KENTUCKY BOARD OF PHARMACY

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

Join Zoom Meeting
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Meeting ID: 878 9921 7803 **Passcode: 3I1a5f**

Dial by Location

- **+1 312 626 6799 US (Chicago)**
- **+1 646 558 8656 US (New York)**

Meeting ID: 878 9921 7803 **Passcode: 480303**

January 24, 2024
10:00 a.m.

Board Meeting Agenda

I. CALL TO ORDER

II. INSTALLATION OF OFFICERS

III. MINUTES

IV. APPEARANCES
- A. Initial Pharmacist Application
  - i. Schultz, Richard
- B. Pharmacy Technician Applications
  - i. Brasfield, Austin Cole
  - ii. Hinkle, Jaremeia
  - iii. Hubbell, Connor
  - iv. Moore, Angela
  - v. Scroggin, Keaton
  - vi. Yazell, Vanessa

V. INTERAGENCY/PROFESSIONAL ASSOCIATIONS

VI. BOARD REPORTS
- A. Executive Director
  - a. eMars
  - b. Legislative Update

c. 2024 Travel Request

B. General Counsel
   a. Open Records Court of Appeals Decision, 2022-CA-0170-MR
   b. Ethics Review
   c. 2024 Travel Requests
   d. Expungement Request, 19-0314B
   e. Regulation Status Update
   f. Proposed Change of Ownership Regulation

C. Deputy Executive Director/Inspection Staff

VII. COMMITTEE REPORTS

A. KYPRN

B. Regulation Committee
   i. 201 KAR 2:220 Recommendation
   ii. 201 KAR 2:070 Recommendation

C. Advisory Council

D. Protocol Review Committee
   i. Acute Group A Streptococcal Pharyngitis
   ii. Acute Influenza Infection Antiviral Therapy

VIII. FACILITY APPLICATIONS

A. Non-Resident Pharmacy Application
   i. Express Med Pharmaceuticals DBA SelectRx PA
   ii. Almac Clinical Services LLC

IX. CORRESPONDENCE

A. Off-site storage request - Pikeville Medical Center (P06519)

B. Dual PIC request – AZ2831 and AZ2841

C. Dual PIC request – P08295 and CP00143

D. Non-Resident Pharmacy Permit Waiver Request- Monroe Pharmacy

X. OLD BUSINESS

A. 201 KAR 2:460 Out of State Pharmacy Permit- New Regulation

B. 201 KAR 2:030 License Transfer and Non-Resident Pharmacist License- Amended Regulation and 201 KAR 2:050 Licenses and permits; fees.

XI. NEW BUSINESS

A. APRN Council Appointment

B. Pharmacist Recovery Network Committee Member Applications (2 Vacancies)
   i. Akins, Tonya
   ii. Ali, Brittany
   iii. Anderson, Heather

iv. Ashley, Kailen
v. Awudu, Rekiyatu
vi. Babb, Ryan
vii. Blair, Amanda
viii. Bolton, Spencer
ix. Byrd, Brooke
x. Cantrell, Michael
xi. Craycraft, Lauren
xii. David, Gary
xiii. Divers, Cari
xiv. Eatmon, Courtney
xv. Epps, Amy
xvi. Hancock, Brian
xvii. Hankinson, Willaim
xviii. Honerlaw, David
xix. Karrick, Kristina
xx. Keller, Kimberly
xxi. Kramer, Andrea
xxii. Lamkin, Lynn
xxiii. Lockwood, Anna
xxiv. Lyles, Jacob
xxv. Lyons, Allie
xxvi. Mahan, Jamie
xxvii. McMahon, Laura
xxviii. Newsome, Colby
xxix. Schreihofer, Amber
xxx. Szesny, Derek
xxxi. Taylor, Durran
xxxii. Warren, Dalton
xxxiii. Whisman, Emma
xxxiv. White, Jessalynn
xxxv. Wills, Rheagan

XII. CLOSED SESSION DISCUSSION REQUIRED

A. Daniel Justin, 20-0120(O) Reinstatement
B. 23-0132 Final Order Issuance
C. 2022 Case Review Panel Consideration of Proposed Settlement Agreement
    i. 22-0005
    ii. 22-0069
D. 2023 Case Review Panel Consideration of Proposed Settlement Agreement
    i. 23-0023

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 2:220. Collaborative care agreements.

