COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor **(804) 367-4456 (Tel)**
Henrico, Virginia 23233 **(804) 527-4472(Fax)**

Tentative Agenda of Statewide Protocol Workgroup Meeting

August 17, 2020 Virtual Meeting

9AM

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

TOPIC	PAGES

Call to Order: Ryan Logan, Chairman

- Welcome & Introductions
- Approval of Agenda

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 17, 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

• Adopt minutes from August 4, 2020 workgroup meeting	1-7
• Adopt 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:	
o 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;	8-9
o Epinephrine;	10
o Prenatal vitamins for which a prescription is required;	11
o 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;	12
o 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	13
o Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use	14-38
• Adopt recommended emergency regulations for board consideration to implement provisions	39-41

Adjourn

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

Virginia Board of Pharmacy

Instructions for Accessing August 17, 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 17, 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.
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(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF STATEWIDE PROTOCOLS WORKGROUP TO INITIATE TREATMENT

Tuesday, August 4, 2020
Virtual Meeting

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

CALL TO ORDER:

A virtual Webex meeting of a Statewide Protocol workgroup convened by the Board of Pharmacy was called to order at 9:13 AM. Due to the COVID-19 declared state of emergency and consistent with Amendment 28 to HB29 (Budget Bill for 2018-2020) and the applicable provisions of § 2.2-3708.2 in the Freedom of Information Act, the workgroup convened a virtual meeting to consider such regulatory and business matters as was presented on the agenda necessary for the board to discharge its lawful purposes, duties, and responsibilities.

PRESIDING VIRTUALLY:

Ryan Logan, *RPh, Workgroup Chairman*

WORKGROUP MEMBERS PARTICIPATING VIRTUALLY:

Kristopher Ratliff, *DPh, Chairman, Board of Pharmacy*
Jake Miller, D.O., *Member, Board of Medicine*
Brenda Stokes, M.D., *Member, Board of Medicine*
Emily Yeatts, *VDH, Reproductive Health Supervisor*
Stephanie Wheawill, *PharmD, VDH, Director of Division of Pharmacy Services*

STAFF PARTICIPATING VIRTUALLY:

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*

Due to inclement weather and state offices in the metro-Richmond area being closed this day, all workgroup members and staff listed above participated virtually. No other workgroup members or staff participated virtually or from the Perimeter Center building.

APPROVAL OF AGENDA:
MOTION:

The workgroup voted unanimously to approve the agenda as presented. (motion by Ratliff, seconded by Wheawill)

PUBLIC COMMENT:

As noticed in the agenda, Mr. Logan invited those persons who had requested via email to offer comment prior to 8am on August 4, 2020 to offer public comment to the workgroup.

Clark Barrineau, representing Medical Society of Virginia, thanked everyone for a good legislative session and emphasized that it is critical to keep the requirement for referral to primary care providers in mind during the development of the statewide protocols.

Christina Barrille, Executive Director, Virginia Pharmacists Association (VPhA), shared that it introduced HB1506. She thanked Delegate Sickles, Senator Dunnavant and the Medical Society of Virginia for their assistance with the legislation. She said that VPhA members are excited to offer patients another convenient access to point of care and bridging the gap and referring patients back to physicians in order to provide a better relationship between patients and their medical provider. She offered support to the workgroup.

Jill McCormack, Regional Director of Government Affairs for the National Association of Chain Drug Stores, echoed Ms. Barrille's comments about the work that went into the legislative session. She recommended that the workgroup consider protocols that address generally accepted standards of care vs. specific requirements dictating how pharmacist must provide care to patients. She offered that pharmacists should not be required to complete redundant training that could create barriers. She asked that the counseling requirement for naloxone be made broader allowing pharmacist the flexibility to use the best available and most up to date information for education, instead of a specific brochure. She asked that the workgroup allow access to all possible contraceptive options that may be appropriate given unique circumstances and preferences, and that the workgroup not replicate the 15-day waiting period required of Maryland as this appears arbitrary and creates delays. She requested the protocol for prenatal vitamins replace "evidence based

guidelines" and with a reference to ACOG, WHO, or FDA guidelines.

Jodi Roth, representing the Virginia Association of Chain Drug Stores, echoed comments of Christina Barrille and Jill McCormack.

CHARGE OF WORKGROUP, 2nd Enactment Clause of HB 1506:

Mr. Logan reviewed the charge of the workgroup, and Ms. Juran provided background of HB 1506. It was noted that this workgroup will meet twice to 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 paraphernalia for administering it;
- Epinephrine;
- Injectable or self-administered hormonal contraception provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;
- Prenatal vitamins for which a prescription is required;
- Dietary fluoride supplement, in accordance with the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below recommendation of the US Department of Health and Human Services;
- Medication covered by the patient's health carrier when the patients out-of-pocket cost is lower than out-of-pocket purchase of the over-the-counter equivalent of the same drug.

It was stated the workgroup must also develop recommended emergency regulations for board consideration to implement the provisions.

OVERVIEW OF PHARMACIST EDUCATIONAL/TRAINING STANDARDS:

Dave L. Dixon, PharmD, FACC, FCCP, FNLA, BCPS, BCACP, CDCES, CLS, Associate Professor in Ambulatory Care and Vice Chair of Clinical Services in the Department of Pharmacotherapy and Outcome Science at the Virginia Commonwealth University School of Pharmacy, shared a PowerPoint presentation (Attachment

1) and provided a brief overview of Pharmacy Education and Training Standards. He concluded: detailed dosing guidelines in the statewide protocols are likely unnecessary as dosing for epinephrine, naloxone, prenatal vitamins, fluoride, and OTC medications is standardized and does not change; hormonal contraception dosing is based on symptoms and patient preference, and that additional guidance or training on assessing symptoms and patient preferences may be appropriate; and, that pharmacists regularly dispense and make dosing recommendations for the medications being discussed today, therefore, additional guidance or training is not needed.

REVIEW OF WORKFORCE STATISTICS:

Ms. Juran shared the following statistics from the Draft 2019 Pharmacist Workforce Survey:

- 15,875 pharmacist licensees, 97% of renewing pharmacists responded to the survey;
- 8,734 in Virginia's workforce with 7,137 FTEs;
- Large community pharmacies (>10 locations) most common working establishment, followed by hospital pharmacies and smaller pharmacies;
- Educational attainment continues to increase; 66% in 2019 held pharmacy doctorate with 34% holding baccalaureate;
- 19% completed 1-year residency program; 7% completed 2-year residency program; 10% hold board certification;
- 66% female, median age of 44;
- 528 participate in collaborative practice management agreements involving anticoagulation, diabetes, hypertension, hypercholesterolemia, asthma, tobacco cessation, or travel medications;
- 32% provide immunization services, 29% provide medication management services, and 25% provide compounding services.

