KENTUCKY BOARD OF PHARMACY

Justice and Public Safety Building
125 Holmes Street, 1st Floor Conference Room
Frankfort, KY 40601

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September 25, 2024
10:00 a.m.

Board Meeting Agenda

I. CALL TO ORDER

II. MINUTES

III. APPEARANCES
- A. Reinstatement Requests
  - i. Perpich, John
  - ii. Bowles, Jeremy
- B. Pharmacist Applicants
  - i. Conatser, Mikala (MPJE Request)
- C. Pharmacy Technician Applicants
  - i. Barber, Branden
  - ii. Caldwell, Jalen
  - iii. Dawson, Jon
  - iv. Miles, Satira

IV. INTERAGENCY/PROFESSIONAL ASSOCIATIONS

V. BOARD REPORTS
- A. Executive Director
  - a. eMARs

b. Compounding Survey Update (Preliminary Data)

B. General Counsel
   a. Expungement Request
      i. 19-0312B
      ii. 20-0001B
      iii. 21-0003C
   b. Memo on the Regulatory Use of Waivers

VI. COMMITTEE REPORTS

A. KYPRN
B. Regulation Committee
   i. 201 KAR 2:045 Pharmacy Technician (Amendment)
C. Diversity & Inclusion Task Force
D. Protocol Review Committee
   i. Self-Care Conditions Protocol: Diabetes Testing Supplies V3 (revision)
   ii. Self-Care Conditions Protocol: Hormonal Contraception (new)
   iii. SARS-CoV-2 Infection Protocol (new)

VII. CORRESPONDENCE

A. Baptist Health Hardin Cancer Care Center (P08135), Offsite Storage Request
B. Dual PIC Requests
   i. Ramey, Ryan (021478); Kroger Pharmacy L-785 (P02433) & Kroger Pharmacy L-376 (P02068)
   ii. Gandhi, Vishal (017613); Polaris Specialty Rx (CA2979) & Owl Specialty Pharmacy (pending permit)

VIII. OLD BUSINESS

A. Public Comments on Proposed Regulations
   i. Proposed Amendment 201 KAR 2:210
      1. CVS – Oral Comments
      2. Neil Medical Group – Oral and Written Comments
      3. Publix
      4. CenterWell Pharmacy
   ii. Proposed 201 KAR 2:480
      1. National Association of Chain Drug Stores
      2. Neil Medical Group- Oral and Written Comments
      3. CenterWell Pharmacy
   iii. Proposed Amendments to 201 KAR 2:370
      1. Agency amendment request
      2. CVS- Written Comments

IX. NEW BUSINESS

A. Joint Statement of the Kentucky Boards of Medical Licensure, Nursing, and Pharmacy Regarding Retail IV Therapy

X. CLOSED SESSION

A. 2024 CRP Modification Request 24-0060

ATTENTION: A portion of the meeting may be held in closed/executive session for the purpose of discussing and deliberating upon open investigations or the review of information required to be conducted in private according to federal and state law. The specific statutory sections authorizing closed session are KRS 61.810(1)(c) KRS 61.878(1)(a) KRS 61.810(1)(j) KRS 61.878(1)(h) KRS 61.810(1)(k). Following discussion and deliberation, any and all action will be taken in open/public session.

201 KAR 2:045. Technicians.
(Amended Regulation)

RELATES TO: KRS 315.010(12), (20), (26), 315.020(4)(b), (5)(b), 315.191(1)(a), (g), (l)
STATUTORY AUTHORITY: KRS 315.010(21)~~(20)~~, 315.020(4)(b), 315.191(1)(a), (g), (l)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the Board to promulgate administrative regulations governing pharmacy technicians. KRS 315.020(4)(b) authorizes the board to establish the scope of practice for pharmacy technicians. KRS 315.010(20) and 315.191(1)(l) authorize the board to promulgate administrative regulations establishing when a pharmacy technician may ~~can~~ be under the general supervision of a pharmacist, and establishes the scope of practice for a pharmacy technician.

Section 1. A person shall be recognized by the board as a certified pharmacy technician, if:
(1)
(a) The person has successfully completed the Pharmacy Technician Certification Exam (PTCE) administered by the Pharmacy Technician Certification Board (PTCB) or the Examination for the Certification of Pharmacy Technicians (ExCPT) by the National Healthcareer Association (NHA); and
(b) The certificate issued by the PTCB or NHA is current; or
(2) The person has successfully completed the Nuclear Pharmacy Technician Training Program at the University of Tennessee.

