacist prescription of hormonal contraception, as intended to support and pursuant to, New Mexico Board of Pharmacy Regulations.

II. PURPOSE

This protocol will set criteria for properly trained pharmacists to prescribe hormonal contraception directly to eligible patients of New Mexico. This prescriptive authority of pharmacists will increase access to effective contraception. It is expected that increased access may improve contraceptive use and therefore increase individuals' ability to plan and space pregnancies and decrease the high rate of unintended pregnancy in New Mexico.

III. BACKGROUND

1. The Pregnancy Risk Assessment Monitoring Systems (NM PRAMS) is an ongoing project of the New Mexico Department of Health and the National Centers for Disease Control and Prevention (CDC).¹ NM PRAMS samples over 2000 mothers each year and has determined that among NM women with a recent live birth in 2009-2010, just over half (53%) said their pregnancy was intended (wanted at that time or sooner) and the remaining (47%) were unintended (wanted later or never). Pregnancy intention is also associated with family income level, and 44% of women with a household income at 100% of the Federal Poverty Level said their pregnancy was intended while the remaining 56% of women with a household income at 100% of the Federal Poverty Level said their pregnancy was unintended. Among women who were not trying to get pregnant and giving live birth in 2009-2010, almost one-half (48%) said they were using a form of contraception at the time of conception while slightly over one-half (52%) did not report using contraception at the time of

conception. Native American women were less likely to report contraception at conception compared to Hispanic and non-Hispanic White women.¹

2. For more than a decade, the World Health Organization (WHO), has advised that hormonal contraception can safely be provided to women based on a blood pressure measurement and a limited history to determine the presence or absence of risk factors for use of hormones. The same recommendation is now included in the U.S adaptation of the WHO guidance, the U.S. Medical Eligibility Criteria for Contraceptive Use (US MEC) 2010.² This WHO US MEC guidance was specifically intended to apply to the United States. Blood pressure measurement and careful evaluation of a medical history are well within the capabilities of a pharmacist.
3. In 2004, pharmacists and technicians in eight Seattle area pharmacies began collaborating in the Direct Access study to provide hormonal contraception to women without the requirement of a visit to a traditional clinician (Advanced Practice Clinician or Medical Provider).³ The objective of the study was to test the feasibility of pharmacists prescribing hormonal contraception and also to decrease the rate of unintended pregnancies. Outcomes included high satisfaction for women, with 97.7% reporting being satisfied with the experience and 96.8% reporting feeling comfortable with continuing to receive prescriptions for hormonal contraceptives from the pharmacist after study completion. Higher one-year continuation rates of contraception use were observed, with 70% of participants still using the contraception at the 12 month follow-up period versus a continuation rate of 50%, with traditional contraceptive prescription prescribing practices after visit to a traditional clinician (Advanced Practice Clinician or Medical Provider).^{3,4,5}
4. The Oregon State Board of Pharmacy explained that the ability of pharmacist prescribed hormonal contraception, passed into law as of January 1, 2016, will greatly benefit women who live in the more rural areas of Oregon and often times, must wait up to 18 weeks to see a provider. Access to birth control is a major public health concern as a contributor to the risk of unwanted pregnancies in states such as Oregon and New Mexico.⁶ New Mexico covers 121,356 square miles, with a 2014 estimated population of 2,085,572 people – 695,360 people living in rural New Mexico in which the status of health care varies as much as the terrain and people who live here.⁷ There are only 9 public health offices in rural New Mexico, leaving numerous New Mexicans without access to health care or a primary care provider for their health care needs.⁷