RELATES TO: KRS 315.010(4), 315.121, 315.040(4), 315.191(1)(a)

STATUTORY AUTHORITY: KRS 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the Board of Pharmacy to promulgate administrative regulations to regulate and control matters relating to pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale distributors, and manufacturers. This administrative regulation establishes minimum requirements for the development and maintenance of collaborative care agreements between pharmacist and practitioner.

Section 1. A collaborative care agreement shall:

(1) Be in writing;

(2) Be signed and dated by:

(a) Each practitioner; and

(b) Each pharmacist who is a party to the agreement;

(3) Provide the method for referral of patients to be managed under the agreement; and

(4) State the method for termination of the agreement.

Section 2. The following information relating to a patient managed under the collaborative care agreement shall be maintained by the pharmacist:

(1) Name;

(2) Address and phone number;

(3) Emergency notification contact;

(4) Date of birth, weight, height, and gender;

(5) Medical history, including:

(a) Known diseases;

(b) Known allergies;

(c) Reactions and conditions relating to:

1. Prescription medications; and

2. Nonprescription medications;

(d) Current prescription regimen; and

(e) Current nonprescription regimen;

(6) Lab tests ordered, including results of lab tests;

(7) Assessment of patient outcomes;

(8) Notes relating to the care and course of therapy of the patient; and

(9) Documentation of patient consent to receive care under the collaborative care agreement.

Section 3. Documentation relating to the care and course of therapy of the patient pursuant to the agreement shall be documented in the patient's record maintained by the pharmacist, provided to the collaborating practitioner, and be readily available to other healthcare professionals providing care to the patient.

Section 4. A collaborative care agreement shall comply with KRS 315.010(4) and contain the following information:

(1) Protocol, criteria, standing orders, or other method by which services are authorized;

(2) The method established for the assessment of patient outcomes, if appropriate; and

(3) Lab tests that may be ordered.

Section 5. A collaborative care agreement and information and records required by the provisions of this administrative regulation shall be maintained:

(1) At the pharmacist's practice site; and

(2) For at least five (5) years after the termination of the agreement. (23 Ky.R. 3125; Am. 3807; 4109; eff. 6-16-1997; 34 Ky.R. 2421; eff. 8-1-2008; 42 Ky.R.458; 1548; 1710; eff. 12-16-2015; Certified to be amended, filing deadline 3-9-2024.)

BOARDS AND COMMISSIONS

KENTUCKY BOARD OF PHARMACY

(AMENDMENT)

201 KAR 2:070. Prescription intermediary services restricted.

RELATES TO: KRS Chapter 315

STATUTORY AUTHORITY: KRS 315.020(2), 315.121(1), 315.191(2), (8)

NECESSITY, FUNCTION, AND CONFORMITY: By the authority of KRS 315.191(2) the Board of Pharmacy is responsible to control all matters relating to pharmacies and pharmacists with respect to drugs sold by prescriptions only. This administrative regulation assures the public that a registered pharmacist is present and that prescription drugs distribution is curtailed.

Section 1. No pharmacist shall fill and dispense prescriptions obtained from or delivered to an establishment or place which offers to the public, in any manner, its services as a "pickup station" or "intermediary" for the purpose of having prescriptions filled or delivered unless such establishment or place has a registered pharmacist on-site in full charge of such services.

Pharmacy Name: _____

Pharmacy Permit Number: _____

ACUTE GROUP A STREPTOCOCCAL (GAS) PHARYNGITIS INFECTION PROTOCOL v5
Approved 01/24/2024

PURPOSE
This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of antibiotics to treat acute Group A streptococcal (GAS) pharyngitis infection. The purpose of this protocol is to ensure appropriate and timely antibiotic therapy for individuals with streptococcal pharyngitis following diagnostic confirmation via CLIA-waived point-of-care testing.

PHARMACIST EDUCATION AND TRAINING
Prior to initiating testing and dispensing antibiotics under this protocol, pharmacist(s) must have received education and training in point-of-care CLIA-waived testing techniques appropriate to the test employed by the pharmacy from a provider accredited by the Accreditation Council for Pharmacy Education, or by a comparable provider approved by the Kentucky Board of Pharmacy. Additionally, pharmacist(s) must maintain knowledge of the Infectious Disease Society of America (IDSA)'s current guidelines for the treatment of GAS pharyngitis.[1]

CRITERIA
Pharmacist(s) authorized to initiate the dispensing of antibiotics to treat acute GAS infection will treat individuals according to current IDSA guidelines or in accordance with the Center for Disease Control and Prevention.[1,2]

Inclusion criteria:

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

- Age 5 years or older (with consent of a parent/guardian if <18 years old)
- Complaint of any sign or symptom consistent with GAS pharyngitis (sore throat, pain on swallowing, fever, headache, swollen or tender cervical lymph nodes, inflamed or swollen tonsils or uvula)
- Positive GAS result via CLIA-waived point-of-care test

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[1] *Clinical Practice Guideline for the Diagnosis and Management of Group A Streptococcal Pharyngitis: 2012 Update by the Infectious Diseases Society of America.* Available online at http://www.idsociety.org/Guidelines/Patient_Care/IDSA_Practice_Guidelines/Infections_By_Organ_System-81567/Lower/Upper_Respiratory/Streptococcal_Pharyngitis/

[2] https://www.cdc.gov/groupastrep/diseases-hcp/strep-throat.html

Exclusion criteria:

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

- Age <5 years old
- Pregnant or breastfeeding
- Renal dysfunction (based on individual's report or pharmacy records)
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than 2 weeks, HIV/AIDS)
- History of rheumatic fever, rheumatic heart disease, scarlet fever, or GAS- induced glomerulonephritis
- Other antibiotic therapy prescribed for sore throat or upper respiratory infection 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
- Presenting with overt viral features, such as: rhinorrhea, cough, oral ulcers, and/or hoarseness
- Presenting with a stiff neck consistent with meningismus

All individuals who do not qualify for antibiotic 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 medication regimens to an individual meeting criteria:

First-line Treatments (unless contraindicated due to history of penicillin allergy)

1a. Amoxicillin PO 25 mg/kg/dose (max 500 mg/dose) twice daily for 10 days

1b. Amoxicillin PO 50 mg/kg/dose (max 1000 mg/dose) once daily for 10 days

Second-line Treatments (for those with mild allergic reactions e.g. rash to penicillin or first-line treatment appears on the FDA Shortage List)

2a. Cephalexin PO 20 mg/kg/dose (max 500 mg/dose) twice daily for 10 days

2b. Cefadroxil PO 30 mg/kg/dose (max 1000 mg/dose) once daily for 10 days

Third-line Treatments (for those with mild allergies allergic reactions to penicillin and cephalosporins or severe allergic reactions e.g. anaphylaxis to penicillin)

3a. Azithromycin PO 12 mg/kg/dose (max 500 mg/dose) day 1 , then 6 mg/kg/dose (max 250 mg/dose) once daily for days 2 through 5

3b. Azithromycin PO 12 mg/kg/dose (max 500 mg/dose) once daily for 5 days

3c. Clindamycin PO 7 mg/kg/dose (max 300 mg/dose) three times daily for 10 days

3d. Clarithromycin PO 7.5 mg/kg/dose (max 250 mg/dose) twice daily for 10 days

Adjunctive therapy may be useful for treatment of moderate to severe symptoms or control of high fever associated with acute GAS pharyngitis and should be considered as an adjunct to an appropriate antibiotic.

- **Acetaminophen** PO; follow over the counter (OTC) dosing recommendations

- **Ibuprofen** PO; follow over the counter (OTC) dosing recommendations

PROCEDURES FOR INITIATION OF THERAPY

Perform CLIA-waived point-of-care test to distinguish between acute GAS and viral pharyngitis

- If positive: continue to evaluate with protocol
- If negative:
    - Adult: no back up throat culture needed for adults
    - Children and adolescents (<18 y/o): back up throat culture must be done, thus referral to primary care provider or urgent treatment center is required

Antibiotic 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.

Assess for Relevant Medical and Social History

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

PROCEDURES FOR MONITORING AND CONTINUATION OR ADJUSTMENT OF THERAPIES

Telephone follow-up within 24 to 48 hours of dispensing to assess the need for additional medical intervention. Follow-up will assess for clinical stability, symptom burden, and medication adverse effects. Referral to a primary care provider or urgent/emergent treatment facility will occur if any of the following are reported:

- 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

All individuals tested under this protocol will receive counseling on:

- Appropriate self-care, including symptom control, hygiene, and infection control measures.
- Per IDSA guidelines people with acute GAS pharyngitis should stay home from work, school, or daycare until they are afebrile and until 24 hours after starting appropriate antibiotic therapy

Individuals receiving antibiotics under this protocol will also receive the following:

- 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
- Upon request, documentation for work/school absence

DOCUMENTATION

Pharmacist(s) will document via prescription record each person who is tested for GAS under this protocol, including:

- Documentation as required in 201 KAR 2:171 for the dispensing of prescription medication
- Documentation of the presenting signs and symptoms that warranted testing
- Documentation of parental consent for individuals under age 18
- Documentation of the manufacturer, lot, expiration date, and result of the CLIA-waived point-of-care test used to determine GAS status
- Documentation that the individual (or caregiver) received the education required by this protocol
- Documentation of clinical follow up, as appropriate

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, GAS 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.

Pharmacy Name: _____

Pharmacy Permit Number: _____

ACUTE INFLUENZA INFECTION: ANTIVIRAL THERAPY PROTOCOL
v6
Approved 01/24/2024

PURPOSE
This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of antiviral therapies to treat acute influenza infection. The purpose of this protocol is to ensure appropriate and timely antiviral therapy for individuals with influenza following diagnostic confirmation via CLIA-waived point-of-care testing.[1]

PHARMACIST EDUCATION AND TRAINING
Prior to initiating influenza testing and dispensing of antiviral therapy under this protocol, pharmacist(s) must have received education and training in point-of-care CLIA-waived testing techniques appropriate to the test employed by the pharmacy from a provider accredited by the Accreditation Council for Pharmacy Education, or by a comparable provider approved by the Kentucky Board of Pharmacy. Additionally, pharmacist(s) must maintain knowledge of the Centers for Disease Control and Prevention (CDC)'s current recommendations for the use of antiviral drugs in the treatment of influenza.[2]

CRITERIA
Pharmacist(s) authorized to initiate the dispensing of antiviral therapy to treat acute influenza infection will treat individuals according to annual guidance from the CDC.[2]

Inclusion criteria:
Any individual who presents to the pharmacy during influenza season, when known influenza viruses are circulating in the community, and meets **ALL** of the following criteria:

- Age 5 years or older (with consent of a parent/guardian if < 18 years old)
- Complaint of **ANY** sign/symptom consistent with influenza (fever, myalgia, headache, malaise, nonproductive cough, sore throat, rhinitis)
- Reported symptom onset < 48 hours before time of presentation
- Positive influenza virus result via CLIA-waived point-of-care RIDT or PCR

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[1] https://www.cdc.gov/flu/professionals/diagnosis/table-nucleic-acid-detection.html
[2] https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm
Influenza Antiviral Medications: Summary for Clinicians | CDC

Exclusion criteria:
Any individual who meets **any** of the following criteria:

- Age < 5 years
- Pregnant or breastfeeding
- Renal dysfunction (based on individual's report or pharmacy records)
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than 2 weeks, HIV/AIDS)
- Long-term aspirin therapy in individuals younger than 19 years of age
- Antiviral agent for influenza prescribed currently or within the previous 2 weeks
- Any condition requiring home oxygen therapy
- Known hypersensitivity to all antiviral therapies for influenza and to any common component of the products.
- Receipt of FluMist within past 2 weeks
- Clinically unstable based on the clinical judgment of the pharmacist for any of the following criteria:
    - Acutely 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

All individuals who do not qualify for antiviral therapy dispensing under this protocol will be referred to a primary care provider or urgent/emergent treatment facility if clinically appropriate and in cases of high suspicion of false-negative result.

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

Oral **Oseltamivir** dosing:

- Adults: 75 mg twice a day x 5 days
- Children (current weight determined using pharmacy's scale) x 5 days**:**
    - **≤15 kg:** 30 mg twice a day
    - **>15 to 23 kg**: 45 mg twice a day
    - **>23 to 40 kg**: 60 mg twice a day
    - **> 40 kg**: 75 mg twice a day

Oral **Baloxavir** dosing:

- Adults and children 5 and older:
    - **<20 kg:** 2 mg/kg single dose
    - **≥20 kg to <80 kg:** single dose of 40 mg
    - **≥80 kg:** single dose of 80 mg

Inhaled **Zanamivir** dosing:

- Adults: 10 mg (two 5 mg inhalations) twice a day x 5 days
- Children 7 or older: 10 mg (two 5 mg inhalations) twice a day x 5 days

Adjunctive therapy may be useful for treatment of moderate to severe symptoms or control of high fever associated and should be considered as an adjunct to an appropriate antivirals.

- **Acetaminophen** PO; follow over the counter (OTC) dosing recommendations
- **Ibuprofen** PO; follow over the counter (OTC) dosing recommendations

PROCEDURES FOR INITIATION OF THERAPY

Perform CLIA-waived point-of-care test to determine presence of influenza virus:

- If positive: continue to evaluate with protocol
- If negative: refer patient to urgent care

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.

Assess for Relevant Medical and Social History

- Patient demographics and weight if <18 y/o using scale in pharmacy
- Medical history
- Relevant social history
- Current medications
- Allergies and hypersensitivities
- Onset and duration of flu-like symptoms

Medication Specific Contraindications and Precautions

- Known hypersensitivity to oseltamivir, zanamivir or baloxavir
- Underlying respiratory disease or asthma (zanamivir)
- Severe renal dysfunction (est. CrCl < 30 ml/min, oseltamavir)
- Fructose/sorbitol intolerance (oseltamivir)
- Patients allergic to milk protein (zanamivir)
- Under 12 years of age with underlying medical conditions (baloxavir)

PROCEDURES FOR MONITORING AND CONTINUATION OR ADJUSTMENT OF THERAPIES

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

- 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

All individuals tested under this protocol will receive counseling on:

- Influenza vaccination
- Appropriate self-care, including symptom control, hygiene, and infection control measures.
- Per CDC guidelines, people with acute influenza should stay home from work, school, or daycare until they are afebrile for 24 hours

Individuals receiving antiviral therapies under this protocol will also receive the following:

- 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
- Upon request, documentation for work/school absence

DOCUMENTATION

Pharmacist(s) will document via prescription record each person who is tested for influenza under this protocol, including:

- Documentation as required in 201 KAR 2:171 for the dispensing of prescription medication
- Documentation of the presenting signs and symptoms that warranted testing
- Documentation of parental consent for individuals under age 18
- Documentation of the manufacturer, lot, expiration date, and result of the CLIA-waived point-of-care test used to determine influenza status
- Documentation that the individual (or caregiver) received the education required by this protocol
- Documentation of clinical follow up as appropriate

NOTIFICATION

Pharmacist(s) shall ask all persons tested under this protocol for the name and contact information of a primary care provider. If an individual or parent/guardian 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, influenza 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 antiviral therapy 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.

GENERAL GOVERNMENT CABINET

Kentucky Board of Pharmacy

(New Administrative Regulation)

201 KAR 2:460. Non-Resident Pharmacy Applications and Exemptions.

RELATES TO: KRS 315.191(1)(a), (d), KRS 315.0351, 201 KAR 2:050

STATUTORY AUTHORITY: KRS 315.191(1)(a), (d)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a), (d) authorize the board to promulgate administrative regulations and issue and renew permits for all pharmacies and require all persons who engage in the practice of the profession of pharmacy for a Kentucky resident to hold an active Kentucky pharmacist license. This administrative regulation establishes the requirements to obtain a non-resident pharmacy permit to engage in the practice of pharmacy in the Commonwealth.

Section 1. Inspection Requirements.

(1) Each pharmacy shall provide to the Board and also maintain, in readily retrievable form, the record of a satisfactory inspection conducted within the previous twenty-four (24) month period by the licensing entity of the state where the pharmacy is located.

(2) If no such inspection record is readily available, the record of the satisfactory inspection conducted at the expense of the pharmacy within the previous twenty-four (24) months by a third party recognized by the Board to inspect may be accepted.

(3) If no such inspection has been performed within the previous twenty-four (24) months, the Board shall conduct or contract with a third party recognized by the Board to inspect the pharmacy, for which all costs shall be borne by the applicant.

Section 2. Pharmacist-in-Charge.

(1) The pharmacist-in-charge shall directly and timely respond to any lawful request for information from the Board or law enforcement authorities.

(2) The pharmacist-in-charge shall be responsible for receiving and maintaining publications distributed by the Board.

(3) The pharmacist-in-charge shall be responsible for answering the toll-free telephone service six days a week and a minimum of forty hours per week. The toll-free telephone number shall be present on the label of each prescription dispensed by the pharmacy to a Kentucky resident. If the pharmacist-in-charge is unavailable, a staff pharmacist with access to patient records may answer the call but the staff pharmacist shall notify the pharmacist-in-charge of the call and provide the pharmacist-in-charge with a callback number for the patient. If the staff pharmacist is unable to resolve the patient's question, the pharmacist-in-charge shall return the call of the patient within forty-eight hours.

Section 3. Exemptions.

(1) The Board may grant an exemption from the permitting requirements of this section to any nonresident pharmacy which limits its dispensing activity to isolated transactions.