Section 2. Registered Technician.
(1) A registered pharmacy technician may, under the immediate supervision of a pharmacist, engage in the following activities at a permitted location to the extent that the activities do not require the exercise of professional judgment:
(a) Initiate or receive telephonic or electronic communication from a practitioner or practitioner's agent concerning refill authorization. If the practitioner or practitioner's agent communicates information that does not relate to the refill authorization:
1. The technician shall immediately inform the pharmacist; and
2. The pharmacist shall receive the communication;
(b) Enter information into and retrieve information from a database or patient profile, including order entry;
(c) Prepare and affix labels;
(d) Stock and retrieve product from the pharmacy inventory;
(e) Count and pour prescription drugs into patient storage containers;
(f) Obtain, record or maintain information for a patient record;
(g) Make an offer to counsel;
(h) Sell and record the sale of an over-the-counter ephedrine, pseudoephedrine, or phenylpropanolamine product;
(i) Certify for delivery unit dose mobile transport systems that have been refilled by another technician in an institutional pharmacy;
(j) Receive diagnostic orders within a nuclear pharmacy;
and

(k) Non-sterile and sterile drug compounding.
(2) A registered pharmacy technician may, under electronic supervision, perform order entry from a location outside of the permitted pharmacy pursuant to KRS 315.020(5)(b) and (c).
(3) A registered pharmacy technician may, under general supervision:
(a) Administer a vaccine to an individual if the technician:
1. Completes a minimum of two (2) hours of immunization-related continuing education accredited by the Accreditation Council for Pharmacy Education (ACPE) per each state registration period;
2. Completes, or has completed, a practical training program accredited by ACPE that includes hands-on injection technique and the recognition and treatment of emergency reactions to vaccines; and
3. Possesses a current certificate in basic cardiopulmonary resuscitation.
(b) Stock an automated dispensing system in a residential hospice facility if a pharmacist is on-site.

Section 3. Certified Pharmacy Technician.
(1) A certified pharmacy technician, under the general supervision of a pharmacist, may be delegated by the supervising pharmacist to perform any function within the practice of pharmacy except the following:
(a) Patient counseling, including clinical advisement necessary to all areas of a patient's health;
(b) Drug evaluation, utilization, and regiment review;
(c) Interpretation of medical orders and prescriptions;
(d) Clinical conflict resolution;
(e) Final prescription verification; and
(f) Other acts, services, or decisions that require professional judgement. ~~perform the following functions under the general supervision of a pharmacist~~:
~~(1) Certify for delivery unit dose mobile transport systems that have been refilled by another technician;~~
~~(2) Within a nuclear pharmacy, receive diagnostic orders; and~~
~~(3)~~
~~(a) Initiate or receive a telephonic communication from a practitioner or practitioner's agent concerning refill authorization, after the certified pharmacy technician clearly identified himself or herself as a certified pharmacy technician; and~~
~~(b) If a practitioner or practitioner's agent communicates information that does not relate to the refill authorization:~~
~~1. A technician shall immediately inform the pharmacist; and~~
~~2. The pharmacist shall receive the communication~~.

Section 4. Directing pharmacist responsibility.
(1) ~~A technician who has not been certified by PTCB or NHA may perform the functions specified by Section 2 of this administrative regulation under the immediate supervision of a pharmacist.~~

~~(2)~~ A function performed by a certified pharmacy technician or pharmacy technician shall be performed subject to review of the pharmacist who directed the technician to perform the function.
(2) ~~(3)~~ A pharmacist who directs a certified pharmacy technician or pharmacy technician to perform a function shall be responsible for the technician and the performance of the function.
(3) A pharmacy technician shall only perform tasks for which they have been specifically trained. The pharmacist in charge shall ensure documentation of training is readily retrievable at the permitted location and shall be provided to delegating pharmacists and board of pharmacy staff, upon request.