RECOMMENDED COMPONENTS OF STATEWIDE PROTOCOL:

The workgroup reviewed the excerpt included in the agenda packet from *PHARMACIST STATEWIDE PROTCOLS: KEY ELEMENTS FOR LEGISLATIVE AND REGULATORY AUTHORITY,* March 2017.

DEVELOPMENT OF RECOMMENDED STATEWIDE PROTOCOLS:

The workgroup discussed the material included in the agenda packet for each drug category.

Naloxone, other opioid antagonist, including paraphernalia

Dr. Stokes questioned if there could be some inclusion criteria put into the guidance similar to Board of Medicine (BOM) co-prescribing requirements. It was noted that certain populations should be excluded from receiving naloxone such as hospice or end of life patients. Staff noted they would refer to the BOM regulations for possible language.

Ms. Juran confirmed that the dispensing of naloxone would be reported to the PMP. Dr. Wheawill commented about the counseling requirement. Ms. Yeatts suggested that the Department of Behavioral Health and Developmental Services be consulted regarding use of the REVIVE! Brochure. Ms. Juran confirmed for Dr. Miller that the pharmacist cannot require the patient to obtain the naloxone.

Epinephrine

Dr. Miller recommended the protocol should allow for prescribing/dispensing epinephrine to children. However, the current statute restricts protocols to 18 years of age and older. Under Patient Inclusion Criteria, it was recommended to insert "or demonstrating signs and symptoms of anaphylaxis" after "at risk for experiencing anaphylaxis". It was suggested to include language on how to identify persons "at risk" such as someone with a dispensing history of obtaining epinephrine or who informs the pharmacist of a history of allergies that could result in anaphylaxis.

Prenatal Vitamins

The workgroup identified that sometimes patients use their OB/GYN as their primary care provider, and offered that the notification should be to the patient's primary care provider and/or OB/GYN. Under Pharmacist Education and Training, Ms. Juran noted that NACDS provided comment suggesting that "evidence based guidelines" be replaced with "guidelines from ACOG, FDA, or WHO". Dr. Stokes recommended leaving as written since the broader language would include these specific guidelines. Staff reported that the referenced statute under Notification of Primary Care Provider in all of the draft protocols should read 54.1-3303.1.

Fluoride Supplements

Ms. Juran shared that the American Dental Association (ADA) does not recommend the use of fluoride supplements to persons over the age of 16. Ms. Yeatts recommended that the protocol should simply read that the ADA does not recommend the use of fluoride supplements in persons 18 years of age and older.

Over-the-Counter Medications

The workgroup had some discussion about the term "equivalent" and if the protocol was intended to capture both OTC drugs and prescription drugs. Suggested examples provided for the protocol included the prescribing of an OTC if the health carrier would cover the expense which may be cheaper than paying out-of-pocket for the OTC drug, and the prescribing of a prescription drug in the same therapeutic class as an OTC drug, e.g., nasal corticorsteroid sprays or antacids, that may be covered by the health carrier and cheaper than paying out-of-pocket for the similar or "equivalent" OTC drug. Mr. Ratliff recommended the protocol also include needles, syringes, and diabetic test strips, because often the prescriber fails to issue a prescription for these accompanying items. There was some discussion regarding whether "medication" included paraphernalia and medical devices.

Hormonal Contraceptives

Ms. Emily Yeatts and Dr. Stokes indicated they liked Colorado's protocol, algorithm, and color-coded questionnaire the best of the options provided in the agenda packet. Both recommended that the protocol should include emergency contraception. Ms. Emily Yeatts recommended inserting "vaping" in the questionnaire and including a question about use of emergency contraception in the last five days. For depot medroxyprogesterone acetate, it was recommended to look at Oregon or California's algorithm. There was discussion that pharmacists should be required to obtain ACPE-accredited training through continuing education as was recommended by Dr. Dixon from VCU. It was noted that several states appear to recognize a 4-hour online ACPE-accredited program. Staff indicated they would work on preparing a draft protocol for the next meeting.

Regulations

There was discussion that the regulations should include a recordkeeping requirement. Ms. Elaine Yeatts recommended looking at the Board of Medicine's requirements of six years. There was consensus that six years would not be overly burdensome.

ADJOURNED:

With all business concluded, the workgroup adjourned the meeting at 12:33 pm.

Ryan Logan, Chair

Date

Caroline Juran, Executive Director

Date

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 knowledgable 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 or other opioid antagonist approved by the FDA for overdose reversal under this protocol:

- An individual, 18 years of age or older, experiencing or at risk of experiencing an opioid-related overdose, e.g., patient has a history of prior overdose, substance misuse, a morphine milligram equivalency of 120MME/day, or is currently prescribed an opioid with a concomitant benzodiazepine present;
- 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.

PATIENT EXCLUSION CRITERIA

Patients NOT eligible for naloxone or other opioid antagonist approved by the FDA for overdose reversal under this protocol:

- An individual less than 18 years of age or older;
- An individual receiving treatment of acute or chronic pain related to (i) cancer, (ii) sickle cell, (iii) a patient in hospice care, (iv) a patient in palliative care, (v) a patient enrolled in a clinical trial as authorized by state or federal law.

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 Regulation 18VAC110-21-46.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303.1, 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.

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 knowledgable 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, demonstrating signs and symptoms of anaphylaxis or at risk for experiencing anaphylaxis, e.g., patients reporting having previously been prescribed epinephrine for treatment of possible anaphylaxis or reporting a diagnosis of allergies that may result in anaphylaxis.

COUNSELING

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

RECORDKEEPING

The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303.1, 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.

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 knowledgable 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 Regulation 18VAC110-21-46.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303.1, 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.

VIRGINIA BOARD OF PHARMACY

Pharmacist Dietary Fluoride Supplement Statewide Protocol

The American Dental Association does not recommend the prescribing of dietary fluoride supplements for persons 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, therefore pharmacists are not currently authorized to initiate treatment with, dispense, or administer dietary fluoride supplements under a pharmacist statewide protocol.

