Ohio Administrative Code

Rule 4729:1-3-07 Dispensing nicotine replacement therapy by pharmacists.

Effective: May 6, 2022

(A) As used in this rule, "nicotine replacement therapy" means a drug, including a dangerous drug, that delivers small doses of nicotine to an individual for the purpose of aiding in tobacco cessation or smoking cessation including for the cessation of alternative nicotine delivery systems, such as e-cigarettes.

(B) A pharmacist may dispense nicotine replacement therapy to individuals who are eighteen years old or older and seeking to quit using tobacco-containing products in accordance with paragraph (C) of this rule.

(C) For a pharmacist to be authorized to dispense nicotine replacement therapy under this rule, the pharmacist shall do both of the following:

(1) Successfully complete a course on nicotine replacement therapy that is taught by a provider that is accredited by the accreditation council for pharmacy education, or another provider approved by the state board of pharmacy, and that meets requirements established in paragraph (H) of this rule; and

(2) Practice in accordance with a physician-authorized protocol that meets the requirements of paragraph (D) of this rule.

(D) All of the following apply with respect to the protocol required by this rule:

(1) The protocol shall be established by a physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.

(2) The protocol shall specify a definitive set of treatment guidelines and the locations at which a pharmacist may dispense nicotine replacement therapy under this rule.

(3) The protocol shall specify the types of nicotine replacement therapy that may be dispensed.

(4) The protocol shall include provisions for implementation of the following requirements:

(a) Use by the pharmacist of a screening procedure, recommended by the United States centers for disease control and prevention or another organization approved by the board, to determine if an individual is a good candidate to receive nicotine replacement therapy dispensed as authorized by this rule;

(b) A requirement that the pharmacist refer high-risk individuals, as defined in the protocol, or individuals with contraindications to a primary care provider or, as appropriate, to another type of provider;

(c) A requirement that the pharmacist develop and implement a follow-up care plan in accordance with paragraph (D)(5) of this rule, including a recommendation by the pharmacist that the individual seek additional assistance with behavior change, including assistance from the Ohio tobacco quit line made available by the department of health.

(5) A follow-up care plan shall include all the following:

(a) A recommendation that the individual notify their provider that they have initiated a quit attempt;

(b) A plan to deal with the psychological aspects of tobacco addiction, including information regarding how to seek services from the Ohio Tobacco Quit Line;

(c) A plan for how to deal with possible side effects;

(d) Instructions regarding how, when, and how many times to refill the medication;

(e) Follow-up with patient should occur within a clinically appropriate length of time after the initiation of the nicotine replacement therapy as deemed appropriate by the pharmacist;

(f) How and when to stop using nicotine replacement therapy;

(g) Instructions to seek assistance from the pharmacist or provider before continuing to use the medication if a relapse occurs and tobacco use is reinitiated;

(h) If a patient returns to the pharmacy to report a relapse, the follow-up care plan should include efforts to identify smoking cues and triggers and decide upon alternative coping strategies before a follow-up attempt to quit tobacco;

(i) If dual therapy is indicated for the patient, instructions to seek assistance from a prescribing provider to add prescription-only smoking cessation medication to the pharmacist-initiated nicotine replacement therapy.

(6) All physician-established protocols must be signed and dated by the physician prior to implementation and maintained by the terminal distributor of dangerous drugs. The protocols shall be renewed by a physician on a biennial basis.

(a) A physician may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs.

(b) Each location licensed as a terminal distributor of dangerous drugs shall maintain a copy of the protocol on-site for inspection by an agent, inspector, or employee of the state board of pharmacy.

(E)

(1) Documentation related to screening, dispensing, and follow-up care plans shall be maintained in the records of the terminal distributor of dangerous drugs where the pharmacist practices for at least three years. Dispensing of nicotine replacement therapy may be documented on a prescription form, and the form may be assigned a number for recordkeeping purposes.

(2) Not later than seventy-two hours after a screening is conducted under this rule and the patient has been identified as a candidate for smoking cessation therapy, the pharmacist shall provide notice to the individual's primary care provider, if known, or to the individual if the primary care provider is unknown. The notice shall include results of the screening, and if applicable, the dispensing record

and follow-up care plan. Notification shall be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(a) Electronic mail;

(b) Interoperable electronic medical records system;

(c) Facsimile;

(d) Electronic prescribing system;

(e) Electronic pharmacy record system;

(f) Documented verbal communication; or

(g) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

(3) A copy of the documentation identified in paragraph (E)(1) of this rule shall also be provided to the individual or the individual's primary care provider on request.

(F) This rule does not affect the authority of a pharmacist to do any of the following:

(1) Fill or refill prescriptions for nicotine replacement therapy;

(2) Sell nicotine replacement therapy that does not require a prescription.

(G) A provider who is not accredited by the accreditation council for pharmacy education may petition the board for approval of a course in accordance with division (C) of section 4729.284 of the Revised Code. The board shall develop and post a petition application on its website providing the criteria for approval.

(H) No pharmacist shall do either of the following:

(1) Dispense nicotine replacement therapy in accordance with a protocol unless the requirements of paragraph (C) of this rule have been met;

(2) Delegate to any person the pharmacist's authority to engage in or supervise the dispensing of nicotine replacement therapy.

(I) A terminal distributor of dangerous drugs shall ensure that all pharmacists that dispense nicotine replacement therapy pursuant to this rule have completed the requirements set forth in paragraph (C) of this rule.

(J) A terminal distributor of dangerous drugs dispensing nicotine replacement therapy in accordance with this rule shall also comply with the record keeping provisions of the applicable chapters of the Administrative Code: 4729:5-5, 4729:5-8, or 4729:5-9.