Section 5. Application.
1. An applicant shall provide the following information as part of their technician registration application:
(a) Name, maiden, and other names used currently or previously;
(b) telephone number;
(c) address;
(d) social security number;
(e) NABP eprofile number;
(f) email address;
(g) place of employment;
(h) Record of convictions of any felony or misdemeanor offense, other than traffic offenses, and whether or not a sentence was imposed or suspended;
(i) Record of any technician registration revocation, suspension, restriction, termination, or other disciplinary action by any board of pharmacy or other state authority;
(j) Record of any condition of impairment, such as substance or alcohol abuse or dependency that in any way impacts the technician's ability to assist in the practice of pharmacy in a safe and competent manner;
(k) Record of licensure, certification or registration as a pharmacy technician in any other state, if applicable; and
(l) Record of certification as a pharmacy technician with a national organization, if applicable.

Section 6. Material Incorporated by Reference.
1. The following material is incorporated by reference:
(a) "Application for Registration as a Pharmacy Technician", 07/2024
(b) "Application for Pharmacy Technician Renewal", 07/2024
(c) "Charitable Pharmacy Technician Application" 07/2024
(d) "Charitable Pharmacy Technician Renewal Application", 07/2024
2. This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m. This material is also available on the Board's website at: https://pharmacy.ky.gov/professionals/Pages/Pharmacy-Technicians.aspx.

Pharmacy Name: _____

Pharmacy Permit Number: _____

SARS-CoV-2 INFECTION PROTOCOL
V1
Approved 09/25/2024

PURPOSE
This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of medication therapies for the treatment of SARS-CoV-2 infection. The purpose of this protocol is to ensure appropriate and timely therapy for individuals with SARS-CoV-2 following diagnostic confirmation via nucleic acid amplification test (NAAT) or rapid antigen detection test (RADT).

PHARMACIST EDUCATION AND TRAINING
Prior to initiating testing and dispensing antivirals under this protocol, pharmacist(s) must have received education and maintain knowledge of the Centers for Disease Control current guidelines for the treatment of SARS-CoV-2 from a provider accredited by the Accreditation Council for Pharmacy Education, or by a comparable provider approved by the Kentucky Board of Pharmacy.

CRITERIA
Pharmacist(s) authorized to initiate the dispensing of antivirals to treat acute COVID-19 infection will treat individuals in accordance with guidance issued by the Center for Disease Control and Prevention.

Inclusion criteria:
Any individual who presents to the pharmacy and meets ALL of the following inclusion criteria:

- ≥ 12 years old (with consent of a parent/guardian if <18 years old)
- Documentation of positive SARS-CoV-2 viral testing within the last 5 days from a CLIA-waived NAAT or RADT ordered and conducted onsite as authorized by this protocol or documented as being performed by a healthcare professional offsite **[Note: antibody tests are NOT considered to be direct SARS-CoV-2 tests]**
- Underlying conditions associated with increased risk for progression to severe COVID-19 per CDC guidance[1]

[1] Available at: https://www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html?CDC_AAref_Val=https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html

Exclusion criteria:
Any individual who meets ANY of the following criteria:

- Pregnant or breastfeeding
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than 2 weeks, HIV/AIDS)
- Other pharmacologic therapy prescribed for upper respiratory conditions within the previous 30 days
- Clinically unstable based on the clinical judgment of the pharmacist or any of the following criteria:
  - Acute altered mental status
  - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
  - Pulse > 125 beats/min
  - Respiratory rate > 30 breaths/min
  - Temperature ≥ 103 °F
- Symptoms indicating developing or progressing pulmonary involvement, including:
  - Persistent or progressive dyspnea
  - SpO2 ≤ 94% on room air at sea level
  - Other high acuity symptoms, including:
    - Chest pain or tightness
    - Dizziness
    - Confusion or other mental status changes

All individuals who do not qualify for antiviral dispensing under this protocol will be referred to a primary care provider or urgent/emergent treatment facility if clinically appropriate.

MEDICATIONS
This protocol authorizes pharmacist(s) to initiate the dispensing of one of the following antiviral agents. The pharmacists may dispense any dosage form deemed appropriate for the individual:

First-line Treatments
Oral **Nirmatrelvir with Ritonavir** dosing:

- Adults and Children (≥ 12 years old, ≥ 40 kg):
  - eGFR ≥ 60 mL/min.: Nirmatrelvir 300 mg with Ritonavir 100 mg administered together twice a day x 5 days
  - eGFR ≥ 30 to < 60 mL/min.: Nirmatrelvir 150 mg with Ritonavir 50 mg administered together twice a day x 5 days

Alternate Treatments
Oral **Molnupiravir** dosing:

- Adults: 800 mg every 12 hours x 5 days
- Children (<18 years old): Contraindicated due to the potential for bone and cartilage toxicity

Adjunctive Treatments

Adjunctive therapy may be useful for treatment of symptoms, including fever, headache, myalgias, and cough associated with COVID-19 infection. Treatment of symptoms includes using over-the-counter antipyretics, analgesics, or antitussives. Patients should be advised to drink fluids regularly and to rest as needed.

