PURPOSE
This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of medications for symptomatic relief of allergic rhinitis.

PHARMACIST EDUCATION AND TRAINING
Prior to initiating the dispensing of allergic rhinitis therapies under this protocol, pharmacist(s) must have received education and training in the treatment of allergic rhinitis from 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 allergic rhinitis therapies will follow the most current practice guidelines for allergic rhinitis treatment.¹

Inclusion criteria:

• Any individual, 12 years or older, who currently presents with one or more symptoms of allergic rhinitis:
  o nasal congestion
  o clear rhinorrhea
  o sneezing
  o itchy nose

Exclusion criteria:

• Individuals who are pregnant or lactating
• Children under 12 years of age
• Individuals presenting with any of the following:
  o Severe persistent allergic rhinitis
  o Symptoms of undiagnosed or uncontrolled asthma
    ▪ Prolonged expiration and diffuse wheezing

- Cough
- Difficulty breathing
- Symptoms associated with sinusitis
  - Purulent discharge
  - Facial pain
  - Fever
- Symptoms usually not associated with allergic rhinitis:
  - Loss of smell
  - Nasal obstruction without discharge or unilateral obstruction
  - Posterior discharge
  - Malaise
- Earache
- Recurrent epistaxis

**MEDICATIONS**
This protocol authorizes pharmacist(s) to initiate the dispensing of any medication approved by the FDA for treatment of allergic rhinitis or upper respiratory allergies included in the therapeutic classes listed below using the drugs and doses provided in the attached medication guide. Sufficient quantities to provide up to a 30-day supply of medication may be dispensed.

- Intranasal corticosteroids (INCS)
- Intranasal antihistamines
- Second generation oral antihistamines
- Oral decongestants
- Combination second generation oral antihistamines and decongestants

**PROCEDURES FOR INITIATION OF THERAPY**
Allergic rhinitis therapy initiation will follow current guidelines\(^1\) and will be individualized based on relevant medical and social history, patient preferences, and consideration of contraindications and precautions of therapy as outlined below and in the attached medication guide.

**Relevant Medical and Social History**

- Past medical history
- Current medications
- Allergies and hypersensitivities

**Contraindications Precautions (see medication guide for details)**

- Known hypersensitivity
- Concurrent MAOI therapy
• Cardiovascular disease
• Uncontrolled hypertension
• Urinary retention
• Glaucoma
• Geriatrics

PROCEDURES FOR MONITORING AND CONTINUATION OR ADJUSTMENT OF THERAPIES
Follow-up monitoring and evaluation to determine effectiveness, adverse effects, and patient progress with therapy is required if therapy is to continue following the initial dispensation. If follow-up monitoring and evaluation indicates therapy continuation is warranted, medication refills may be authorized.

Should follow-up evaluation and monitoring indicate an adjustment in therapy 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 allergic rhinitis therapies under the protocol will receive education regarding:

1. Nonpharmacologic recommendations to reduce allergic response.
2. Education specific to the individual medication(s) dispensed.

DOCUMENTATION
Pharmacist(s) shall document via prescription record each person who receives allergic rhinitis therapies under this protocol, including:

1. Documentation as required in 201 KAR 2:170 for the dispensing of prescription medication; and
2. Documentation that the individual receiving the allergic rhinitis therapy (or caregiver) was provided with the required education pursuant to this protocol
3. 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 allergic rhinitis therapies 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 have allergic rhinitis therapies 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 allergic rhinitis therapies 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 require prior notice to all parties of no less than sixty (60) days.

