

Colorado State Board of Pharmacy Approved Statewide Protocol for Dispensing Tobacco Cessation Products

(Appendix B)

This collaborative pharmacy practice statewide protocol authorizes qualified Colorado-licensed pharmacists (“Pharmacists”) to dispense safe and effective tobacco cessation products according to and in compliance with all applicable state and federal laws and rules.

The pharmacists will perform health screening according to this protocol and may then determine the need for and dispense a tobacco cessation product pursuant to the terms of the attached protocol.

Pharmacists must have a valid Colorado pharmacist license and have completed an Accreditation Council for Pharmacy Education (ACPE) accredited program in tobacco cessation.

The pharmacy shall ensure that appropriate space is provided to prevent the spread of infection and to ensure confidentiality.

Protocol

PHARMACISTS GENERAL REQUIREMENTS:

- a. All pharmacists participating in this protocol for tobacco cessation drug therapy will follow the US Department of Health and Human Services, Public Health Services, Clinical Practice Guideline: Treating Tobacco Use and Dependence: 2008 Update (or subsequent updates as they become available). Additionally, all product information (PI) and dosing from any products dispensed;
- b. Pharmacists will implement the Five A's (ask, advise, assess, assist, arrange) to help patients quit using all forms of tobacco; and
- c. Pharmacists services will include an educational component to include counseling on medication therapies and cessation strategies as well as referral to sources provided by the Colorado Quit Line program.

SCREENING AND HISTORY

- a. Under this protocol, pharmacists should offer assistance to tobacco users motivated and ready to quit. Medications should be offered as appropriate.
- b. A standardized screening tool will be used to assess the following for each patient intending to use medications:
 1. Medical and social history including current medications;
 2. Previous medication attempts, failures, intolerances;
 3. Allergies and hypersensitivities;
 4. Potential drug interactions with potential medication treatments (per Guidelines/Dispensing Information);
 5. Precautions/contraindications of potential medication treatments (per Guidelines/Dispensing Information); and
 6. Patient preferences with regards to treatment options
- c. A standardized screening tool will be used to identify patients who do **NOT** qualify for specified medication therapies under this protocol and will be referred to a primary care provider for further assessment:
 1. Age under 18 years (any/all medications);
 2. Pregnancy or plan to become pregnant (any/all medications);
 3. History of seizure disorder (bupropion);
 4. History of eating disorder (bupropion);

5. History of mental illness / psychiatric disorder (bupropion or varenicline);
6. Patients undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs (bupropion);
7. Hypersensitivity to any previous use of nicotine, bupropion or varenicline;
8. Use of a monoamine oxidase inhibitor (MAOI) within 14 days (bupropion);
9. Recent history of myocardial infarction (within 14 days), serious cardiac arrhythmias, unstable or severe angina (nicotine replacement);
10. Known moderate/severe hepatic or renal impairment (any/all medications); and
11. Smokeless tobacco use (any/all medications).

DISPENSING

- a. FDA First-Line Approved Medications which may be prescribed (dosing per Clinical Practice Guidelines/Package Inserts). This information should be updated no less frequently than every 2 years.

1. Nicotine Replacement Therapies

Patch

- Treatment of 8 weeks or less has been shown to be as efficacious as longer treatment periods. Patches of different doses sometimes are available as well as different recommended dosing regimens. Clinicians should consider individualizing treatment based on specific patient characteristics, such as previous experience with the patch, amount smoked, degree of dependence, etc.
- Step-down Dosage

4 weeks	21 mg/24 hours
then 2 weeks	14 mg/24 hours
then 2 weeks	7 mg/24 hours

Gum

- Nicotine gum is available in 2-mg and 4-mg (per piece) doses. The 2-mg gum is recommended for patients smoking less than 25 cigarettes per day; the 4-mg gum is recommended for patients smoking 25 or more cigarettes per day. Smokers should use at least one piece every 1 to 2 hours for the first 6 weeks; the gum should be used for up to 12 weeks with no more than 24 pieces to be used per day.

Lozenge

- Nicotine lozenges are available in 2-mg and 4-mg (per piece) doses. The 2-mg lozenge is recommended for patients who smoke their first cigarette more than 30 minutes after waking, and the 4-mg lozenge is recommended for patients who smoke their first cigarette within 30 minutes of waking. Generally, smokers should use at least nine lozenges per day in the first 6 weeks; the lozenge should be used for up to 12 weeks, with no more than 20 lozenges to be used per day.

Nasal Spray

- A dose of nicotine nasal spray consists of one 0.5-mg dose delivered to each nostril (1 mg total). Initial dosing should be 1–2 doses per hour, increasing as needed for symptom relief. Minimum recommended treatment is 8 doses/day, with a maximum limit of 40 doses/day (5 doses/hour). Each bottle contains approximately 100 doses. Recommended duration of therapy is 3–6 months.

Inhaler

- A dose from the nicotine inhaler consists of a puff or inhalation. Each cartridge delivers a total of 4 mg of nicotine over 80 inhalations. Recommended dosage is 6–16 cartridges/day. Recommended duration of therapy is up to 6 months. Patient should taper dosage during the final 3 months of treatment.

2. Bupropion

- Begin bupropion SR treatment 1-2 weeks before they quit smoking. Patients should begin with a dose of 150 mg every morning for 3 days, then increase to 150 mg twice daily. Dosage should not exceed 300 mg per day. Dosing at 150 mg twice daily should continue for 7-12 weeks. For long-term therapy, consider use of bupropion SR 150 mg for up to 6 months post-quit.

3. Varenicline

- Start varenicline 1 week before the quit date at 0.5 mg once daily, followed by 0.5 mg twice daily for 4 days, followed by 1 mg twice daily for 3 months. Varenicline is approved for a maintenance indication for up to 6 months. Note: Patient should be instructed to quit smoking on day 8 when dosage is increased to 1 mg twice daily.

4. Evidence-Based Combination Therapies

- Bupropion + Nicotine patch (standard dosing as detailed above). If this combination is used, patient shall be monitored for treatment emergent hypertension and include a follow up blood pressure within 1-2 weeks.

- Long term nicotine patch (>14 weeks) + other nicotine replacement products (gum and spray) – doses as detailed above.
 - Nicotine patch + Nicotine inhaler (doses as detailed above)
- b. Duration of the above therapies, if not specifically detailed above, shall not exceed 6 months.
 - c. Dosing, Precautions, Contraindications and Monitoring considerations shall follow Clinical Practice Guidelines and manufacturer prescribing information.
 - d. Patients will be supplied with written educational information on any therapies prescribed.
 - e. Pharmacists will implement an appropriate monitoring and follow up plan with each patient.
 - f. Pharmacists may continue to provide over-the-counter smoking cessation products to tobacco users without the use of this protocol.

RECORDS

- a. Pursuant to Pharmacy Board Rule 17.00.50, a process shall be in place for the pharmacist to communicate with the patient's primary care provider and document changes to the patient's medical record. 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 drugs or devices furnished and advise the patient to consult an appropriate health care professional of the patient's choice.
- b. Pharmacists shall comply with all aspects of Pharmacy Board Rules 17.01.00 and 17.02.00 with respect to the maintenance of proper records.