VIRGINIA BOARD OF PHARMACY

Pharmacist ~~Over-the-Counter Drug~~ Statewide Protocol to Lower Out-of Pocket Expense

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 knowledgable 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 over-the-counter medication is covered by the patient's health carrier and when the patient's out-of-pocket cost for the prescribed drug is lower than the out-of-pocket cost to purchase ~~an over-the-counter equivalent of~~ the same drug over-the-counter;
- An individual, 18 years of age or older, whose over-the-counter medication would cost more out-of-pocket than a prescribed prescription-only medication that is in the same therapeutic category as the over-the-counter medication.

RECORDKEEPING

The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303.1, 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 packet:

- Draft *Pharmacist Hormonal Contraceptive Statewide Protocol* based on Colorado
- Draft *Virginia Hormonal Contraceptive Self-Screening Questionnaire* based on Colorado
- Draft *Summary Chart of US Medical Eligibility Criteria for Contraceptive Use* based on Colorado
- Draft *Standard Procedures Algorithm for Va Pharmacist Prescribing of Contraceptives* based on Colorado
- Draft *Standard Procedures Algorithm for Va Pharmacist Prescribing & Administering Depot Medroxyprogesterone Acetate (DMPA)* based on Oregon

- Draft *Emergency Contraception Statewide Protocol* based on California
- Draft *Virginia Emergency Contraception Self-Screening Questionnaire*
- CDC USMEC, Classifications for Emergency Contraception
- Background information from California
    - Regulations
    - Key Facts about Emergency Contraception
    - ASEC Emergency Contraception Guide for Pharmacies and Retailers

Possible actions:

- Discuss and finalize wording in *Pharmacist Hormonal Contraceptive Statewide Protocol* and determine if highlighted sections or other information warranted
- Amend wording in *Standard Procedures Algorithm for Va Pharmacist Prescribing & Administering Depot Medroxyprogesterone Acetate (DMPA)* to correspond with *Virginia Hormonal Contraceptive Self-Screening Questionnaire* and *Pharmacist Hormonal Contraceptive Statewide Protocol*
- Review and amend newly added DMPA column on *Summary Chart of US Medical Eligibility Criteria for Contraceptive Use*
- Discuss and amend draft *Emergency Contraception Statewide Protocol*; discuss if pharmacist should be required to provide written educational information to patient
- Adopt each listed document for Board of Pharmacy consideration as presented or amended.

VIRGINIA BOARD OF PHARMACY

Pharmacist Hormonal Contraceptive Statewide Protocol
(Excluding Emergency Contraception)

Consistent with the hormonal contraceptive manufacturer's instructions for use approved by the US Food and Drug Administration (FDA), 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:

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

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering injectable or self-administered hormonal contraceptive under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use and shall have completed an Accreditation Council for Pharmacy Education (ACPE)-accredited educational training program related to the prescribing of contraceptives by a pharmacist.

PATIENT INCLUSION CRITERIA

Patients eligible for injectable or self-administered hormonal contraceptives approved by the FDA under this protocol:

- An individual, 18 years of age or older, who has completed the *Virginia Hormonal Contraceptive Self-Screening Questionnaire* and who the pharmacist has determined is eligible for a hormonal contraceptive, consistent with the Centers for Disease Control and Prevention *Summary Chart of US Medical Eligibility Criteria for Contraceptive Use.*

PROCESS FOR DETERMINING PATIENT ELIGIBILITY

To determine patient eligibility, the pharmacist shall:

1. Obtain from each new patient and, at a minimum of every twelve months for each returning patient, a completed *Virginia Self-Screening Risk Assessment Questionnaire*; and,
2. Utilize and follow the *Virginia Standard Procedures Algorithm for Prescribing Contraceptives* to perform the patient assessment.

PROCESS FOR HANDLING INELIGIBLE PATIENTS

Patients identified by the pharmacist to NOT to be eligible for a hormonal contraceptive as indicated by the *Summary Chart of US Medical Eligibility Criteria for Contraceptive Use* and the *Virginia Standard Procedures Algorithm for Prescribing Contraceptives* shall be referred to a healthcare practitioner and may not receive a hormonal contractive under this statewide protocol.

FURTHER CONDITIONS

1. For each new patient requesting a contraceptive service a participating pharmacist must:
   a. Provide the patient with a Visit Summary; and,

b. Refer any patient that may be subject to abuse to an appropriate social services agency.

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

3. A pharmacist shall 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 Virginia Standard Procedures Algorithm requires referral to a provider.

DRUG INCLUSION CRITERIA

The following drug formulations approved by the FDA to prevent pregnancy are included in this statewide protocol:

- injectable depot medroxyprogesterone acetate;
- transdermal patches;
- vaginal rings; and,
- contraceptives intended to be taken orally.

RECORDKEEPING

The pharmacist shall maintain records in accordance with Regulation 18 VAC 110-21-46.

NOTIFICATION OF PRIMARY CARE PROVIDER

1. If the pharmacist initiates treatment with or dispenses or administers a hormonal contraceptive, 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; and,
2. Additionally, 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.

Virginia 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: _____

Background Information:

1	Do you think you might be pregnant now?	Yes □ No□
	Have you used emergency contraception within the last 5 days?	Yes □ No□
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 □ No □ Yes □ No □
	Did you ever experience a bad reaction to using hormonal birth control?	Yes □ No □
	- If yes, what kind of reaction occurred?	_____
	Are you currently using any method of birth control including pills, or a birth control patch, ring or shot/injection?	Yes □ No □
	- If yes, which one do you use?	_____
4	Have you ever been told by a medical professional not to take hormones?	Yes □ No □
5	Do you smoke cigarettes or vape nicotine?	Yes □ No □

Medical History:

6	Have you given birth within 21 days? If yes, how long ago?	Yes □ No □
7	Are you currently breastfeeding?	Yes □ No □
8	Do you have diabetes?	Yes □ No □
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 □ No □
10	Do you have high blood pressure, hypertension, or high cholesterol? (Please indicate yes, even if it is controlled by medication)	Yes □ No □
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes □ No □
12	Have you ever had a blood clot?	Yes □ No □
13	Have you ever been told by a medical professional that you are at risk of developing a blood clot?	Yes □ No □
14	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes □ No □
15	Have you had bariatric surgery or stomach reduction surgery?	Yes □ No □
16	Do you have or have you ever had breast cancer?	Yes □ No □
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 □ No □
18	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes □ No □
19	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes □ No □
	- If yes, list them here:	
20	Do you have any other medical problems or take any medications, including herbs or supplements?	Yes □ No □
	- If yes, list them here:	
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: _____

DRAFT 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 Virginia Hormonal Contraception Self-Screening 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