**SIGNATURES**

______________________________  _______________________
Prescriber Name                Date

______________________________
Prescriber Signature

______________________________  _______________________
Pharmacist Name                Date

______________________________
Pharmacist Signature
<table>
<thead>
<tr>
<th>Drug class</th>
<th>Generic</th>
<th>Brand</th>
<th>Formulation(s)</th>
<th>Indication</th>
<th>Dosage(s)</th>
<th>Pediatric dose</th>
<th>AEs (frequent and/or clinically significant)</th>
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<tr>
<td>Intranasal Corticosteroids (INCS)</td>
<td>Budesonide</td>
<td>Rhinocort</td>
<td>nasal solution</td>
<td>allergy symptoms</td>
<td>Allergic rhinitis: Intranasal: One spray (32 mcg) in each nostril once daily (total daily dose: 64 mcg/day). Some patients who do not achieve adequate control may benefit from increased dosage. A reduced dosage may be effective after initial control is achieved (maximum dose: 4 sprays [128 mcg] in each nostril once daily [total daily dose: 256 mcg/day]).</td>
<td>Allergic rhinitis (Rx): Children ≥12 years and Adolescents: Refer to adult dosing.</td>
<td>headache, dry nose, epistaxis, bitter taste</td>
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<td></td>
<td>Fluticasone Propionate</td>
<td>Flonase; Flonase Allergy relief</td>
<td>nasal solution</td>
<td>allergy symptoms</td>
<td>Upper respiratory allergies (OTC): Intranasal: ClarSpray, Flonase Allergy Relief, Good Sense Nasiflow (fluticasone propionate): Initial: Two sprays (50 mcg/spray) per nostril once daily (200 mcg/day); after 3 weeks, may adjust to 1 or 2 sprays per nostril once daily (100 to 200 mcg/day). Do not use for more than 6 months unless instructed by health care provider.</td>
<td>Children ≥12 years and Adolescents: Refer to adult dosing.</td>
<td>headache, dry nose, epistaxis, bitter taste</td>
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<td></td>
<td>Fluticasone Furoate</td>
<td>Flonase Sensimist</td>
<td>nasal solution</td>
<td>allergy symptoms</td>
<td>Initial: Two sprays (27.5 mcg/spray) per nostril once daily (110 mcg/day); after 1 week, may adjust to 1 or 2 sprays per nostril once daily (55 to 110 mcg/day). Do not use for more than 6 months unless instructed by healthcare provider.</td>
<td>Children ≥12 years and Adolescents: Refer to adult dosing.</td>
<td>headache, dry nose, epistaxis, bitter taste</td>
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<td></td>
<td>Flunisolide (Rx only)</td>
<td>Apo-Flunisolide, Nasalide, Rhinalar</td>
<td>nasal solution</td>
<td>allergy symptoms</td>
<td>Intranasal: Two sprays (50 mcg) in each nostril twice daily (total daily dose: 200 mcg/day); may increase to 2 sprays in each nostril 3 times daily (total daily dose: 300 mcg/day); maximum: 8 sprays/day in each nostril (total daily dose: 400 mcg/day);</td>
<td>Children and Adolescents 6 to 14 years: One spray (25 mcg) in each nostril 3 times daily or 2 sprays (50 mcg) in each nostril twice daily; not to exceed 4 sprays/day in each nostril (total daily dose: 200 mcg/day); Adolescents ≥15 years: Refer to adult dosing.</td>