(2) An isolated transaction is defined as a transaction in which dispensing is limited to an established patient of the dispensing pharmacy no more than three times per calendar year.

Section 4. Applications.

(1) A prerequisite for receiving a permit as an out-of-state pharmacy is that the facility must be in good standing in the state where it is located and submit evidence consisting of the following:

(a) a copy of a valid license, permit or registration issued by the regulatory or licensing agency of the state in which the pharmacy is located; and

(b) a letter from the regulatory or licensing agency of the state in which the pharmacy is located that certifies the pharmacy is compliant with the pharmacy laws of that state.

(2) Each applicant must disclose the following:

(a) names and license numbers of all pharmacists and pharmacist-managers dispensing prescription legend drugs to an ultimate user in Kentucky, the names and, if available, the license or registration numbers of all supportive personnel employed by the out-of-state pharmacy who assist pharmacists in such dispensing;

(b) names, locations, titles, social security number and date of birth of all principal corporate officers or members, if incorporated; and

(c) if the pharmacy is owned by a partnership or sole proprietorship, the name, location, title, social security number, and date of birth of any partner or owner of the pharmacy.

(d) A report containing this information shall be made on an annual basis and within thirty (30) days of each change for any principal office, pharmacist manager, corporate officer, partner, or owner of the pharmacy.

(3) Each non-resident pharmacy shall develop and provide the Board with a policy and procedure manual that sets forth:

(a) normal delivery protocols and times;

(b) the procedure to be followed if the patient's medication is not available at the out-of-state pharmacy, or if delivery will be delayed beyond normal delivery time;

(c) the procedure to be followed upon receipt of a prescription for an acute illness, which shall include a procedure for delivery of the medication to the patient from the out-of-state pharmacy at the earliest possible time, or an alternative that assures the patient the opportunity to obtain medication at the earliest possible time;

(d) the procedure to be followed when the out-of-state pharmacy is advised that the patient's medication has not been received within the normal delivery time and that the patient is out of medication and requires interim dosage until mail prescription drugs become available; and

(e) the procedure for shipping products pursuant to FDA approved and manufacturer guidelines.

(4) An applicant for an out-of-state pharmacy permit must designate a resident agent in Kentucky for service of process. Any such out-of-state pharmacy that does not so designate a resident agent shall be deemed to have appointed the Secretary of State of the State of Kentucky to be its true and lawful attorney upon whom process may be served. All legal process in any action or proceeding against such pharmacy arising from shipping, mailing or delivering prescription drugs in Kentucky shall be served on the resident agent. In addition, a copy of such service of process shall be mailed to the out-of-state pharmacy by certified mail, return receipt requested, at the address of the out-of-state pharmacy as designated on the registration form filed with the Board. Any out-of-state pharmacy which does not register in this State, shall be deemed to have consented to service of process on the Secretary of State as sufficient service.

(5) Any person who ships, mails, or delivers prescription drugs to Kentucky residents from more than one out-of-state pharmacy shall register each pharmacy separately.

(6) An out-of-state pharmacy shall report to the disciplinary action taken by another state or jurisdiction against the pharmacy or pharmacy staff within thirty days of final case resolution.

(7) An applicant shall submit photographs of the exterior of the pharmacy building and working areas.

(8) An out-of-state pharmacy that has not completed the application process and is not permitted by the Board may not advertise its services to residents of Kentucky.

(9) A person who engages in the practice of the profession of pharmacy for a Kentucky resident shall hold an active Kentucky pharmacist license except under Section 3 of this regulation.

GENERAL GOVERNMENT CABINET

Kentucky Board of Pharmacy

(Amendment)

201 KAR 2:030. License transfer and Non-Resident Pharmacist License.

RELATES TO: KRS 315.191(1)(c), (d), 315.210. KRS 315.050

STATUTORY AUTHORITY: KRS 218A.205(8), 315.191(1)(a), (c), (d), 315.210

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.210 authorizes the board to establish conditions for licensure by reciprocity. KRS 218A.205(8) requires the board to establish requirements for background checks for licensees. This administrative regulation establishes conditions, forms, and examination requirements for licensure by reciprocity and for licensure of non-resident pharmacists.

Section 1. Definitions.

(1) “Board” is defined by KRS 315.010(4).

(2) "License transfer" means a license to practice pharmacy in Kentucky issued by the board to a pharmacist licensed in another jurisdiction.

(3) "NABP" means the National Association of Boards of Pharmacy.

(4) “Non-Resident Pharmacist License” means a license issued by the Board to a pharmacist licensed and located in another jurisdiction to practice pharmacy to citizens in Kentucky.

Section 2. An application licensed in another jurisdiction shall be eligible for license transfer, if the:

(1) Requirements for licensure of the jurisdiction that granted his or her license met or exceeded Kentucky requirements for licensure when the license in the other jurisdiction was granted;

(2) Applicant holds in good standing, an active license to practice pharmacy;

(3) Applicant has:

(a) Completed and certified the NABP Preliminary Application for Transfer of Pharmacist License form; and

(b) Received an NABP Official Application for Transfer of Pharmacist License;

(4) Applicant is currently in good standing in the jurisdiction from which he or she has applied;

(5) Applicant has successfully completed an examination in jurisprudence;

(6) Applicant has submitted to a nation-wide criminal background investigation by means of fingerprint check by the Department of Kentucky State Police and the Federal Bureau of Investigation; and

(7) Applicant has submitted to a query to the National Practitioner Data Bank of the United States Department of Health and Human Services.

Section 3.

Required Information. An applicant shall provide the information required by the NABP Preliminary Application for Transfer of Pharmacist License form, including:

(1) Name, maiden, and other names used currently or previously;

(2) Address, telephone number;

(3) Date of birth;

(4) Social Security number;

(5) Citizenship;

(6) Sex;

(7) State of original license by examination, including:

(a) License number;

(b) Original date of issue;

(c) Current status of original licensure; and

(d) State for which license transfer is requested;

(8) Pharmacy education, including:

(a) Name and location of pharmacy school;

(b) Name of pharmacy degree;

(c) Date degree was received; and

(d) Other professional degrees, including the information specified by paragraphs (a) to (c) of this subsection;

(9) Whether the applicant has earned certification by the Foreign Pharmacy Graduate Examination Committee, and, if so, the examination equivalency number assigned;

(10) Total hours of practical experience as an intern prior to licensure as a pharmacist;

(11) States, dates, and results of pharmacist licensure examinations;

(12) Pharmacist licenses currently held, including issue date, expiration date, status, and any board action taken against the licensee;

(13) Practice and employment, including nonpharmacist employment, from the past three (3) years;

(14) Record of charges or convictions of any felony or misdemeanor offense, other than traffic offenses, and whether or not a sentence was imposed or suspended;

(15) Record of any surrender of a pharmacist license or registration issued by the federal government or any state controlled substance authority;

(16) Record of any pharmacist license revocation, suspension, restriction, termination, or other disciplinary action by any board of pharmacy or other state authority;

(17) Record of whether the pharmacist is currently under investigation or subject to disciplinary action by the licensing jurisdiction, federal Food and Drug Administration, federal Drug Enforcement Administration or any state drug enforcement authority for the violation of any state or federal pharmacy, liquor, or drug laws;

(18) Record of any condition or impairment, such as substance or alcohol abuse or dependency that in any way affects the pharmacist's ability to practice pharmacy in a safe and competent manner; and

(19) Record of any application for initial licensure, renewal licensure, or licensure by transfer that was denied by any licensing authority, whether in pharmacy or any other profession.

Section 4.

The board shall accept license transfer applications from jurisdictions that:

(1) Are an active member of the NABP; and

(2) Grant license transfers to pharmacists pursuant to conditions and requirements that are the equivalent of conditions and requirements established by the board.

Section 5. An applicant <u>for license transfer</u> shall take and pass the Multistate Pharmacy Jurisprudence Examination administered by the NABP.

Section 6. An applicant licensed in another jurisdiction shall be eligible for non-resident pharmacist license if the applicant:

(1) Holds in good standing an active license to practice pharmacy in any state;

(2) The applicant is issued a NABP Verify credential; and

(3) The applicant submits to a fingerprint-supported criminal record check by the Department of Kentucky State Police and the Federal Bureau of Investigation pursuant to KRS 218A.205(8).

Section 7. An applicant for non-resident pharmacist license shall be exempt from:

(1) The requirements for license transfer;

(2) The Multistate Pharmacy Jurisprudence Examination administered by NABP;

(3) Continuing Education requirements of Kentucky.

Section 8. A non-resident pharmacist licensee shall:

(1) Maintain participation in the NABP Verify Program;

(2) Submit an annual renewal of pharmacist license; and

(3) Pay the annual renewal of a pharmacist non-resident license fee specified by 201 KAR 2:050.

Section 9. The following acts are prohibited with the utilization of a non-resident pharmacist license:

(1) Engaging in the practice of pharmacy in Kentucky while:

(a) Residing in Kentucky; or

(b) Employed by a pharmacy located in Kentucky; and

(2) Serving as a pharmacist-in-charge of a Kentucky permitted resident or nonresident pharmacy.

~~Section 6.~~ Section 10.

~~Section 7.~~ Board Discretion.

(1)The Board maintains the discretion to deny an applicant a licensee if the applicant fails to demonstrate good mental health and moral character pursuant to KRS 315.050(1);

(2) The board may waive the provisions of section 9 during a declared state of emergency.

Section 12. Incorporation by Reference (1) The following material is incorporated by reference:

(a) "NABP Preliminary Application for Transfer of Pharmacist License", April 2018~~, is incorporated by reference~~.

(b)"Application for Non-Resident Pharmacist License," 01/2024.

(c) "Renewal Application for Non-Resident Pharmacist License," 01/2024.

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201 KAR 2:050. Licenses and permits; fees.

RELATES TO: KRS 218A.205(3)(g), 315.035(1), (2), (4), 315.0351(1), 315.036(1), 315.050(5), 315.060, 315.110, 315.120, 315.191, 315.402
STATUTORY AUTHORITY: KRS 218A.205(3)(g), 315.035(1), (2), (4), 315.036(1), 315.050(5), 315.060, 315.110(1), 315.120(4), 315.191(1)(i), 315.402(1)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(i) authorizes the board to assess reasonable fees for services rendered to perform its duties and responsibilities. This administrative regulation establishes reasonable fees for the board to perform all the functions for which it is responsible.

Section 1. The following fees shall be paid in connection with pharmacist examinations and licenses, pharmacy permits, intern certificates, and the issuance and renewal of licenses and permits:
(1) Application for initial pharmacist license - $150;
(2) Application and initial license for a pharmacist license by license transfer - $250;
(3) Annual renewal of a pharmacist license - ninety-five (95) dollars;
(4) Delinquent renewal penalty for a pharmacist license - ninety-five (95) dollars;
(5) Annual renewal of an inactive pharmacist license - ten (10) dollars;
(6) Pharmacy intern certificate valid six (6) years - twenty-five (25) dollars;
(7) Duplicate of original pharmacist license wall certificate - seventy-five (75) dollars;
(8) Application for a permit to operate a pharmacy - $150;
(9) Renewal of a permit to operate a pharmacy - $150;
(10) Delinquent renewal penalty for a permit to operate a pharmacy - $150 dollars;
(11) Change of location or change of ownership of a pharmacy or manufacturer permit - $150;
(12) Application for a permit to operate as a manufacturer - $150;
(13) Renewal of a permit to operate as a manufacturer - $150;
(14) Delinquent renewal penalty for a permit to operate as a manufacturer - $150;
(15) Change of location or change of ownership of a wholesale distributor license - $150;
(16) Application for a license to operate as a wholesale distributor -$150;
(17) Renewal of a license to operate as a wholesale distributor -$150;
(18) Delinquent renewal penalty for a license to operate as a wholesale distributor -$150; and
(19) Query to the National Practitioner Data Bank of the United States Department of Health and Human Services - twenty-five (25) dollars; ~~.~~
(20) Application for non-resident pharmacist license – fifty (50) dollars;
(21) Renewal for non-resident pharmacist license – fifty (50) dollars;
(22) Delinquent renewal penalty for non-resident pharmacist license – fifty (50) dollars.

Section 2. An applicant shall submit:
(1) An initial or renewal application for a pharmacy permit on either the:
(a)
1. Application for Permit to Operate a Pharmacy in Kentucky; or
2. Application for Resident Pharmacy Permit Renewal; or
(b)
1. Application for Non-Resident Pharmacy Permit; or
2. Application for Non-Resident Pharmacy Permit Renewal; and
(2) As appropriate, the:
(a) Initial application fee established by Section 1(8) of this administrative regulation; or
(b) Renewal fee established by Section 1(9) of this administrative regulation.

Section 3. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) "Application for Non-Resident Pharmacy Permit", Form 3, 01/2024 ~~9/2023~~;

(b) "Application for Non-Resident Pharmacy Permit Renewal", Form 4, 01/2024 ~~9/2023~~;

(c) "Application for Permit to Operate a Pharmacy in Kentucky", Form 1, 6/2023; and

(d) "Application for Resident Pharmacy Permit Renewal", Form 2, 6/2023.

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