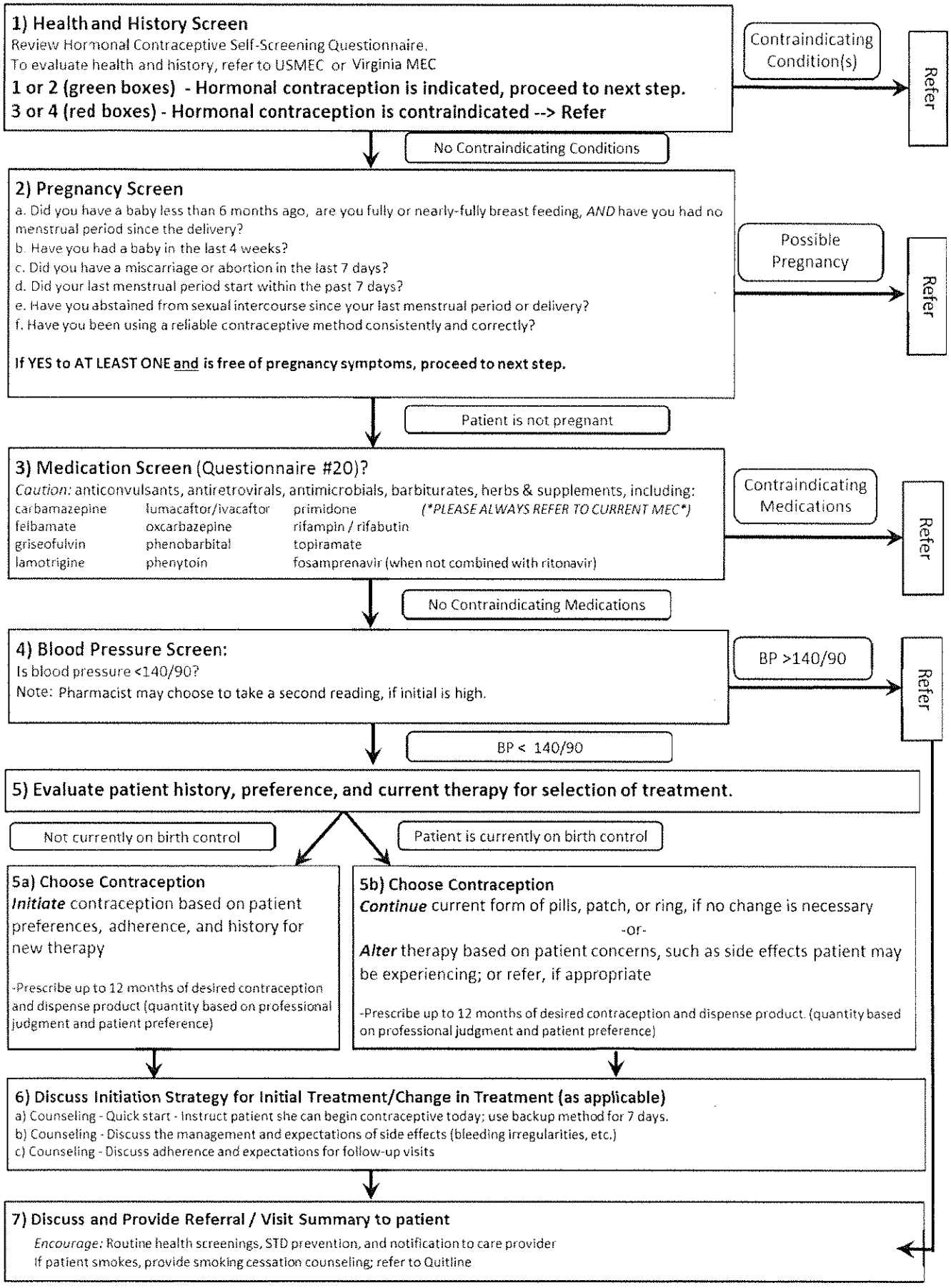
Corresponding to the order of the Virginia Hormonal Contraception Self Screening Tool Questionnaire:

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

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

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

STANDARD PROCEDURES ALGORITHM FOR VIRGINIA PHARMACIST PRESCRIBING OF CONTRACEPTIVES



STANDARD PROCEDURES ALGORITHM FOR PRESCRIBING & ADMINISTERING DEPOT MEDROXYPROGESTERONE ACETATE

1) Health and History Screen
Review Hormonal Contraceptive Self-Screening Questionnaire.
To evaluate health and history, refer to USMEC or Virginia MEC.
1 or 2 (green boxes) - Hormonal contraception is indicated, proceed to next step.
3 or 4 (red boxes) - Hormonal contraception is contraindicated --> Refer

Contraindicating Condition(s) → Refer

No Contraindicating Conditions

2) 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?
b. Have you had a baby in the last 4 weeks?
c. Did you have a miscarriage or abortion in the last 7 days?
d. Did your last menstrual period start within the past 7 days?
e. Have you abstained from sexual intercourse since your last menstrual period or delivery?
f. Have you been using a reliable contraceptive method consistently and correctly?

If YES to AT LEAST ONE and is free of pregnancy symptoms, proceed to next step.
If NO to ALL of these questions, pregnancy can NOT be ruled out --> Refer

Possible Pregnancy → Refer

Patient is not pregnant

3) Medication and Disease State Screen (incl Questionnaire #11, 17, 20, 22 + med list)?
Caution: Long-term corticosteriod therapy
*(*PLEASE ALWAYS REFER TO CURRENT MEC*)*

Contraindicating Diseases/ Medications → Refer

No Contraindicating Diseases/Medications

4) Blood Pressure Reading
Take and document patient's current blood pressure. Is BP < 160/100?
Note: Pharmacist may choose to take a second reading, if initial is high.

BP ≥ 160/100 → Refer

BP < 160/100

5) Discuss DMPA therapy with patient.
a) Address any unexplained vaginal bleeding that worries patient (Questionnaire #6) - Refer when necessary, such as when not related to a recent pap or sexual intercourse.
b) Counseling - Discuss the management and expectations of side effects (bleeding irregularities, etc.)
c) Counseling - Discuss plans for follow-up visits, particularly for q 3 month administration of DMPA; Stress importance of returning for next injection within 11-13 weeks of previous injection. Provide patient with specific calendar date range for next injection.
d) Counseling - Caution with use of DMPA > 2 years (due to loss of bone mineral density). For therapy > 2 years, consultation with healthcare provider is indicated.

First dose of DMPA

6) Issue prescription and administer DMPA
Pharmacist shall issue a prescription for depo-medroxyprogesterone and administer the medication. Monitor patient for 20 minutes for adverse reactions.