<td>headache, dry nose, epistaxis, bitter taste</td>
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<td></td>
<td>Mometasone Furoate</td>
<td>Nasonex</td>
<td>nasal solution</td>
<td>allergy symptoms</td>
<td>Allergic rhinitis (seasonal and perennial): Intranasal: 2 sprays (100 mcg) in each nostril once daily (total daily dose: 200 mcg); Nasal congestion associated with seasonal rhinitis: Intranasal: 2 sprays (100 mcg) in each nostril once daily (total daily dose: 200 mcg); Seasonal allergic rhinitis (prophylaxis): Intranasal: 2 sprays (100 mcg) in each nostril once daily (total daily dose: 200 mcg); treatment should begin 2 to 4 weeks prior to the anticipated start of pollen season. Rhinosinusitis, adjunctive treatment [acute] (off-label use): Intranasal: Intranasal corticosteroids such as mometasone are recommended by IDSA and AAO-HNS guidelines but no specific dosing recommendations are made. Alternatively, the following dosing recommendations have been made: 2 sprays (100 mcg) in each nostril twice daily (total daily dose: 400 mcg); if inadequate symptom control, may increase to 4 sprays (200 mcg) in each nostril twice daily (total daily dose: 800 mcg) (Nasonex Canadian product labeling 2013).</td>
<td>Allergic rhinitis [seasonal and perennial]: Intranasal: Children ≥12 years and Adolescents: Refer to adult dosing.</td>
<td>Seasonal allergic rhinitis [prophylaxis]: Intranasal: Children ≥12 years and Adolescents: Refer to adult dosing.</td>
<td>headache, dry nose, epistaxis, bitter taste</td>
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<td></td>
<td>Ciclesonide (Rx only)</td>
<td>Omnaris</td>
<td>nasal solution</td>
<td>allergy symptoms</td>
<td>Two sprays (50 mcg/spray) per nostril once daily; maximum: 200 mcg/day</td>
<td>Children ≥6 years and Adolescents: Refer to adult dosing.</td>
<td>headache, dry nose, epistaxis, bitter taste</td>
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<td></td>
<td>Beclomethasone Dipropionate (Rx only)</td>
<td>Qnasl</td>
<td>nasal solution</td>
<td>allergy symptoms</td>
<td>Inhalation, nasal: Qnasl 80 mcg: Two inhalations (160 mcg) in each nostril once daily (maximum: 2 sprays [310 mcg] in each nostril once daily).</td>
<td>Children ≥12 years and Adolescents: Qnasl 80 mcg: Refer to adult dosing.</td>
<td>headache, dry nose, epistaxis, bitter taste</td>
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<td>Triamcinolone Acetonide</td>
<td>Nasacort Allergy</td>
<td>nasal solution</td>
<td>allergy symptoms</td>
<td>Two sprays (110 mcg) in each nostril once daily; once symptoms controlled reduce to 1 spray (55 mcg) in each nostril once daily (maximum: 2 sprays [310 mcg] in each nostril once daily). Discontinue therapy if adequate symptomatic relief is not observed within 3 weeks (1 week for OTC use).</td>
<td>Children ≥12 years and Adolescents: Refer to adult dosing.</td>
<td>headache, dry nose, epistaxis, bitter taste</td>
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</table>
## Medication Guide