IV. GUIDELINES

1. All pharmacists participating in prescriptive authority for hormonal contraception should follow the Board of Pharmacy Protocol as outlined.
2. The service will be available to all patients who are capable of becoming pregnant and wish to use hormonal contraception, as detailed in the formulary section XIII.
3. The hormonal contraceptive prescribed may be written with allowable refills or refills for up to one year, as authorized by the certified prescribing pharmacist.
4. All patients who are capable of becoming pregnant and wish to use hormonal contraception must meet criteria of eligibility based on health history and blood pressure to be eligible for this service as per the US MEC.² Patients not meeting the criteria may not receive hormonal contraception, and must be referred to a primary provider or local clinic for complete evaluation.
5. All patient specific documents must be securely stored electronically or in a locked cabinet in the pharmacy, and HIPAA policies must be followed, as with other pharmacy related materials. These documents will include patient informed consent, screening documents including medical history, medications, and other relevant information.
6. All patients who are capable of becoming pregnant and wish to use hormonal contraception will receive information about the service, information about the contraceptive options available, as detailed in the formulary section XIII, and other patient education materials, as provided in the pharmacist prescriptive authority training course.
7. All patients who are capable of becoming pregnant and wish to use hormonal contraception methods not available, as detailed in the formulary section XIII, must be referred to a primary provider or local clinic.

V. PROCEDURE

When a patient requests contraception at a participating pharmacy, the patient and her pharmacist will assess the need for treatment and/or referral for hormonal contraception care by evaluating the patient's answers to the screening questions. The patient's blood pressure will be measured by the pharmacist and eligibility for the service will be determined. No further physical exams of any kind will be performed by the certified prescribing pharmacist. All patient responses to the screening questions at any time during the pharmacist/patient consultation, must be clearly consistent and confirm that use of hormonal contraception is safe. The pharmacist will refer to the hormonal contraception formulary, as detailed in the formulary section XIII, and as included in the protocol, for the contraceptive choices available. The pharmacist will provide patient information, education, and answer the patient's questions, to assist the patient in choosing the method that is right for them. After evaluation, if the patient is determined to be an eligible candidate, the patient must sign the written informed consent form provided.

VI. SCREENING QUESTIONS

Will be based on the most current version of the US MEC and clearly identified in the pharmacist prescriptive authority training course.²

VII. PHARMACIST MANDATES

1. Training will be done in accordance with the curriculum approved by the New Mexico Board of Pharmacy. The training course will be based on the current recommendations of the World Health Organization, Centers for Disease Control, Office of Population Affairs, American Academy of Family Physicians, American Congress of Obstetricians and Gynecologists, and the Association of Reproductive Health Professionals.
2. Pharmacists with prescriptive authority will document all prescription orders and advise the patient's **primary care provider** within 15 days of the prescription with patient approval as stated in the informed consent.

New Mexico Regulation and Licensing Department
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3. Pharmacists with prescriptive authority will follow this protocol as approved and will have on site access to a copy of the most recent New Mexico Board of Pharmacy approved protocol.
4. Pharmacists with prescriptive authority will maintain patient confidentiality and refer patients who do not meet the pharmacist prescribing criteria to a primary provider or local clinic.
5. Pharmacists with prescriptive authority will maintain patient confidentiality and refer patients wishing to obtain hormonal contraception methods not available, as detailed in the formulary section XIII, to a primary provider or local clinic.
6. Pharmacists with prescriptive authority will maintain active certification and are responsible for 2 hours of live ACPE accredited continuing education credits in the field of hormonal contraception every two years.

VIII. CONTRAINDICATIONS TO HORMONAL CONTRACEPTION

Pharmacists will refer to the screening for eligibility and appropriate selection of contraceptive method(s) guidelines in accordance with the most current version of the US MEC.²

IX. REFERRALS

1. All patients who are capable of becoming pregnant and wish to use hormonal contraception and do not meet the criteria may not receive hormonal contraception and must be referred to a primary provider or local clinic for complete evaluation.
2. All patients who are capable of becoming pregnant and wish to use hormonal contraception methods not available, as detailed in the formulary section XIII, must be referred to a primary provider or local clinic.
3. All patients who are experiencing contraception failures or symptoms of pregnancy or contraception failure will be given a referral to a primary provider or local clinic.
4. All patients experiencing side effects or symptoms, as detailed in the side effect/symptoms section X, and wishes intervention, require referral to a primary provider or local clinic for complete evaluation.

5. All patients experiencing side effects or symptoms, not detailed in the side effect/symptoms section X, require referral to a primary provider or local clinic for complete evaluation.