Note: Instruct patient that if this injection is *not* within 7 days of start of her period, then abstain or use backup method for 7 days.

q 3 month dose of DMPA

6) Ongoing administration of DMPA
Pharmacist shall confirm that date of last injection was within 11-15 weeks.

-If > 15 weeks ago, then pharmacist must rule out pregnancy (repeat Step 2, and document), and instruct patient to abstain or use backup method for 7 days.

-If between 11-15 weeks ago, adminster the medication.

-Do not administer if < 11 weeks ago.

7) Discuss and Provide Referral / Visit Summary to patient
Encourage: Routine health screenings, STD prevention, and notification to care provider

VIRGINIA BOARD OF PHARMACY

Pharmacist Emergency Contraception Statewide Protocol

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:

- Self-administered hormonal emergency contraception (EC) provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, or dispensing of a self-administered hormonal EC under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use or standard protocol and shall have completed at least one hour of continuing education specific to the prescribing of EC.

PATIENT INCLUSION CRITERIA

Patients eligible for self-administered hormonal EC under this protocol:

- An individual, 18 years of age or older, who has completed the *Virginia Emergency Contraception Self-Screening Questionnaire* indicating the last day of unprotected intercourse was within the previous 5 days (120 hours) and who the pharmacist has determined is eligible for a hormonal emergency contraceptive, consistent with the Centers for Disease Control and Prevention *US Medical Eligibility Criteria for Contraceptive Use, Classifications for Emergency Contraception.*

PROCESS FOR HANDLING INELIGIBLE PATIENTS

Patients identified by the pharmacist to NOT to be eligible for EC shall be referred to a healthcare practitioner and may not receive EC under this statewide protocol.

DRUG INCLUSION CRITERIA

The following drug formulations are included in this EC statewide protocol:

Dedicated Approved EC – One Tablet Regimens

Plan B One-Step	1 tablet	1.5mg levonorgestrel	OTC
Levonorgestrel	1 tablet	1.5mg levonorgestrel	OTC
Next Choice One Dose	1 tablet	1.5mg levonorgestrel	OTC
Ella	1 tablet	30mg ulipristal	Rx only

In addition to the products specified in the above chart, generic equivalent products may be prescribed and dispensed.

Oral Contraceptive Pills

Brand	Tablets per dose (2 doses 12 hours apart*)	Ethinyl Estradiol per dose (mcg)	Levonorgestrel per dose (mg)*	Status
Alesse	5 pink tablets	100	0.50	Rx only
Aviane	5 orange tablets	100	0.5	Rx only
Levlen	4 light-orange tablets	120	0.6	Rx only
Levlite	5 pink tablets	100	0.5	Rx only
Levora	4 white tablets	120	0.60	Rx only
Lo/Ovral	4 white tablets	120	0.60	Rx only
Low-Ogestrel	4 white tablets	120	0.60	Rx only
Nordette	4 light-orange tablets	120	0.60	Rx only
Ogestrel	2 white tablets	100	0.50	Rx only
Ovral	2 white tablets	100	0.50	Rx only
Tri-Levlen	4 yellow tablets	100	0.50	Rx only
Triphasil	4 yellow tablets	120	0.50	Rx only
Trivora	4 pink tablets	120	0.50	Rx only
Ovrette	20 yellow tablets	0	0.75	Rx only

*The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrol, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

In addition to the products specified in the above chart, generic equivalent products may be prescribed and dispensed. Estrogen containing regimens are not preferred and should be used only when other options are not available.

Anti-nausea Treatment Options for use with EC

Drug	Dose	Timing of Administration	Status
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25mg tablets	1 hour before first EC dose; repeat if needed in 24 hours	OTC
Diphenhydramine hydrochloride (Benadryl)	One or two 25mg tablets or capsules	1 hour before first EC dose; repeat as needed every 4-6 hours	OTC
Dimenhydrinate (Dramamine)	One or two 50mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first EC dose; repeat as needed every 4-6 hours	OTC
Cyclizine hydrochloride (Marezine)	One 50mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours	OTC

ADDITIONAL PRESCRIBING AND DISPENSING CONSIDERATIONS*

- For women who weigh more than 165 lbs, levonorgestrel may be less effective than ulipristal acetate.
- Levonorgestrel may be preferable for women who need EC due to missed or late pills, patch, or ring.
- Starting hormonal birth control immediately after taking ulipristal acetate may make it ineffective.
- For women with prescription insurance coverage, OTC drugs may be covered by the health carrier when prescribed for the patient.

RECORDKEEPING

The pharmacist shall maintain records in accordance with Regulation 18 VAC 110-21-46.

NOTIFICATION OF PRIMARY CARE PROVIDER AND COUNSELING

1. If the pharmacist initiates treatment with or dispenses or administers a self-administered hormonal EC, 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; and,
2. Additionally, 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.

***Per the American Society for Emergency Contraception.**

Virginia Emergency Contraception Self-Screening Questionnaire

Timing is an essential element of the effectiveness of emergency contraception (EC). EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) after unprotected intercourse.

Patient's Name_____ **Date**_____

Healthcare Provider's Name_____

Healthcare Provider's Telephone or Email address_____

Date of Birth _____ **Age** _____ **Weight** _____

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

Any allergies to medications? _____

Number of hours/days since last unprotected intercourse _____

Internal use only ☐ verified DOB* with valid photo ID

Pharmacist Name_____ Pharmacist Signature _____

☐ Drug Prescribed_____ Rx#_____ -or- referred-circle reason(s)

Sig:_____ (Pharmacy Phone_____ Address_____)

Notes: _____

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Reproductive Health

Classifications for Emergency Contraception

Pages in this Report

On this Page

A copper-containing intrauterine device (Cu-IUD) can be used within 5 days of unprotected intercourse as an emergency contraceptive. However, when the time of ovulation can be estimated, the Cu-IUD can be inserted beyond 5 days after intercourse, if necessary, as long as the insertion does not occur >5 days after ovulation. The eligibility criteria for interval Cu-IUD insertion also apply for the insertion of Cu-IUDs as emergency contraception (Box J1) (Table J1).

Classifications for emergency contraceptive pills (ECPs) are given for ulipristal acetate (UPA), levonorgestrel (LNG), and combined oral contraceptives (COCs). Cu-IUDs, UPA, LNG, and COCs do not protect against sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), and women using these methods should be counseled that consistent and correct use of the male latex condom reduces the risk for transmission of HIV and other STDs. Use of female condoms can provide protection from transmission of STDs, although data are limited.

