Mike Braun
Governor
Lindsay M. Weaver, MD, FACEP
State Health Commissioner

CSO-26-02

Statewide Standing Order ("Standing Order") for Smoking Cessation Products

Purpose: To broaden patient access to FDA-approved medications for smoking cessation through pharmacists who are trained to screen, and dispense appropriate medication(s) for cessation, and provide evidence-based counseling interventions with referral, as appropriate. This includes cessation of e-cigarettes or other devices used for nicotine inhalation. This standing order is to be used in conjunction with the Protocol for Dispensing Smoking Cessation Products under Statewide Standing Order ("the Protocol").

Eligible Providers: Pharmacists properly licensed pursuant to Indiana Code 25-26-13 may operate under this standing order. Licensed pharmacists who meet the qualifications delineated in the Protocol and who provide care to patients but are not in a medication "dispensing" role are included under this standing order as long as they follow the steps outlined in the Protocol and provide a written order to the patient that can then be dispensed by another pharmacist.

Eligible Recipients: Any individual 18 years or older who is:

- Ready to quit based on individual assessment; and
- Not determined to be high-risk after a health screening conducted by the pharmacist.

Eligible products: Eligible products are FDA approved tobacco cessation products which are allowed under the Protocol.

Procedure:

1. **Assessment:** The pharmacist shall assess a patient's readiness to quit and apply the 5 A's approach for quitting: Ask, Advise, Assess, Assist, and Arrange, as described in the Clinical Practice Guideline for Treating Tobacco Use and Dependence, or a similar strategy based on current evidence.

2. **Health Screening:** The pharmacist shall perform and document a health screening on the patient based on clinical guidelines as outlined in the protocol to identify appropriate candidates for treatment by the pharmacist. The health screenings should be reviewed and revised as necessary to reflect current practice.

3. **Referral of high-risk patients:** If a patient is determined to be high-risk based on the health screening, the pharmacist shall refer the patient to a primary care provider or to another provider as appropriate**.**

4. **Dispensing eligible products:** The pharmacists, in consultation with the patient, may select and dispense any eligible products. Combination therapy (e.g. the nicotine patch plus the nicotine gum, lozenge, inhaler, or nasal spray; or bupropion SR plus the nicotine patch) may be used, per the current clinical guideline recommendations, and is appropriate based on patient needs and preferences.

5. **Counseling:**
    a. The pharmacist shall provide necessary information about the product pursuant to 856 IAC 1-33-2 regarding counseling when dispensing a tobacco cessation product under the standing order.
    b. The pharmacist shall provide counseling to the patient on the administration, possible side effects, contraindications, and warnings associated with the therapy. The pharmacist shall provide educational material on any therapies dispensed and encourage patients to ask questions.
    c. The pharmacist shall provide appropriate behavioral counseling and/or refer the patient to other resources for assistance, such as (but not limited to) the Indiana Tobacco Quitline 1-800-QUITNOW and www.quitnowindiana.com/.

6. **Follow-up:** Pharmacists are encouraged to follow-up with patients as outlined in the protocol.

7. **Notification:**
    a. The pharmacist shall inform the patient that the patient must have a follow-up consultation with the patient's licensed prescriber or consult a licensed prescriber of the patient's choice.
    b. If the patient has a primary care provider, the pharmacist must notify the primary care provider of the prescription record and follow-up care plan within three business days.
    c. The pharmacist must provide the patient with a record of the drug(s).

8. **Documentation:** The pharmacist or pharmacy shall maintain documentation of patient's health screening and the prescription record for all drugs in the pharmacy records for seven years in accordance with Indiana Code 16-39-7-1. A copy shall be made available to the patient and/or patient's provider upon request.

Geographic Region: This Standing Order is applicable statewide.

Standing Orders Authorization: This standing order is issued pursuant to Indiana Code 16-19-4-11, which allows the State Health Commissioner to issue a standing order that allows pharmacists to administer or dispense tobacco cessation products.

This Standing Order shall be reviewed annually by the Indiana Department of Health and revised as needed. This Standing Order is effective January 1 through December 31, 2026.

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Statewide Protocol for Dispensing Smoking Cessation Products by Pharmacists

A. Introduction

Pursuant to Indiana Code 16-19-4-11, the State Health Commissioner issued a Statewide Standing Order for Tobacco Cessation Products (the Statewide Standing Order) which authorizes qualified pharmacists to dispense Food and Drug Administration (FDA)-approved medications with an indication for tobacco cessation in accordance with this Protocol. This Protocol is to be used in conjunction with the Statewide Standing Order. Licensed pharmacists who meet the qualifications delineated in article B, below, and who provide care to patients but are *not* in a medication "dispensing" role can implement the protocol as long as they follow the steps outlined below and provide a written order to the patient that can then be dispensed by another pharmacist.

B. Purpose

This protocol specifies the criteria and procedures to assist pharmacists in providing safe and effective tobacco cessation therapy in Indiana. This includes cessation of e-cigarettes or other devices used for nicotine inhalation.

C. Qualifications

To operate under the Statewide Standing Order, the pharmacist must:

- Have an active Indiana pharmacist license pursuant to Indiana Code 25-26-13;
- Have received education and training in tobacco use disorder and tobacco cessation therapies, including review of the US Department of Health and Human Services, Public Health Services (USPHS), Clinical Practice Guideline for Tobacco Use and Dependence; and
- Complete continuing education on tobacco cessation counseling each biennium.
- Be acting in good faith and exercising reasonable care

D. Products Covered

Notwithstanding any other provision of law, a pharmacist may administer or dispense any FDA-approved medication with an indication for tobacco and/or smoking cessation, including the following:

- Nicotine gum
- Nicotine lozenge
- Nicotine transdermal patch
- Nicotine nasal spray
- Bupropion SR oral tablets
- Varenicline oral tablets

E. Procedure

When a patient requests a medication for smoking cessation, or when a pharmacist in his or her professional judgment decides to ask about smoking and offer to initiate smoking cessation counseling and treatment, the pharmacist shall complete the following steps, which may be reviewed and revised as necessary:

9. Assessment
   - The pharmacist shall assess a patient's readiness to quit and apply the 5 A's approach for quitting: Ask, Advise, Assess, Assist, and Arrange, as described in the Clinical Practice Guideline for Treating Tobacco Use and Dependence, or a similar strategy based on current evidence.
   - The pharmacist may offer smoking cessation medication to persons who smoke who are deemed ready to quit and provide behavioral counseling and/or a referral to counseling.

10. Health Screening
    - The pharmacist shall utilize and document a health screening procedure based on the Clinical Practice Guideline for Treating Tobacco Use and Dependence to identify appropriate candidates for treatment by the pharmacist.
    - The health screen shall include:
      - patient history, including medical and social history
      - family history
      - current living environment
      - concurrent illness
      - allergies and hypersensitivities
      - medication history

11. Referral of high-risk patients
    - The pharmacist shall assess and consult with or refer high-risk patients to a primary care provider, psychiatrist, or other provider, as appropriate. For purposes of this protocol, the following patients are considered high-risk:
    - Patient is pregnant or planning to become pregnant in the next six months
    - Patient has cardiovascular disease and:
      - Has had a heart attack in the past 2 weeks
      - Has a history of arrhythmias or irregular heartbeat
      - Has unstable angina or experience chest pain with strenuous activity
    - Patient has history of mental health disorder(s) and is perceived to not be stable.

- History of seizure disorder if being considered for bupropion.

12. Dispensing eligible products
    - The pharmacist, in consultation with the patient, may select and dispense any tobacco cessation product (alone or in combination) approved by the FDA.
    - Combination therapy (e.g., the nicotine patch plus the nicotine gum, lozenge, inhaler or nasal spray; or bupropion SR plus the nicotine patch) may be used, per current clinical practice guideline recommendations and/or published peer-reviewed literature recommendations, and is acceptable as appropriate based on patient needs and preferences.
    - When a tobacco cessation product is dispensed under the protocol, the pharmacist shall provide necessary information about the product pursuant to 856 IAC 1-33-2, including but not limited to:
        - The name and description of the medicine.
        - The route, dosage form, dosage, route of administration, and recommended duration of drug therapy.
        - Special directions and precautions.
        - Common adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required if they occur.
        - Techniques for self-monitoring drug therapy.
        - Proper storage.
        - Prescription refill information.
        - Action to be taken in the event of a missed dose.

13. Counseling
    - Once the appropriate tobacco cessation product(s) has been determined, the pharmacist shall provide the patient with counseling on the administration, possible side effects, contraindications, and warnings associated with the therapy.
    - The patient should be encouraged to ask questions and will be supplied with educational material on any therapies dispensed.
    - Pharmacists shall provide appropriate behavioral counseling and/or refer the patient to other resources for assistance, including but not limited to the Indiana Tobacco Quitline 1-800-QUITNOW.

14. Follow-up
    - To reassess the appropriateness and/or continuation of therapy, pharmacists shall follow up with patients:
        - Within two weeks of initiating therapy

- After completion of a course of therapy

F. Notification

The pharmacist must provide the patient with a record of the drug(s) dispensed and inform the patient to follow up with his or her primary care provider or consult a licensed provider of the patient's choice, pursuant to IC 16-19-4-11.

If the patient has a primary care provider, the pharmacist must notify the primary care provider of the prescription record and follow-up care plan within three business days.

G. Documentation

- Documentation of a patient's screening and the prescription record for all drugs shall be maintained in the pharmacy records for seven years in accordance with Indiana Code 16-39-7-1.
- A copy shall be made available to the patient and/or patient's provider upon request.

This protocol shall be reviewed annually by the Indiana department of health and revised as needed. This protocol shall remain valid for the duration of the standing order.

Last Reviewed December 30, 2025