I. Purpose
The purpose of this protocol is to reduce tobacco-related morbidity and mortality in Arkansas by allowing Arkansas-licensed pharmacists to initiate nicotine replacement therapy (NRT) including ordering, dispensing, and/or administering NRT products, along with any necessary supplies for administration, to persons eligible to receive NRT.

II. Authority
This protocol is issued pursuant to Act 651 of 2019 (HB 1263) (Arkansas Code § 17-92-101) to authorize licensed pharmacists in Arkansas to order, dispense, and/or administer all FDA-approved NRT products according to the provisions of Arkansas Code § 17-92-101(16) and the requirements of this protocol. Pharmacists may continue to provide over-the-counter smoking cessation products without use of this protocol.

III. Initial Patient Screening
When a patient requests NRT or when a pharmacist, in his or her professional judgement, decides to initiate smoking cessation treatment and counseling, the pharmacist shall assess, at a minimum, the following patient criteria in determining the appropriate therapy to initiate:

- Current tobacco use and prior attempts to quit
- Medical and social history, including current medications
- Allergies / hypersensitivities
- Precautions of potential medication treatments
- Patient preferences regarding treatment options
- Ask the patient the following screening questions:
  - Are you pregnant or plan to become pregnant?
    - If yes, do not furnish NRT and refer to appropriate health care provider
  - Have you had a heart attack within the last 2 weeks?
    - If yes, furnish NRT with caution and refer to appropriate healthcare provider
  - Do you have any history of heart palpitations, irregular heartbeats, or have you been diagnosed with a serious arrhythmia?
    - If yes, furnish NRT with caution and refer to appropriate healthcare provider
  - Do you currently experience frequent chest pain or have you been diagnosed with unstable angina?
    - If yes, furnish NRT with caution and refer to appropriate healthcare provider
  - Do you have any history of allergic rhinitis (e.g., nasal allergies)?
    - If yes, avoid nasal spray
  - Have you been diagnosed with temporal mandibular joint (TMJ) dysfunction?
    - If yes, avoid nicotine gum
IV. Precautions/Contraindications
The pharmacist shall assess the patient for the following precautions/contraindications and, if any identified, the pharmacist is authorized to dispense at the professional discretion of the pharmacist only if the patient has identified a primary care provider with whom the pharmacist has conferred prior to dispensing.

- Recent history of myocardial infarction (within 14 days)
- Known serious cardiac arrhythmia, unstable or severe angina
- Known moderate/severe hepatic or renal impairment

NRT initiation will be individualized based on relevant medical and social history obtained and patient preferences, involving consideration of contraindications and precautions of therapy as outlined in Appendix 1.

V. Dispensing Guidelines
A. Medications Authorized
This protocol authorizes Arkansas-licensed pharmacists, upon assessment of the patient and determination that a nicotine replacement smoking cessation product is appropriate, to initiate dispensing of NRT products (alone or in combination) as provided in Appendix 1 or from FDA approved product labeling.

NRT Product Selection: The pharmacist, in consultation with the patient, may select any NRT product (alone or in combination) from all FDA approved NRT products including by not limited to the list of therapies either specified in this protocol in Appendix 1 or from FDA approved product labeling. Generic equivalent products may be furnished.

B. Patient Education and Follow-Up
Follow-up monitoring and evaluation shall occur at a minimum of every four weeks to determine effectiveness, adverse effects, and patient progress with therapy. If follow-up monitoring and evaluation indicates therapy continuation is warranted, medication refills may be authorized as appropriate. Should follow-up evaluation and monitoring indicate an adjustment in therapy is warranted, all procedures as outlined for initiation of therapy, including education, documentation, and notification, shall be followed.

Patients receiving NRT under this protocol shall receive education regarding:

- Motivation to cease tobacco use
- Drug information related to the specific dosage form dispensed, including directions for use and adverse effects
- Nicotine withdrawal symptoms
- Lifestyle modifications
- Techniques to prevent relapse
C. Labeling
A prescription label shall be affixed to the nicotine replacement product dispensed.