BOX J1. Categories for classifying emergency contraception

1 = A condition for which there is no restriction for the use of the contraceptive method.2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.

3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.

4 = A condition that represents an unacceptable health risk if the contraceptive method is used.

TABLE J1. Classifications for emergency contraception, including the copper-containing intrauterine device, ulipristal acetate, levonorgestrel, and combined oral contraceptives

	Category				
Condition	**Cu-IUD**	**UPA**	**LNG**	**COC**	**Clarifications/Evidence/Comments**
Personal Characteristics and Reproductive History					
Pregnancy	4	NA	NA	NA	**Clarification (IUD):** The IUD is not indicated during pregnancy and should not be used because of the risk for serious pelvic infection and septic spontaneous abortion. **Clarification (ECPs):** Although this method is not indicated for a woman with a known or suspected pregnancy, no harm to the woman, the course of her pregnancy, or the fetus if ECPs are inadvertently used is known to exist. **Evidence:** Evidence suggests that poor pregnancy outcomes are rare among pregnant women who used ECPs during conception cycle or early in pregnancy *(1)*.
Breastfeeding	1	1	1	1	**Clarification (UPA):** Breastfeeding is not recommended for 24 hours after taking UPA because it is excreted in breast milk, with highest concentrations in the first 24 hours, and maximum maternal serum levels are reached 1–3 hours after administration. Mean UPA concentrations in breast milk decrease markedly from 0 to 24–48 hours and then slowly decrease over 5 days *(2)*. Breast milk should be expressed and discarded for 24 hours after taking UPA. **Evidence:** Breastfeeding outcomes do not seem to differ between women exposed to LNG and those who are not exposed. One pharmacokinetic study demonstrated that LNG passes to breast milk but in minimal quantities *(1)*.
Past ectopic pregnancy	1	1	1	1	—
History of bariatric surgery This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					

Condition	Category Cu-IUD	UPA	LNG	COC	Clarifications/Evidence/Comments
a. Restrictive procedures: decrease storage capacity of the stomach (vertical banded gastroplasty, laparoscopic adjustable gastric band, or laparoscopic sleeve gastrectomy)	1	1	1	1	—
b. Malabsorptive procedures: decrease absorption of nutrients and calories by shortening the functional length of the small intestine (Roux-en-Y gastric bypass or biliopancreatic diversion)	1	1	1	1	**Comment:** Bariatric surgical procedures involving a malabsorptive component have the potential to decrease oral contraceptive effectiveness, perhaps further decreased by postoperative complications such as long-term diarrhea, vomiting, or both. Because of these malabsorptive concerns, an emergency IUD might be more appropriate than ECPs.
Cardiovascular Disease					
History of severe cardiovascular disease (ischemic heart disease, cerebrovascular attack, or other thromboembolic conditions) This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	2	2	2	**Comment:** The duration of ECP use is less than that of regular use of COCs or POPs and thus would be expected to have less clinical impact.
Rheumatic Diseases					
Rheumatoid arthritis					
a. Receiving immunosuppressive therapy	2	1	1	1	—
b. Not receiving immunosuppressive therapy	1	1	1	1	—
Neurologic Conditions					
Migraine	1	1	1	2	**Comment:** The duration of ECP use is less than that of regular use of COCs and thus would be expected to have less clinical impact.
Gastrointestinal Conditions					
Inflammatory bowel disease (ulcerative colitis or Crohn's disease)	1	1	1	1	—

Condition	Category Cu-IUD	UPA	LNG	COC	Clarifications/Evidence/Comments
Severe liver disease (including jaundice) This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	2	2	2	**Comment:** The duration of ECP use is less than that of regular use of COCs or POPs and thus would be expected to have less clinical impact.
Solid Organ Transplantation					
Solid organ transplantation This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					
a. Complicated: graft failure (acute or chronic), rejection, or cardiac allograft vasculopathy	3	1	1	1	—
b. Uncomplicated	2	1	1	1	—
Other					
Repeated ECP use	1	1	1	1	**Clarification:** Recurrent ECP use is an indication that the woman requires further counseling about other contraceptive options. Frequently repeated ECP use might be harmful for women with conditions classified as 2, 3, or 4 for CHC or POC use. **Evidence:** In one case-control study, risk for ectopic pregnancy compared with intrauterine pregnancy did not increase after repeated use of LNG ECPs compared with nonuse *(1)*.
Sexual assault	2	1	1	1	**Clarification (IUD):** Women who have experienced sexual assault are at increased risk for STDs. According to CDC STD treatment guidelines, routine presumptive treatment of chlamydia, gonorrhea, and trichomonas is recommended after sexual assault *(3)*. Women with current purulent cervicitis or chlamydial infection or gonococcal infection should not undergo IUD insertion (category 4).
Obesity (BMI ≥30 kg/m²)	1	2	2	2	**Clarification (ECPs):** ECPs might be less effective among women with BMI ≥30 kg/m² than among women with BMI <25 kg/m². Despite this, no safety concerns exist. **Evidence:** Limited evidence from secondary data analyses suggests that women with BMI ≥30 kg/m² experience an increased risk for pregnancy after use of LNG compared with women with BMI <25 kg/m². Two analyses suggest obese women might also experience an increased risk for pregnancy after use of UPA compared with nonobese women, although this increase was not significant in one study *(4)*.
CYP3A4 inducers (e.g., bosentan, carbamazepine, felbamate, griseofulvin,	1	2	2	2	**Clarification (ECPs):** Strong CYP3A4 inducers might reduce the effectiveness of ECPs.

Condition	Category			Clarifications/Evidence/Comments
	Cu-IUD	UPA	LNG COC	
oxcarbazepine, phenytoin, rifampin, St. John's wort, topiramate, efavirenz, and lumacaftor)				**Evidence:** According to labelling information, rifampin markedly decreases UPA levels by ≥90%, which might decrease its efficacy *(2)*. Therefore, theoretical concerns extend to use of other CYP3A4 inducers as well as to COC and LNG ECPs, which have metabolic pathways similar to those of UPA. A small pharmacokinetic study found that concomitant efavirenz use decreased LNG levels in women taking LNG ECPs (0.75 mg) by 56% compared with LNG ECPs alone *(5)*.

Abbreviations: BMI = body mass index; CHC = combined hormonal contraceptive; COC = combined oral contraceptive; Cu-IUD = copper-containing intrauterine device; ECP = emergency contraceptive pill; HIV = human immunodeficiency virus; IUD = intrauterine device; LNG = levonorgestrel; NA = not applicable; POC = progestin-only contraceptive; POP = progestin-only pill; STD = sexually transmitted disease; UPA = ulipristal acetate.

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Section 1746. Emergency Contraception

(a) A pharmacist furnishing emergency contraception pursuant to Section 4052.3(a)(2) of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Emergency Contraception (EC).

(1) Authority: Section 4052.3(a)(2) of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol specified in this section satisfies that requirement.

(2) Purpose: To provide timely access to emergency contraceptive medication and ensure that the patient receives adequate information to successfully complete therapy.

(3) Procedure: When a patient requests emergency contraception, the pharmacist will ask and communicate the following:

- Are you allergic to any medications?
- Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) after unprotected intercourse.

EC use will not interfere with an established or implanted pregnancy.

If more than 72 hours have elapsed since unprotected intercourse, the use of ella™ (ulipristal) may be more effective than levonorgestrel. For other options for EC, consult with your health care provider.

Please follow up with your health care provider after the use of EC.

(4) The pharmacist shall provide a fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medication record required by Section 1707.1 of Title 16 of the California Code of Regulations.

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy as required by Business and Professions Code Section 4052.3(e).

(5) Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(6) The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

(7) Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

(8) EC Product Selection: The pharmacist will provide emergency contraception medication from the list of products specified in this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC containing estrogen. Patients will be provided information concerning dosing and potential adverse effects.

(9) Documentation: Each prescription authorized by a pharmacist will be documented in a patient medication record as required by law.

(10) Training: Prior to furnishing emergency contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

(11) Medications Used for Emergency Contraception

Dedicated Approved Products for Emergency Contraception

Brand	*Dose*	*Ethinyl Estradiol per dose (mcg)*	
One Tablet Regimens			
Plan B™ One-Step	1 tablet	0	1.5mg levonorgestrel
ella™	1 tablet	0	30mg ulipristal
Levonorgestrel	1 tablet	0	1.5mg levonorgestrel
Two Tablet Regimens			
Next Choice™	2 tablets at once (1.5mg total dose) or 1 tablet (0.75mg) followed by 1 tablet (0.75mg) 12 hours later	0	Each tablet is 0.75 mg levonorgestrel
Levonorgestrel	2 tablets at once (1.5mg total dose) or 1 tablet (0.75mg) followed by 1 tablet (0.75mg) 12 hours later	0	Each tablet is 0.75 mg levonorgestrel

Oral Contraceptive Pills

Brand	*Tablets per Dose (two doses 12 hours apart*)*	*Ethinyl Estradiol per dose (mcg)*	*Levonorgestrel per dose (mg)**
Alesse	5 pink tablets	100	0.50
Aviane	5 orange tablets	100	0.50
Levlen	4 light-orange tablets	120	0.60
Levlite	5 pink tablets	100	0.50
Levora	4 white tablets	120	0.60
Lo/Ovral	4 white tablets	120	0.50
Low-Ogestrel	4 white tablets	120	0.60
Nordette	4 light-orange tablets	120	0.60
Ogestrel	2 white tablets	100	0.50
Ovral	2 white tablets	100	0.50
Tri-Levlen	4 yellow tablets	100	0.50
Triphasil	4 yellow tablets	120	0.50
Trivora	4 pink tablets	120	0.50
Ovrette	20 yellow tablets	0	0.75

*The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

In addition to the products specified in this paragraph, generic equivalent products may be furnished. Estrogen containing regimens are not preferred and should be used only when the other options are not available.

(12) Anti-nausea Treatment Options for use with Emergency Contraception

Non-Prescription Drugs	*Dose*	*Timing of Administration*
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose; Repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first EC dose; repeat as needed every 4-6 hours
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.3, Business and Professions Code.

(Amended effective 7-1-2013)

Key Facts About Emergency Contraception

Emergency Contraception (EC) is a safe and effective way to prevent pregnancy after sex.

Consider using Emergency Contraception (EC) if:

- You had unprotected sex, or
- You think your contraceptive didn't work.

What are Emergency Contraceptive pills?

Emergency Contraceptive pills contain the same medication as regular birth control pills, and help to prevent pregnancy. There are three basic types of Emergency Contraceptive pills:

- Progestin-only pills (Plan B® One-Step, Next Choice®)
- Ulipristal acetate (ella®)
- High doses of regular oral contraceptive pills

Don't wait! Take EC as soon as possible.

- It is best to take EC as soon as possible; the sooner you take EC the more effective it is.
- It has been shown to be effective for up to 5 days.
- For more information talk to your pharmacist or doctor.

When taken as directed Emergency Contraception has been shown to be safe and effective.

- Emergency Contraception may reduce the risk of pregnancy by up to 89 percent.
- The effectiveness of EC varies based on the type used and when it is taken.
- EC is only recommended as a backup and should not be used as your primary method of birth control.
- Emergency Contraceptive pills do not protect against sexually transmitted infections, including HIV/AIDS.

What EC does:

- Emergency Contraceptive pills prevent pregnancy.
- Emergency Contraceptive pills are not effective after pregnancy has occurred and they will not harm the developing fetus.
- Emergency Contraceptive pills are NOT the same as RU-486 (the abortion pill).
- Using Emergency Contraceptive pills will not affect a woman's ability to become pregnancy in the future.

Follow-up after taking Emergency Contraceptive pills:

- If you vomit after taking emergency contraception you may need to take another dose. Before you do, contact a pharmacist or healthcare provider immediately.
- If you do not get a normal period within three weeks, take a pregnancy test.
- It is important to visit your doctor or clinic for a regular birth control method and information about preventing sexually transmitted infections.
- Medical providers or your pharmacist can provide Emergency Contraception for future use if needed.

In California, women and men may receive free family planning services through Family PACT based on income.

If you don't have a doctor or clinic, call (800) 942-1054 to find a Family PACT provider near you.

Under the Affordable Care Act (ACA), Emergency Contraception may be covered with a prescription.

EMERGENCY CONTRACEPTION: A GUIDE FOR PHARMACIES AND RETAILERS (OCT 2018)

What is emergency contraception (also known as "the morning-after pill")?

- Emergency contraception (EC) prevents pregnancy. EC will not disrupt an existing pregnancy.
- EC pills that contain the progestin hormone, levonorgestrel (LNG), are sold under several names. One-pill LNG EC products are available over-the-counter (OTC) without age restrictions. *(See reverse side for specific details.)*
- Two-pill LNG EC products are no longer sold in the U.S.
- EC pills containing ulipristal acetate (UPA) are prescription-only.
- EC pills work best if taken as soon as possible after unprotected sex but may work up to 5 days after.
- EC is safe for women of all ages to use.