<table>
<thead>
<tr>
<th>Drug class</th>
<th>Generic</th>
<th>Brand</th>
<th>Formulation(s)</th>
<th>Indication</th>
<th>Dosage(s)</th>
<th>Pediatric dose</th>
<th>ADEs (frequent and/or clinically significant)</th>
<th>Contraindications</th>
<th>Notes</th>
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<tr>
<td><strong>Intranasal Antihistamine</strong></td>
<td>Azelastine (Rx only)</td>
<td>Astelin, Astepro</td>
<td>nasal solution</td>
<td>rhinitis</td>
<td>Perennial allergic rhinitis: Intranasal: Astepro (0.15% solution): Two sprays in each nostril twice daily. Seasonal allergic rhinitis: Intranasal: Astepro (0.1% or 0.15% solution): One or two sprays (0.1% solution) in each nostril twice daily or two sprays (0.15% solution) in each nostril once daily. Azelastine [generic] 0.1% solution: One or two sprays in each nostril twice daily</td>
<td>Perennial allergic rhinitis: Intranasal: Astepro: Children ≥12 years and Adolescents: Refer to adult dosing. Seasonal allergic rhinitis: Intranasal: Astepro: Children ≥12 years and Adolescents: Refer to adult dosing. Azelastine [generic] 0.1% solution: Children ≥12 years and Adolescents: Refer to adult dosing.</td>
<td>bitter taste, headache, drowsiness, rhinitis exacerbation</td>
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<td></td>
<td>Olopatadine (Rx only)</td>
<td>Patanase</td>
<td>nasal solution</td>
<td>rhinitis</td>
<td>Intranasal: 2 sprays into each nostril twice daily</td>
<td>Children ≥12 years: refer to adult dose</td>
<td>bitter taste, epistaxis, nasal mucosa ulcer</td>
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<td>Fexofenadine</td>
<td>Allegra, Mucinex Allergy</td>
<td>suspension, tablet</td>
<td>rhinitis</td>
<td>Twice daily formulations: 60 mg every 12 hours (maximum: 120 mg/day) Once daily formulations: 180 mg once daily (maximum: 180 mg/day)</td>
<td>Children ≥12 years and Adolescents: Refer to adult dosing.</td>
<td>Anticholinergic effects (dry mouth, blurred vision, urinary retention, constipation)</td>
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<td>Take with water (not juice due to decreased absorption); avoid administration with aluminum or magnesium-containing products.</td>
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<td></td>
<td>Loratadine</td>
<td>Alavert, Claritin</td>
<td>tablet, capsule, solution, syrup</td>
<td>rhinitis</td>
<td>Oral: 10 mg daily once daily or 5 mg twice daily [RediTabs]</td>
<td>Children 6 years: Refer to adult dosing.</td>
<td>Anticholinergic effects (dry mouth, blurred vision, urinary retention, constipation)</td>
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<td></td>
<td>Desloratadine (Rx only)</td>
<td>Clarinex</td>
<td>tablet, syrup</td>
<td>rhinitis</td>
<td>Oral: 5 mg once daily</td>
<td>Perennial allergic rhinitis, chronic idiopathic urticaria: Oral: Children ≥12 years and Adolescents: Refer to adult dosing. Seasonal allergic rhinitis: Oral: Children ≥12 years and Adolescents: Refer to adult dosing.</td>
<td>Anticholinergic effects (dry mouth, blurred vision, urinary retention, constipation)</td>
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<tr>
<td></td>
<td>Cetirizine</td>
<td>Zyrtec</td>
<td>capsule, tablet, solution, syrup</td>
<td>rhinitis</td>
<td>Oral: 5 to 10 mg once daily, depending upon symptom severity (maximum dose: 10 mg daily)</td>
<td>Children 6 years and Adolescents: Refer to adult dosing.</td>
<td>Anticholinergic effects (dry mouth, blurred vision, urinary retention, constipation)</td>
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<td></td>
<td>Levocetirizine</td>
<td>Xyzal</td>
<td>tablet, solution</td>
<td>rhinitis</td>
<td>Oral: 5 mg once daily [in the evening]; some patients with less severe symptoms may experience relief with 2.5 mg once daily; maximum dose: 5 mg/day</td>
<td>Allergic rhinitis (OTC only): Oral: Children ≥12 years and Adolescents: Refer to adult dosing.</td>
<td>Anticholinergic effects (dry mouth, blurred vision, urinary retention, constipation)</td>
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<tr>
<td><strong>Oral Antihistamine</strong></td>