PROCEDURES FOR INITIATION OF THERAPY

Evaluate CLIA-waived point-of-care nucleic acid amplification test (NAAT) or rapid antigen detection test (RADT) results

- If positive: continue to evaluate with protocol
- If negative:
  - Evaluate for other minor acute illnesses such as influenza or bacterial infections

Antiviral therapy will be initiated only in carefully selected individuals based on relevant medical and social history and considerations of contraindications and precautions as identified through assessment and screening (see Appendix 1).

Assess for Relevant Medical and Social History

- Patient demographics
- Weight if <18 y/o using scale in pharmacy
- Medical history
- Relevant social history
- Current medications
- Medication allergies and hypersensitivities

Medication Specific Contraindications and Precautions

- Known hypersensitivity to nirmatrelvir, ritonavir, or molnupiravir
- Coadministration with drugs that are highly dependent on CYP3A for clearance or are CYP3A inducers (nirmatrelvir with ritonavir)
- Severe renal dysfunction (nirmatrelvir with ritonavir)
- Reduced efficacy of combination hormonal contraceptives (nirmatrelvir with ritonavir)
- Reproductive considerations (molnupiravir)

PROCEDURES FOR MONITORING AND CONTINUATION OR ADJUSTMENT OF THERAPIES

Telephone follow-up within 48 to 72 hours of dispensing to assess for clinical stability, symptom burden, and adverse effects to treatment. Referral to a primary care provider or urgent/emergent treatment facility will occur if any of the following are reported:

- New onset of dyspnea or persistent/worsening dyspnea (particularly if dyspnea occurs while resting or if it interferes with daily activities); dizziness; and mental status changes, such as confusion.
- Significant deterioration in condition or new evidence of clinical instability
- Lack of improvement in symptoms or onset of symptoms indicative of serious complications
- Medication adverse effects severe enough to warrant discontinuation

EDUCATION REQUIREMENTS

Individuals with a positive test will receive counseling on the following:

- Appropriate self-care, including symptom control, hygiene, and infection control measures.
- Per CDC guidance, people with acute COVID-19 infection should stay home from work, school, or daycare until they are afebrile without pharmacologic intervention AND symptoms are improving overall for at least 24 hours.
- After ending self-isolation, practice additional precautions over the next 5 days, such as:
  - Wearing a well-fitting mask
  - Maintaining distance from others
  - Enhanced hygiene practices
- Medication counseling consistent with state and federal requirements for prescription drug products
- Instructions on signs or symptoms that warrant emergent medical care
- Follow-up details

DOCUMENTATION

Pharmacist(s) will document the dispensing event for each person who is treated for COVID-19 under this protocol in the pharmacy management system, including:

- Documentation as required in 201 KAR 2:171 if dispensing a prescription medication
- Documentation that the individual (or caregiver) received the required education

Upon request, documentation for work/school absence

NOTIFICATION

Pharmacist(s) shall ask all persons receiving treatment under this protocol for the name and contact information of a primary care provider. If an individual (or caregiver) identifies a primary care provider, the pharmacist will provide that provider with a summary of the encounter, including at least the individual's name, date of birth, COVID-19 test results, medication dispensed, and follow-up plan, within 2 business days.

[If directed by the authorizing prescriber, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing prescriber of persons receiving medications under this protocol within 7 days of initiating dispensing.]

TERMS

This protocol is authorized pursuant to 201 KAR 2:380 and is effective when it is submitted to the registry. Any termination shall require prior notice to all parties no later than 30 days after discontinuing the protocol.

SIGNATURES

Prescriber Name _____ Date _____

Prescriber Kentucky License Number _____

Prescriber Signature _____

Pharmacist Name _____ Date _____

Pharmacist Kentucky License Number _____

Pharmacist Signature _____

Course Taken For Training: _____

Provider of Training: _____

Date Training Completed: _____

Any pharmacist not party to the protocol will be subject to discipline should they utilize the protocol. A pharmacist utilizing the protocol must be employed by or contracted with the permit listed in the executed protocol.