What are the restrictions for purchasing EC over-the-counter? Do customers need to show ID?

- There are NO age or point-of-sale restrictions on the OTC purchase of 1.5 mg LNG EC products. Previous age restrictions have been removed by the U.S. Food and Drug Administration (FDA).
- Any woman or man of any age can purchase LNG EC products without needing to show ID.
  - There is no limit on the number of packages that a person can purchase.
  - Until recently, some generic LNG EC product labels stated "for women 17 years and older". If your store's products still carry this labeling, be aware that this is not an enforceable restriction.

Where can EC be found within pharmacies and stores?

- LNG EC products can be sold directly from store shelves.
  - Most retailers stock it in the family planning aisle so it can be found easily.
  - There is no need to keep these EC products only behind the pharmacy counter.
- Ulipristal acetate is available by prescription only. Some states have protocols that allow the pharmacist to write a prescription for various EC products.

Why is it important to stock LNG EC on the over-the-counter shelf?

- EC provides a last chance to prevent an unintended pregnancy after birth control failure, sexual assault, or unprotected sex.
- EC works best when it's taken as soon as possible. Convenient and timely access is critically important.
- Keeping EC behind the pharmacy counter is an unnecessary and harmful barrier; the FDA has approved LNG EC products for sale on store shelves without any restrictions.
- Customers may feel embarrassed about purchasing EC; placing it directly on the shelf without locked security cabinets or boxes protects people's privacy and confidentiality.
- Pharmacies and stores have an important role to play in helping people prevent unintended pregnancy by maintaining a stock of easily accessible EC on the shelf at all times.

Can men purchase LNG EC?

- Yes, men can purchase LNG EC. There are no sex/gender restrictions on the sale of OTC EC products.
- Prescriptions for EC (for women using UPA EC or who want/need a prescription for LNG EC for insurance reimbursement) can only be issued to the patient who will be taking it..

What can I do if my store doesn't stock LNG EC on the over-the-counter shelf?

- If you are the person who makes stocking decisions, you make space for EC in the family planning aisle.
- If your store doesn't sell EC on the OTC shelf, it may be because the regulations around EC have changed frequently in the past few years, and it can be confusing. Share these guidelines with your management and encourage them to stock EC on the OTC shelf.
- If you cannot fulfill a customer's request for EC, please refer them to Not-2-Late's EC locator: www.not-2-late.com

FDA-Approved Emergency Contraceptive Pills (as of October 2018)

Levonorgestrel EC

Formulation	• Levonorgestrel 1.5 mg
Where to stock	• On OTC shelves; does *not* need to be stocked behind the pharmacy counter
Regulatory status	• OTC for all ages for women and men: ID check is *not* required
How to use	• Take as soon as possible; may be effective up to 5 days after unprotected sex
Cost	• ~$50 for branded product • ~$35-40 for generics • Should be covered by insurance with prescription
Good to know	• May be less effective for women who weigh more than 165 lbs • Preferable for women who need EC due to missed or late pills, patch or ring

Ulipristal Acetate EC

Formulation	• Ulipristal acetate 30 mg
Where to stock	• Behind the pharmacy counter on the pharmacy shelves
Regulatory status	• Prescription-only
How to use	• Take as soon as possible; may be effective up to 5 days after unprotected sex • Don't start a hormonal method within 5 days of unprotected sex after taking UPA
Cost	• ~$50 • Should be covered by insurance
Good to know	• More effective than LNG for women who weigh more than 165 lbs • Not recommended for women who need EC due to missed or late birth control pills, patch or ring due to a theoretical drug interaction • Starting hormonal birth control immediately after UPA EC may make it ineffective

If you have questions or comments about how EC is sold at your store, contact ASEC:
asec@americansocietyforec.org

To request education or training on EC or related topics, contact Dr. Sally Rafie:
sally@birthcontrolpharmacist.com

Learn more about EC at www.not-2-late.com

18VAC110-21-46. Initiation of treatment by a pharmacist.

A. Pursuant to § 54.1-3303.1, a pharmacist may initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

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. Pharmacists who initiate treatment with, dispense, or administer a drug or device pursuant to subsection A shall:

1. Follow the statewide protocol adopted by the board for each drug or device.

2. Notify the patient's primary health care provider that treatment has been initiated 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.

3. Maintain a patient record for a minimum of six years following the last patient encounter with the following exceptions:

a. Records that have previously been transferred to another practitioner or health care provider or provided to the patient or the patient's personal representative; or

b. Records that are required by contractual obligation or federal law to be maintained for a longer period of time.

4. Perform the activities in a manner that protects patient confidentiality and complies with the Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d et seq.

18VAC110-20-150. Physical standards for all pharmacies.

A. The prescription department shall not be less than 240 square feet. The patient waiting area or the area used for counseling, devices, cosmetics, and proprietary medicines shall not be considered a part of the minimum 240 square feet. The total area shall be consistent with the size and scope of the services provided.

B. Access to stock rooms, rest rooms, and other areas other than an office that is exclusively used by the pharmacist shall not be through the prescription department. A rest room in the prescription department, used exclusively by pharmacists and personnel assisting with dispensing functions, may be allowed provided there is another rest room outside the prescription department available to other employees and the public. This subsection shall not apply to prescription departments in existence prior to November 4, 1993.

C. The pharmacy shall be constructed of permanent and secure materials. Trailers or other moveable facilities or temporary construction shall not be permitted.

D. The entire area of the location of the pharmacy practice, including all areas where drugs are stored, shall be well lighted and well ventilated; the proper storage temperature shall be maintained to meet USP-NF specifications for drug storage.

E. The prescription department counter work space shall be used only for the compounding and dispensing of drugs and necessary recordkeeping.

F. A sink with hot and cold running water shall be within the prescription department. A pharmacy issued a limited-use permit that does not stock prescription drugs as part of its operation is exempt from this requirement.

G. Adequate refrigeration facilities equipped with a monitoring thermometer for the storage of drugs requiring cold storage temperature shall be maintained within the prescription department if the pharmacy stocks such drugs.

H. A pharmacy stocking drugs requiring cold storage temperature shall record the temperature daily and adjust the thermostat as necessary to ensure an appropriate temperature range. The record shall be maintained manually or electronically for a period of two years.

I. The physical settings of a pharmacy in which a pharmacist initiates treatment with, dispenses, or administers drugs and devices pursuant to § 54.1-3303.1 and 18VAC110-21-46 shall protect patient confidentiality and comply with the Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d et seq.