<td>Phenylephrine</td>
<td>Sudafed PE</td>
<td>Tablet, solution</td>
<td>nasal congestion</td>
<td>10 mg every 4 hours as needed (maximum: 60 mg/24 hours)</td>
<td>≥12 years: Refer to adult dosing</td>
<td>tachycardia, increased BP, anxiety, insomnia, dizziness</td>
<td>Use with or within 14 days of MAO inhibitor therapy</td>
<td>Phenylephrine has low bioavailability (~38%). Use with caution in patients with cardiovascular disease and uncontrolled hypertension.</td>
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<tr>
<td></td>
<td>Pseudoephedrine</td>
<td>Sudafed, Nexafed</td>
<td>Tablet, syrup</td>
<td>nasal congestion</td>
<td>Immediate release: 60 mg every 4 to 6 hours; Extended release: 120 mg every 12 hours or 240 mg every 24 hours; maximum: 240 mg per 24 hours</td>
<td>≥12 years and Adolescents: Refer to adult dosing</td>
<td>tachycardia, increased BP, anxiety, insomnia, dizziness</td>
<td>When used for self-medication: Use with or within 14 days of MAO inhibitor therapy</td>
<td>Use with caution in patients with cardiovascular disease and uncontrolled hypertension</td>
</tr>
<tr>
<td>Drug class</td>
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<tr>
<td>2nd Generation Antihistamine/Pseudoephedrine Combination Products</td>
<td>Cetirizine/Pseudoephedrine</td>
<td>Zyrtec D</td>
<td>Tablet</td>
<td>Upper Respiratory Allergies</td>
<td>One tablet (cetirizine 5 mg/pseudoephedrine 120 mg) twice daily (maximum: 2 tablets)</td>
<td>Children ≥12 years and Adolescents: Refer to adult dosing.</td>
<td>Anticholinergic effects (dry mouth, blurred vision, urinary retention, constipation), tachycardia, increased BP, anxiety, insomnia, dizziness</td>
<td>When used for self-medication: Use with or within 14 days of MAO inhibitor therapy</td>
<td>Use with caution in patients with cardiovascular disease and uncontrolled hypertension</td>
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<tr>
<td>Fexofenadine/Pseudoephedrine</td>
<td>Allegra D</td>
<td>Tablet</td>
<td>Seasonal Allergic Rhinitis</td>
<td>Fexofenadine 60 mg/pseudoephedrine 120 mg 12 Hour: One tablet twice daily. Fexofenadine 180 mg/pseudoephedrine 240 mg 24 Hour: One tablet once daily.</td>
<td>Children ≥12 years and Adolescents: Refer to adult dosing.</td>
<td>Anticholinergic effects (dry mouth, blurred vision, urinary retention, constipation), tachycardia, increased BP, anxiety, insomnia, dizziness</td>
<td>When used for self-medication: Use with or within 14 days of MAO inhibitor therapy</td>
<td>Use with caution in patients with cardiovascular disease and uncontrolled hypertension</td>
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<tr>
<td>Loratadine/Pseudoephedrine</td>
<td>Claritin D</td>
<td>Tablet</td>
<td>Allergy symptoms</td>
<td>Loratadine 5 mg/pseudoephedrine 120 mg per tablet: One tablet every 12 hours. Loratadine 10 mg/pseudoephedrine 240 mg per tablet: One tablet daily (maximum: 1 tablet/day) (maximum: 2 tablets/day).</td>
<td>Children ≥12 years and Adolescents: Refer to adult dosing.</td>
<td>Anticholinergic effects (dry mouth, blurred vision, urinary retention, constipation), tachycardia, increased BP, anxiety, insomnia, dizziness</td>
<td>When used for self-medication: Use with or within 14 days of MAO inhibitor therapy</td>
<td>Use with caution in patients with cardiovascular disease and uncontrolled hypertension</td>
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<tr>
<td>Desloratadine/Pseudoephedrine</td>
<td>Clarinex D</td>
<td>Tablet</td>
<td>Seasonal or Allergic Rhinitis</td>
<td>Desloratadine 2.5 mg/pseudoephedrine 120 mg every 12 hours; Maximum: Desloratadine 5 mg/pseudoephedrine 240 mg daily</td>
<td>Children ≥12 years and Adolescents: Refer to adult dosing.</td>
<td>Anticholinergic effects (dry mouth, blurred vision, urinary retention, constipation), tachycardia, increased BP, anxiety, insomnia, dizziness</td>
<td>When used for self-medication: Use with or within 14 days of MAO inhibitor therapy</td>
<td>Use with caution in patients with cardiovascular disease and uncontrolled hypertension</td>
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References: