§1746.2 Protocol for Pharmacists Furnishing Nicotine Replacement Products

(a) A pharmacist furnishing nicotine replacement products pursuant to Section 4052.9 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Nicotine Replacement Products

(1) Authority: section 4052.9(a) of the California Business and Professions Code authorizes a pharmacist to furnish nicotine replacement products approved by the federal Food and Drug Administration for use by prescription only in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to nicotine replacement products and to ensure that the patient receives information to appropriately initiate smoking cessation medication therapy.

(3) Explanation of Products Covered: Prescription nicotine replacement products approved by the federal Food and Drug Administration and provided by a pharmacist for smoking cessation are covered under this protocol. Pharmacists may continue to provide over-the-counter smoking cessation products without use of this protocol.

(4) Procedure: When a patient requests nicotine replacement therapy or other smoking cessation medication, or when a pharmacist in his or her professional judgment decides to initiate smoking cessation treatment and counseling, the pharmacist shall complete the following steps:

(A) Review the patient’s current tobacco use and past quit attempts.
(B) Ask the patient the following screening questions:
   (i) Are you pregnant or plan to become pregnant? (If yes, do not furnish and refer to an appropriate health care provider)
   (ii) Have you had a heart attack within the last 2 weeks? (If yes, furnish with caution and refer to an appropriate health care provider)
   (iii) Do you have any history of heart palpitations, irregular heartbeats, or have you been diagnosed with a serious arrhythmia? (If yes, furnish with caution and refer to an appropriate health care provider)
   (iv) Do you currently experience frequent chest pain or have you been diagnosed with unstable angina? (If yes, furnish with caution and refer to an appropriate health care provider)
   (v) Do you have any history of allergic rhinitis (e.g., nasal allergies)? (If yes, avoid nasal spray)
   (vi) Have you been diagnosed with temporal mandibular joint (TMJ) dysfunction? (If yes, avoid nicotine gum)

These screening questions shall be made available in alternate languages for patients whose primary language is not English.

(C) When a nicotine replacement product is furnished:
   (i) The pharmacist shall review the instructions for use with every patient using a nicotine replacement product.
(ii) Pharmacists should recommend the patient seek additional assistance for behavior change, including but not limited to the California Smokers’ Helpline (1-800-NO-BUTTS), web-based programs (e.g., http://smokefree.gov), apps, and local cessation programs.

(D) The pharmacist shall answer any questions the patient may have regarding smoking cessation therapy and/or nicotine replacement products.

(5) Product Selection: The pharmacist, in consultation with the patient, may select any nicotine replacement product (alone or in combination) from the list of therapies specified in this protocol in the Table “Nicotine Replacement Therapy Medications for Smoking Cessation.” This list shall be kept current and maintained in the pharmacy or health care facility, and shall be available on the Board of Pharmacy’s website.

Generic equivalent products may be furnished.

(6) Notifications: The pharmacist shall notify the patient’s primary care provider of any prescription drug(s) and/or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the prescription drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient’s choice.

(7) Documentation: Each nicotine replacement product provided for smoking cessation and furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. A patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility’s normal operating hours.

(8) Training: Prior to furnishing prescription nicotine replacement products, pharmacists who participate in this protocol must have completed a minimum of two hours of an approved continuing education program specific to smoking cessation therapy and nicotine replacement therapy, or an equivalent curriculum-based training program completed within the last two years in an accredited California school of pharmacy.

Additionally, pharmacists who participate in this protocol must complete ongoing continuing education focused on smoking cessation therapy from an approved provider once every two years.

(9) Patient Privacy: All pharmacists furnishing nicotine replacement products in a pharmacy or health care facility shall operate under the pharmacy’s or facility’s policies and procedures to ensure that patient confidentiality and privacy are maintained.
**NICOTINE REPLACEMENT THERAPY MEDICATIONS FOR SMOKING CESSATION**

**NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS USED AS MONOTHERAPY**

<table>
<thead>
<tr>
<th>GUM</th>
<th>LOZENGE</th>
<th>PATCH</th>
<th>NASAL SPRAY</th>
<th>INHALER</th>
<th>COMBINATION NRT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicorette, Generic OTC 2 mg, 4 mg original, cinnamon, nut, mint</td>
<td>Nicorette Lozenge, Generic OTC 2 mg, 4 mg cherry, mint</td>
<td>Nicoderm CO, Generic OTC (Nicoderm CO, generic) 7 mg, 14 mg, 21 mg (24-hour release)</td>
<td>Nicotrol NSP Rx Metered spray 0.5 mg nicotine in 50 mL aqueous nicotine solution</td>
<td>Nicotrol Inhaler Rx 10 mg cartridge delivers 0.5 mg inhaled nicotine vapor</td>
<td>Combinations with demonstrated efficacy Nicotine patch + nicotine gum Nicotine patch + nicotine lozenge Nicotine patch + nicotine nasal spray Nicotine patch + nicotine oral inhaler</td>
</tr>
</tbody>
</table>

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

**Dosage**
- **1st cigarette ≤30 minutes after waking:**
  - 4 mg
  - 2 mg

  - Weeks 1-6: 1 piece q 1-2 hours
  - Weeks 7-12: 1 piece q 2-4 hours
  - Weeks 10-12: 1 piece q 4-6 hours

- Maximum, 24 pieces/day
- Chew each piece slowly
- Park between cheek and gum when property of frizzling sensation appears (~15-30 cheeks)
- Resume chewing when tingle fades
- Repeat chew/park steps until most of the nicotine is gone (long does not return, generally 30 min)
- Park in different areas of mouth
- No food or beverages 15 minutes before or during use
- Duration: up to 12 weeks

- **1st cigarette >30 minutes after waking:**
  - 2 mg

  - Weeks 1-6: 1 lozenge q 1-2 hours
  - Weeks 7-12: 1 lozenge q 2-4 hours
  - Weeks 10-12: 1 lozenge q 4-6 hours

- Maximum, 20 lozenges/day
- Allow to dissolve slowly (20-30 minutes for standard; 10 minutes for mini)
- Nicotine release may cause a warm, frizzling sensation
- Do not chew or swallow
- Occasionally rotate to different areas of the mouth
- No food or beverages 15 minutes before or during use
- Duration: up to 12 weeks

- **>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

- May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime)
- Duration: 8-10 weeks

- **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
- Maximum: 10-40 doses/day
- For best results, initial use at least 8 doses/day
- Do not sniff, swallow or inhale through the nose as the spray is being administered
- Duration: 3-6 months

- **6-16 cartridges/day:**
  - Individualize dosing, initially use 1 cartridge q 1-2 hours
  - Best effects with continuous puffing for 20 minutes
  - Initially use at least 6 cartridges/day
  - Nicotine in cartridge is depleted after 20 minutes of active puffing
  - Inhalate into back of throat or puff in short breaths
  - Do NOT inhale into the lungs (like a cigarette) but "puff" as if lighting a pipe
  - Open cartridge retains potency for 24 hours
  - No food or beverages 15 minutes before or during use
  - Duration: 3-6 months

- **Short-acting NRT: to prevent onset of severe withdrawal symptoms**
  - Nicotine patch
  - 21 mg/day x 4-6 weeks
  - 14 mg/day x 2 weeks
  - 7 mg/day x 2 weeks

  **Plus**
  - Nicotine lozenge
  - 1 lozenge q 1-2 hours as needed
  - Nicotine nasal spray
  - 1 spray in each nostril q 1-2 hours as needed
  - Nicotine inhaler
  - 1 cartridge q 1-2 hours as needed
<table>
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<tr>
<th>NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS USED AS MONOTHERAPY</th>
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<tbody>
<tr>
<td><strong>GUM</strong></td>
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<td>Mouthdryness</td>
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<td>Occurps</td>
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<td>Dyspepsia</td>
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<tr>
<td>Hypersecretion</td>
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<td>Throat and mouth irritation</td>
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</tbody>
</table>

**ADVERSE EFFECTS**

- Might serve as an oral substitute for tobacco
- Might delay weight gain
- Can be titrated to manage withdrawal symptoms
- Can be used in combination with other agents to manage situational urges

**ADVANTAGES**

- Need for frequent dosing can compromise adherence
- Might be problematic for patients with significant dental work
- Proper chewing technique is necessary for effectiveness and to minimize adverse effects
- Gum chewing might not be acceptable or desirable for some patients

**DISADVANTAGES**

- Need for frequent dosing can compromise adherence
- Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome
- When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms
- Not recommended for use by patients with dermatologic conditions (e.g., pruritus, eczema, atopic dermatitis)
- Need for frequent dosing can compromise adherence
- Nasal administration might not be acceptable or desirable for some patients; nasal irritation often problematic
- Not recommended for use by patients with chronic nasal disorders or severe reactive airway disease

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1. Marketed by GlaxoSmithKline.
2. Marketed by Pfizer.
3. The U.S. Clinical Practice Guideline states that pregnant smokers should be encouraged to quit without medication based on insufficient evidence of effectiveness and theoretical concerns with safety.

Pregnant smokers should be offered behavioral counseling interventions that exceed minimal advice to quit.

Abbreviations: NRT, nicotine replacement therapy; OTC, over-the-counter (non-prescription product); Rx, prescription product.

For complete prescribing information, please refer to the manufacturers' package inserts.

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Authority: Sections 4005, 4052(a)(10) and 4052.9, Business and Professions Code. Reference: Sections 4052(a)(10) and §4052.9, Business and Professions Code.