NICOTINE REPLACEMENT TOBACCO CESSATION STATEWIDE PROTOCOL Iowa Board of Pharmacy

I. Purpose

This protocol is intended to ensure the timely provision of nicotine replacement tobacco cessation products and to ensure an adult patient receives information to appropriately initiate nicotine replacement smoking cessation therapy.

II. Authority

This protocol is issued pursuant Pursuant to Iowa Code section 155A.46, in collaboration with the Iowa Department of Public Health, which permits a pharmacist to may order and dispense to a patient 18 years or older a nicotine replacement tobacco cessation product, only in accordance with this protocol. For the purpose of this protocol, the pharmacist's order shall constitute a prescription. For the purpose of this protocol, "pharmacist" shall include a licensed pharmacist or registered pharmacist-intern who has completed the training requirements identified in Section III (Qualification).

III. Qualification

A pharmacist shall document successful completion of an Accreditation Council for Pharmacy Education (ACPE)-approved continuing education program of at least one-hour duration related to nicotine replacement tobacco cessation product utilization prior to dispensing nicotine replacement tobacco cessation products pursuant to this protocol.

HI-IV. General requirements

A pharmacist shall follow the most current version of the United States Department of Health and Human Services, Public Health Services, Clinical Practice Guideline – Treating Tobacco Use and Dependence.

A pharmacist shall implement the Five A's (ask, advise, assess, assist, arrange) to help patients quit using all forms of tobacco.

Pharmacist services shall include an educational component to include counseling on medication therapies and cessation strategies as well as referral to sources provided by Quitline Iowa.

A pharmacist participating in this protocol shall have access to the most current nicotine replacement tobacco cessation protocol authorized by the board of pharmacy in collaboration with the department of public health.

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A pharmacist shall ensure a patient's privacy and confidentiality shall be protected.

A pharmacist may continue to provide over-the-counter smoking cessation products to tobacco users without the use of this protocol.

IV. Pharmacist qualification and training

An Iowa-licensed pharmacist who has completed an ACPE-accredited continuing education program of at least one hour in duration related to smoking cessation therapies may participate in this protocol.

V. <u>Initial patient screening</u>

When a patient, aged 18 years or older, requests nicotine replacement smoking cessation therapy or when a pharmacist, in his or her professional judgment, 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:

- 1. Current tobacco use and prior attempts to quit.
- 2. Medical and social history, including current medications.
- 3. Previous medication attempts, failures, intolerances.
- 4. Allergies and hypersensitivities.
- 5. Potential drug interactions with potential medication treatments.
- 6. Precautions of potential medication treatments.
- 7. Patient preferences with regard to treatment options.
- 8. Other recreational substance use.

VI. Contraindications

The pharmacist shall assess the patient for the following contraindications and, if any identified, the pharmacist is authorized to dispense at the professional discretion judgment of the pharmacist only if the patient has identified a primary care provider with whom the pharmacist has conferred prior to dispensing which may include prior consultation with the patient's primary care provider, if identified.

- 1. Pregnancy or the patient's plan to become pregnant.
- 2. Recent history of myocardial infarction (within 14 days), serious cardiac arrhythmias, unstable or severe angina.
- 3. Known moderate/severe hepatic or renal impairment.
- 4. Smokeless tobacco use.

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VII. Medications authorized

This protocol authorizes the pharmacist, upon assessment of the patient and determination that a nicotine replacement smoking cessation product is appropriate, to initiate the dispensing, in sufficient quantities to provide up to a 30-day supply, of nicotine replacement therapy as provided in Appendix 1.

VIII. 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 but shall not exceed six months. Treatment periods longer than six months of continuous therapy are not authorized under this protocol without explicit approval from the authorizing practitioner. 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 nicotine replacement smoking cessation therapy under this protocol shall receive education regarding:

- 1. Motivation to cease tobacco use,
- 2. Drug information related to the specific dosage form dispensed, including directions for use and adverse effects,
- 3. Nicotine withdrawal symptoms,
- 4. Lifestyle modifications, and
- 5. Techniques to prevent relapse.

The pharmacist should recommend the patient seek additional assistance for behavior change, including but not limited to Quitline Iowa (1-800-quit-now), web-based programs (e.g., http://smokefree.gov), apps, and local cessation programs.

IX. Labeling

A prescription label shall be affixed to the nicotine replacement smoking cessation product as required in Iowa Administrative Code (IAC) rule 657—6.10(155A), except that the expiration date of the product shall not be rendered illegible.

X. Records

The pharmacist shall document in the patient medication record the dispensing of a nicotine replacement smoking cessation therapy pursuant to IAC rule 657—6.8(155A).

XI. Prescriber notification

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Within a reasonable amount of time, the pharmacist shall provide notification to the patient's primary care provider of the nicotine replacement smoking cessation 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 advise the patient consult an appropriate health care professional of the patient's choice.

XII. Effective date

This protocol is effective April 5, 2020 July 14, 2021 and shall be in effect for a period of one year and shall automatically renew for subsequent one year periods unless otherwise amended or terminated by the board.