D. Records
Pharmacists shall document in the patient medication record the dispensing of NRT products.

E. Prescriber Notification
Within a reasonable amount of time, the pharmacist shall provide notification to the patient’s primary care provider of the NRT product dispensed to the patient under the protocol. If a patient does not identify a primary care provider, the pharmacist shall provide the patient with a written record of the dispensing and refer the patient to consult an appropriate health care professional of the patient’s choice.
# NICOTINE REPLACEMENT THERAPY

## STATEWIDE PROTOCOL
Arkansas State Board of Pharmacy

**Appendix 1**: Pharmacologic Product Guide of FDA-Approved NRT Products

## Nicotine Replacement Therapy (NRT) Formulations

<table>
<thead>
<tr>
<th>Product</th>
<th>Gum</th>
<th>Lozenge</th>
<th>Oral Inhaler</th>
<th>Nasal Spray</th>
<th>Transdermal Patch</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicorette, Zonnic, Generic OTC</td>
<td>Nicorette Lozenge, Nicorette Mini Lozenge,</td>
<td>Nicotrol Inhaler Rx 10 mg cartridge</td>
<td>Nicotrol NS Rx Metered spray 10 mg/mL aqueous solution</td>
<td>NicoDerm CQ, Generic OTC (NicoDerm CQ, generic) 7 mg, 14 mg, 21 mg (24-hr release)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Generic OTC 2 mg, 4 mg</td>
<td>Delivers 4 mg inhaled vapor</td>
<td>Rx</td>
<td>Rx (generic)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>original, cinnamon, fruit, mint</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

## Precautions

- Recent (<2 weeks) myocardial infarction
- Serious underlying arrhythmias
- Serious / worsening angina pectoris
- Temporomandibular joint disease
- Pregnancy / breastfeeding
- Adolescents (<18 years)

## Duration

- 3–6 months
- 1–2 doses/hour (8-40 doses/day)
- One dose = 2 sprays (one in each nostril)
- Each spray delivers 0.5 mg of nicotine to the nasal mucosa

## NRT: immediate release

- 1st cigarette ≤30 minutes after waking: 4 mg
- 1st cigarette >30 minutes after waking: 2 mg
- Weeks 1–6: 1 piece q 1–2 hours
- Weeks 7–9: 1 piece q 2–4 hours
- Weeks 10–12: 1 piece q 4–8 hours
- Max: 24 pieces/day
- Chew each piece slowly
- Park between cheek & gum when peppery / tingling sensation appears (~15 – 30 chews)
- Resume chewing when tingle fades
- Repeat chew/park steps until most of the nicotine is gone (tingle does not return; ~30 minutes)
- Park in different areas of mouth
- No food or beverages 15 minutes before or during use
- Duration: up to 12 weeks

## NRT: sustained release

- >10 cigarettes/day
- 21 mg/day x 4–6 weeks
- 14 mg/day x 2 weeks
- 7 mg/day x 2 weeks
- <10 cigarettes/day
- 14 mg/day x 6 weeks
- 7 mg/day x 2 weeks

- Rotate patch application site daily
- Do not apply a new patch to the same skin site for at least one week
- May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime)
- Duration: 8–10 weeks

(continued on page 5)
**Appendix 1** *(continued)*

<table>
<thead>
<tr>
<th>Nicotine Replacement Therapy (NRT) Formulations <em>(continued)</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Gum</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td><strong>Adverse Effects</strong></td>
</tr>
<tr>
<td>● Mouth/jaw soreness</td>
</tr>
<tr>
<td>● Hiccups</td>
</tr>
<tr>
<td>● Dyspepsia</td>
</tr>
<tr>
<td>● Hypersalivation</td>
</tr>
<tr>
<td>● Effects associated with incorrect chewing technique:</td>
</tr>
<tr>
<td>– lightheadedness</td>
</tr>
<tr>
<td>– nausea/vomiting</td>
</tr>
<tr>
<td>– throat &amp; mouth irritation</td>
</tr>
<tr>
<td><strong>Advantages</strong></td>
</tr>
<tr>
<td>● Might serve as an oral substitute for tobacco</td>
</tr>
<tr>
<td>● Might delay weight gain</td>
</tr>
<tr>
<td>● Can be used in combination with other agents to manage situational urges</td>
</tr>
<tr>
<td><strong>Disadvantages</strong></td>
</tr>
<tr>
<td>● Need for frequent dosing can compromise adherence</td>
</tr>
<tr>
<td>● Might be problematic for patients with significant dental work</td>
</tr>
<tr>
<td>● Proper chewing technique is necessary for effectiveness &amp; to minimize adverse effects</td>
</tr>
<tr>
<td>● Gum chewing might not be acceptable or desirable for some patients</td>
</tr>
</tbody>
</table>

*This protocol authorizes licensed pharmacists in Arkansas to order, dispense, and/or administer all FDA-approved NRT products either specified in this protocol or according to indications, dosing and contraindications of FDA approved package labeling.*