For additional pharmacists party to this protocol, the pharmacy should keep a list of the additional pharmacists and their training at the pharmacy.

ADDITIONAL SIGNATURE PAGE

By signing below, I attest that I read and understand the Board-authorized protocol, entitled: _____
and that I will follow all guidelines and requirements included in the Board-authorized protocol.

_____ _____
Pharmacist Name Date

_____
Pharmacist Kentucky License Number

_____
Pharmacist Signature

Course Taken for Training: _____

Provider of Training: _____

Date Training Completed: _____

SELF-CARE CONDITIONS PROTOCOL: DIABETES TESTING SUPPLIES v3

Approved 12/11/2019

PURPOSE
This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of diabetes testing supplies for diabetes self-care/management.

PHARMACIST EDUCATION AND TRAINING
Prior to initiating the dispensing of diabetes testing supplies under this protocol, pharmacist(s) must have received education and training in diabetes and the supplies necessary to test blood glucose levels, including review of the most current American Diabetes Association (ADA) Standards of Medical Care in Diabetes and the monitoring parameters associated with pharmacologic therapies for the treatment of diabetes. The education of pharmacist(s) must be conducted by a provider accredited by the Accreditation Council for Pharmacy Education, or by a comparable provider approved by the Kentucky Board of Pharmacy.

Provider of Training: _____

Date Training Completed: _____

CRITERIA
Pharmacist(s) authorized to initiate the dispensing of diabetes testing supplies will follow the most current ADA Standards of Medical Care in Diabetes for pharmacologic options and the associated blood glucose monitoring guidelines.

Inclusion criteria:

- Any individual who currently has a diagnosis of diabetes, as defined by the ADA Standards of Medical Care for Diabetes, and is interested in obtaining diabetic testing supplies for self-care purposes in an outpatient setting.

Exclusion criteria:

- Any individual who exhibits symptoms of hyperglycemic crisis. For both diabetic ketoacidosis (DKA) and hyperosmolar hyperglycemic state (HHS), the classic clinical picture includes a history of polyuria, polydipsia, weightloss, vomiting, dehydration,

Resources

Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S13-S27. Web. 27 Dec. 2017.

Glycemic Targets: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S55-S64. Web. 27 Dec. 2017.

weakness, and mental status change. These individuals should be referred to a setting where they can receive immediate medical attention.

DIABETES TESTING SUPPLIES

This protocol authorizes pharmacist(s) to initiate the dispensing of the following diabetes testing supplies for self-care purposes in quantities sufficient to provide adequate testing based upon patient history, including refills for up to 12 months.

- Glucometer
- Glucometer test strips
- Lancet devices
- Lancets
- Blood glucose control solutions
- Alcohol wipes

PROCEDURES FOR INITIATING DISPENSING OF DIABETES TESTING SUPPLIES

Diabetes testing supply initiation will be individualized based on the diagnosis and pharmacologic treatment of diabetes as defined by the ADA Standards of Medical Care in Diabetes and individual preferences:

- Intensive insulin therapy: 4-10 tests per day
- Basal insulin and/or oral antidiabetic agents: 1-3 tests per day
- Non-pharmacologically managed diabetes: 1-4 tests per day

PROCEDURES FOR MONITORING AND CONTINUATION OF DISPENSING DIABETES TESTING SUPPLIES

Follow-up monitoring and evaluation shall occur at a minimum of every 90 days to determine:

- Changes in pharmacologic treatment for diabetes
- How the individual is utilizing testing supplies and efficacy of performing self-monitoring of blood glucose (SMBG)

If pharmacist(s) believes that SMBG is being performed incorrectly, education is to be provided to the individual in regard to proper use of diabetic testing supplies, as well as education on interpretation of blood glucose levels. If pharmacist(s) suspects an individual is consistently hyperglycemic or periodically hypoglycemic, the primary care provider of the individual is to be contacted. If the individual does not have primary care provider, other healthcare provider with prescribing privilege shall be contacted.

Resources

Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S13-S27. Web. 27 Dec. 2017.

Glycemic Targets: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S55-S64. Web. 27 Dec. 2017.

Should follow-up evaluation and monitoring indicate an adjustment intherapy is warranted, all procedures as outlined for initiation of therapies, including education, documentation and notification, will be followed.