X. SIDE EFFECTS/SYMPTOMS

1. Symptoms that usually resolve in the first three months of use
 - A. Nausea
 - B. Breast tenderness
 - C. Irregular bleeding or spotting

Patients should be reassured that these symptoms are common and usually resolve and should be encouraged to continue careful use of their contraceptives. If the patient wishes intervention, pharmacists will refer the patient to a primary provider or local clinic for complete evaluation.

Pharmacists will refer to management guidelines in accordance with the most current version of the US MEC for proper management of side effects.²

2. Other symptoms require referral to a primary provider or local clinic.

XI. INFORMED CONSENT

The informed consent form and process will be provided during the pharmacist training course and subsequently updated.

XII. PATIENT EDUCATION

1. The pharmacist will provide all patients interested in this service with appropriate patient education as recognized by the World Health Organization, Centers for Disease Control, Office of Population Affairs, American Academy of Family Physicians, American Congress of Obstetricians and Gynecologists, and the Association of Reproductive Health Professionals.
2. Patients wishing to obtain hormonal contraception methods not available, as detailed in the formulary section XIII, must be referred to a primary provider or local clinic.

3. Patients will also be given information regarding their health care needs and referrals to local providers, including well woman care referrals.
4. Contraception failures or symptoms of pregnancy or contraception failure will be given a referral to a primary provider or local clinic.

XIII. FORMULARY

1. Hormonal contraceptive patch
2. Hormonal vaginal contraceptive ring
3. Oral contraceptives, (combined estrogen and progestin)
4. Oral contraceptives, (progestin only)
5. Depot medroxyprogesterone acetate injection
6. Emergency contraception (excluding intrauterine devices)
7. Other FDA approved hormonal contraception products, with the exclusion of implants, intrauterine devices, or devices requiring surgical training and implantation
8. Other FDA-approved non-hormonal contraceptive methods (includes over-the-counter and prescription medications)

XIV. REQUIRED ONSITE DOCUMENTS

1. Patient informed consent form
2. Pharmacist documentation, including medical history
3. Pharmacist documentation of patient education provided
4. Prescription order
5. Physician notification documentation
6. US MEC guidelines

XV. REFERENCES

1. The New Mexico Pregnancy Risk Assessment Monitoring System (NM PRAMS). New Mexico Department of Health. 2012. <https://nmhealth.org/about/phd/fhb/prams/>.
2. Department of Reproductive Health, WHO. United States Medical Eligibility Criteria for Contraceptive Use (US MEC), Fourth Edition. 2010. <http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usmec.htm>.
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4. Frost JJ, Singh S, Finer LB. U.S women's one-year contraceptive use patterns, 2004. Perspect. Sex Reprod. Health. 2007; 39:48-55.
5. Wells ES, Hutchings J, Gardner JS, et al. Using Pharmacies in Washington State To Expand Access to Emergency Contraception. Family Plan Perspect. November/December 1998 :(30).
6. Gilchrist, A. How Oregon Pharmacists are Prescribing Birth Control. Pharm Times. 2016.
7. Rural Health Information Hub. 2016. <https://www.ruralhealthinfo.org/states/new-mexico>.

Agenda Topic: Develop recommended emergency regulations for board consideration to implement provisions

Included in Agenda Package:

- Oregon Regulations regarding Pharmacist Prescriptive Authority

Action:

Identify and adopt concepts that should be included in the emergency regulations for board consideration.

Chapter 855

Division 20

PHARMACIST PRESCRIPTIVE AUTHORITY

855-020-0110

Prescribing Practices

- (1) A pharmacist located and licensed in Oregon may prescribe and dispense FDA-approved drugs and devices included on either the Formulary or Protocol Compendia, set forth in this Division. A pharmacist shall only prescribe a drug or device consistent with the parameters of the Formulary and Protocol Compendia, and in accordance with federal and state regulations.
- (2) A pharmacist must create, approve, and maintain policies and procedures for prescribing post-diagnostic drugs and devices or providing patient care services via implementation of statewide drug therapy management protocols. The policies and procedures shall describe current and referenced clinical guidelines, and include but not be limited to:
 - (a) Patient inclusion and exclusion criteria;
 - (b) Explicit medical referral criteria;
 - (c) Care plan preparation, implementation, and follow-up;
 - (d) Prescribing drugs and devices pursuant to the formulary and protocol compendia;
 - (e) Patient education; and
 - (f) Provider notification.
- (3) The pharmacist is responsible for recognizing limits of knowledge and experience and for resolving situations beyond his or her pharmacist expertise by consulting with or referring patients to another health care provider.
- (4) For each drug or device the pharmacist prescribes, the pharmacist must:
 - (a) Assess patient and collect subjective and objective information, including the diagnosis for Formulary Compendia items, about the patient's health history and clinical status. The pharmacist's patient assessment shall be performed in a face-to-face, in-person interaction and not through electronic means; and
 - (b) Utilize information obtained in the assessment to evaluate and develop an individualized patient-centered care plan, pursuant to the statewide drug therapy management protocol and policies and procedures; and
 - (c) Implement the care plan, to include appropriate treatment goals, monitoring parameters, and follow-up; and
 - (d) Provide notification, preferably via an interoperable information technology system, to the patient's identified primary care provider or other care providers when applicable, within five business days following the prescribing of a Compendia drug or device.
- (5) The pharmacist shall maintain all records associated with prescribing and other related activities performed for a minimum of 10 years, and a copy must be made available to the patient and provider upon request. Pharmacy records must be retained and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and then may be stored in a secure off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.645 & ORS 689.649

History:

BP 7-2019, amend filed 10/15/2019, effective 10/16/2019

BP 5-2018, adopt filed 10/18/2018, effective 10/18/2018

855-020-0120

Prescribing Prohibited Practices

The responsibility and authority to prescribe pursuant to the Formulary and Protocol Compendia is upon the pharmacist. A pharmacist shall not prescribe a drug or device to self or immediate family members.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.645 & ORS 689.649

History:

BP 5-2018, adopt filed 10/18/2018, effective 10/18/2018

855-020-0200

Formulary Compendium

A pharmacist may prescribe, according to regulations outlined in this Division, an FDA-approved drug and device listed in the following compendium, pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis. The diagnosis must be documented.

Devices and supplies:

- (1) Diabetic blood sugar testing supplies;
- (2) Injection supplies;
- (3) Nebulizers and associated supplies;
- (4) Inhalation spacers;
- (5) Peak flow meters;
- (6) International Normalized Ratio (INR) testing supplies;
- (7) Enteral nutrition supplies; and
- (8) Ostomy products and supplies.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.645 & ORS 689.649

History:

BP 7-2019, amend filed 10/15/2019, effective 10/16/2019

BP 5-2018, adopt filed 10/18/2018, effective 10/18/2018

855-020-0300

Protocol Compendium

A pharmacist may prescribe, via statewide drug therapy management protocol and according to regulations outlined in this Division, an FDA-approved drug and device listed in the following compendium:

- (1) Continuation of therapy
 - (a) A pharmacist may prescribe any non-controlled medication to extend a patient's prescription therapy to avoid interruption of treatment; and
 - (b) In such cases, a pharmacist shall only prescribe a drug quantity sufficient for the circumstances, not to exceed a 60 day supply, and no more than two extensions in a 12 month period per medication.
- (2) Conditions
 - (a) Cough and cold symptom management
 - (A) Pseudoephedrine products for patients 18 years of age and older, verified by positive identification, not to exceed 3.6 grams or a 60 count quantity per prescription, whichever is less, or a total of three prescriptions in a 12 month period. Pharmacist must review PDMP prior to issuing prescription and retain documentation of PDMP review;
 - (B) Benzonatate, for the treatment of cough, not to exceed a 7 day supply;
 - (C) Short-acting beta agonists, not to exceed 1 inhaler with or without a spacer, or 1 box of nebulizer ampules, per year;
 - (D) Intranasal corticosteroids.
- (3) Preventative care
 - (a) Emergency Contraception, not including abortifacients.
 - (b) Male and female condoms.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.645 & ORS 689.649

History:

BP 7-2019, amend filed 10/15/2019, effective 10/16/2019

BP 5-2018, adopt filed 10/18/2018, effective 10/18/2018