EDUCATION REQUIREMENTS

Individuals, or their parent/guardian/caregiver, receiving diabetes testing supplies under the protocol will receive education regarding:

- Monitoring technique both initially and at regular intervals, using dispensed test strips, lancets, and meter
- Proper review and interpretation of the data provided by the blood glucose meter
- Signs and symptoms of hypoglycemia and instructions on steps to take if blood glucose level is 70 mg/dL or less

DOCUMENTATION

Pharmacist(s) shall document via prescription record each person who receives any diabetes testing supplies under this protocol, including:

- Documentation as required in 201 KAR 2:170 for the dispensing of prescription medication
- Documentation that the individual receiving the diabetes testing supplies was provided with the required education pursuant to this protocol
- Documentation of the diagnosis and pharmacologic treatment of diabetes, the plan of care implemented, and follow-up monitoring and evaluation

NOTIFICATION

Pharmacist(s) shall ask all individuals receiving diabetes testing supplies under this protocol for the name and contact information of the individual's primary care provider and shall provide notification of the diabetes testing supplies dispensed under the protocol to the identified primary care provider within two (2) business days. Any individual affirmatively stating that the individual does not have a primary care provider may still receive diabetes testing supplies under this protocol provided all other applicable requirements of the protocol are met.

[If directed by the authorizing prescriber, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing prescriber of persons receiving diabetes testing supplies under this protocol within 7 days of initiating dispensing.]

TERMS

This protocol is effective as of the date parties execute this document. It shall remain in effect for a period of one year and shall automatically renew for successive one year periods unless otherwise terminated by any party, with or without cause. Any termination without cause shall

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Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S13-S27. Web. 27 Dec. 2017.

Glycemic Targets: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S55-S64. Web. 27 Dec. 2017.

require prior notice to all parties of no less than sixty (60) days.

Resources

Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S13-S27. Web. 27 Dec. 2017.

Glycemic Targets: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S55-S64. Web. 27 Dec. 2017.

SIGNATURES

Prescriber Name	Prescriber Signature	Date
Pharmacist Name	Pharmacist Signature	Date

Resources

Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S13-S27. Web. 27 Dec. 2017.

Glycemic Targets: Standards of Medical Care in Diabetes—2018." Diabetes Care 41. Supplement 1 (2018): S55-S64. Web. 27 Dec. 2017.

Pharmacy Name: _____

Pharmacy Permit Number: _____

SELF-CARE CONDITIONS: HORMONAL CONTRACEPTION PROTOCOL
V1
Approved 09/25/2024

PURPOSE
This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of self-care hormonal contraceptives.

PHARMACIST EDUCATION AND TRAINING
Prior to initiating the dispensing of hormonal contraception therapy under this protocol, pharmacist(s) must have received education and training on hormonal contraception provision from a provider accredited by the Accreditation Council for Pharmacy Education, or by a comparable provider approved by the Kentucky Board of Pharmacy.

CRITERIA
Pharmacist(s) authorized to initiate the dispensing of hormonal contraception therapy will follow the most current US Medical Eligibility Criteria (US MEC) for Contraceptive Use put forth by the Centers for Disease Control and Prevention (CDC), limiting provision to therapies listed as either category 1 or 2 for any applicable condition/sub-condition.[1]

Inclusion criteria:
- Any individual seeking maintenance hormonal contraception for the purpose of preventing pregnancy

Exclusion criteria:
- Individuals with male sex assigned at birth
- Individuals with conditions listed as category 3 or 4 in the US MEC for progestin-only pills (POPs)
- Hypersensitivity to norgestrel or any ingredients contained in the dispensed drug product
- Concurrent use of another birth control pill, vaginal ring, patch, implant, injection, or intrauterine device (IUD)
- Use of ulipristal acetate within the previous 5 days
- Pregnant individuals or those presenting with symptoms consistent with pregnancy and reporting unprotected/inadequately protected intercourse following their last menstrual period

[1] *US Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2024 | CDC. Published August 6, 2024. Accessed August 15, 2024.* https://www.cdc.gov/contraception/hcp/usmec/index.html

MEDICATIONS

This protocol authorizes pharmacist(s) to initiate the dispensing of the following medication regimen to an individual meeting criteria:

- **Norgestrel 0.075mg once daily at the same time each day**

PROCEDURES FOR INITIATION OF THERAPY

Hormonal contraception initiation will follow current guidelines[1] and will be individualized based on relevant medical, sexual, and social history, patient preferences, and consideration of contraindications and precautions of therapy as outlined below. Refer patient as needed if the patient wishes to seek alternatives not included within this protocol.

Relevant Medical and Social History

- Past medical history
- Sexual history
- Current medications
- Allergies and hypersensitivities

Precautions

- Conditions/circumstances that may limit the effectiveness of the hormonal contraception regimen, including:
  - Concurrent medications (e.g., CYP3A4 Inducers) that may decrease the effectiveness of norgestrel
- Norgestrel should be taken at the same time each day to ensure effectiveness

DURATION OF THERAPY

This protocol authorizes pharmacist(s) to initiate the dispensing of up to a 1-year supply of a medication listed above to individuals who meet criteria

EDUCATION REQUIREMENTS

Individuals receiving hormonal contraception therapy under the protocol will receive education regarding:

- Education regarding safe sexual practices, including the necessity of protection for sexually transmitted infections.
- Refer as needed for provision of permanent or long-acting reversible contraception (LARC), sexually transmitted infection testing, gynecological examinations, other desired contraceptive forms, emergency contraception, and well-woman care.
- Education specific to the norgestrel, including conditions or medications that may decrease the effectiveness or increase risk of norgestrel. This will include (but is not limited to):

    - Use of barrier contraceptive methods for 48 hours after starting/restarting norgestrel upon initiation and if a dose of norgestrel is missed or taken >3 hours later than usual.
    - Norgestrel is NOT an emergency contraceptive
    - Individuals who miss two periods (or a single period and have missed doses of norgestrel) or suspect they may be pregnancy should take a pregnancy test and, if confirmed, discontinue norgestrel.
    - Cannot be taken within 5 days following use of ulipristal acetate. If initiated after 5 days, barrier contraceptive methods should be used until the next menstral period.
- Education regarding the necessity of a visit to a primary care provider or urgent/emergency treatment facility if any of the following occur:
    - Unscheduled or breakthrough bleeding that persists for more than a few cycles
    - Signs of an allergic reaction, such as rash, itching, tightness in chest or throat, trouble breathing or swallowing, or swelling of the face, lips, mouth, tongue, or throat.

DOCUMENTATION

Pharmacist(s) shall document via prescription record each person who receives hormonal contraception therapy under this protocol, including:

- Documentation as required in 201 KAR 2:171 for the dispensing of prescription medication; and
- Documentation that the individual receiving the hormonal contraception (or caregiver) was provided with the required education pursuant to this protocol
- Documentation of the history and assessment, the plan of care implemented, and follow-up monitoring and evaluation.

NOTIFICATION

Pharmacist(s) shall ask all persons receiving hormonal contraception therapy under this protocol for the name and contact information of the individual's primary care provider and shall provide notification of the medications dispensed under the protocol to the identified primary care provider within two (2) business days. Any individual affirmatively stating that the individual does not have a primary care provider may still be provided hormonal contraception therapy under this protocol provided all other applicable requirements of the protocol are met.

[If directed by the authorizing prescriber, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing prescriber of persons receiving medications under this protocol within 7 days of initiating dispensing.]

TERMS

This protocol is authorized pursuant to 201 KAR 2:380 and is effective when it is submitted to the registry. Any termination shall require prior notice to all parties no later than 30 days after discontinuing the protocol.

SIGNATURES

_____ _____

Prescriber Name Date

_____

Prescriber Kentucky License Number

_____

Prescriber Signature

_____ _____

Pharmacist Name Date

_____

Pharmacist Kentucky License Number

_____

Pharmacist Signature

Course Taken for Training: _____

Provider of Training: _____

Date Training Completed: _____

Any pharmacist not party to the protocol will be subject to discipline should they utilize the protocol. A pharmacist utilizing the protocol must be employed by or contracted with the permit listed in the executed protocol.

For additional pharmacists party to this protocol, the pharmacy should keep a list of the additional pharmacists and their training at the pharmacy.

ADDITIONAL SIGNATURE PAGE

By signing below, I attest that I read and understand the Board-authorized protocol, entitled : _____
and that I will follow all guidelines and requirements included in the Board-authorized protocol.

_____ _____
Pharmacist Name Date

_____
Pharmacist Kentucky License Number

_____
Pharmacist Signature

Course Taken for Training: _____

Provider of Training: _____

Date Training Completed: _____