



## **Dispensing Nicotine Replacement Therapy by Pharmacists**

**Updated 8/5/2022**

This document provides guidance on the provisions outlined under OAC [4729:1-3-07](#) (effective 5/1/2022), which provides the standards for dispensing nicotine replacement therapy (NRT) by pharmacists pursuant to a physician-approved protocol.

To assist licensees in complying with the provisions of the rule and its authorizing statute (ORC [4729.284](#)), the Board developed the following frequently asked questions document.

If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: <http://www.pharmacy.ohio.gov/contact.aspx>.

### **Frequently Asked Questions**

#### **Q1) How is nicotine replacement therapy (NRT) defined?**

"Nicotine replacement therapy" is defined as 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.

**IMPORTANT:** NRT does not include the dispensation of nicotine cessation medications such as Chantix (varenicline tartrate) and Zyban (bupropion hydrochloride). Those medications may only be dispensed in accordance with a valid prescription. It does include OTC formulations (patch, gum, lozenge) and prescription formulations (inhaler and nasal spray).

#### **Q2) Under what circumstances is a pharmacist authorized to dispense nicotine replacement therapy pursuant to a physician-authorized protocol?**

In order to dispense nicotine replacement therapy pursuant to a physician-authorized protocol, a pharmacist must 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 (see FAQ #6).

**NOTE:** A provider who is not accredited by the Accreditation Council for Pharmacy Education may petition the Board for approval of a course. The criteria for approval and the petition application can be accessed here:

[www.pharmacy.ohio.gov/NRTapprove](http://www.pharmacy.ohio.gov/NRTapprove).

**IMPORTANT:** A pharmacist may not delegate their authority to engage or supervise the dispensing of nicotine replacement therapy.

***This does not affect the authority of a pharmacist to fill or refill prescriptions for nicotine replacement therapy or sell nicotine replacement therapy that does not require a prescription.***

### **Q3) What are the requirements of physician-authorized protocol?**

Protocol must be established by an Ohio-licensed physician (MD/DO) and must be renewed by the physician on a biennial basis.

The protocol is required to include **ALL** of the following:

1. A definitive set of treatment guidelines and the locations where a pharmacist may dispense nicotine replacement therapy.
2. The types of nicotine replacement therapy that may be dispensed.
3. The provisions of implementation, which **must** include:
  - a. A screening procedure (recommended by the [U.S. Centers for Disease Control and Prevention](#) or another organization approved by the Board [see FAQ #6]) to determine if an individual is a good candidate to receive nicotine replacement therapy.

**IMPORTANT:** If a patient is identified as a candidate, the pharmacist is required to provide notice to the patient's primary care provider, or to the patient if their primary care provider is unknown, no later than 72 hours after a screening. The notice should include: the results of the screening, dispensing record, and follow-up care plan. The pharmacist should keep a copy of the notice for their records.

- b. A requirement that the pharmacist refer high-risk individuals or individuals with contraindications to a primary care provider or to another type of provider (if appropriate).
- c. A requirement that the pharmacist must develop and implement a follow-up care plan, 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 [Ohio Department of Health](#).

**NOTE:** The follow-up plan must include the following:

1. A recommendation that the patient notify their provider regarding their attempt to quit tobacco use.
2. A plan to deal with the psychological aspects of tobacco addiction, including information regarding how to seek services from the [Ohio Tobacco Quit Line](#).
3. A plan for how to deal with potential side effects.
4. Instructions for how, when, and how many times to refill the nicotine replacement therapy medication.
5. A timeline for follow-up with patient, which should occur within a clinically appropriate length of time after the initiation of the nicotine replacement therapy as deemed appropriate by the pharmacist.
6. How and when to stop using nicotine replacement therapy.
7. Instructions to seek assistance from the pharmacist or provider before continuing to use the medication if a relapse occurs and tobacco use is reinitiated.

8. 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 consider an alternative coping strategy before a follow-up attempt to quit tobacco.
9. Instructions to seek assistance from a prescribing provider to add prescription-only smoking cessation medication to the pharmacist-initiated nicotine replacement therapy, if dual therapy is indicated for the patient,

**IMPORTANT:** All physician-established protocols must be signed and dated by the physician **prior to implementation**. A physician may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs.

#### **Q4) What is required of the pharmacy to comply with this rule?**

Each pharmacy licensed as a terminal distributor of dangerous drugs (TDDD) is required to maintain a copy of the physician-authorized protocol **on-site** for inspection by an agent, inspector, or employee of the State Board of Pharmacy.

Additionally, the TDDD where the pharmacist practices must keep record of all documentation related to nicotine replacement therapy (screening, dispensing, and follow-up care plans) for at least three years.

**NOTE:** Documentation of nicotine replacement therapy may be done on a prescription form, which may be assigned a number for recordkeeping purposes.

As a reminder, a pharmacy 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 (for [outpatient pharmacies](#)), 4729:5-8 (for [non-resident pharmacies](#)), or 4729:5-9 (for [institutional pharmacies](#)).

#### **Q5) Are there any notification requirements?**

Yes. Not later than **72 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:

1. Electronic mail;
2. Interoperable electronic medical records system;
3. Facsimile;
4. Electronic prescribing system;
5. Electronic pharmacy record system;
6. Documented verbal communication; or
7. Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

**Q6) What are the requirements for an approved course on nicotine replacement therapy?**

The statute and rule require that, unless otherwise approved by the Board, courses shall meet the following requirements:

1. The course is taught by a provider that is accredited by the [Accreditation Council for Pharmacy Education](#); and
2. [The course is consistent with national guidelines for treatment of tobacco use and dependence \(quick reference guide\) / \(full guidelines\).](#)

The Board may update its rules to include additional requirements. Licensees will be notified of such changes if/when they occur.

**Q7) How does one apply for Board approval of a training course or screening procedure?**

A provider seeking Board approval of a training course or patient screening procedure, must submit the following form and all supporting documentation:

[www.pharmacy.ohio.gov/NRTapproval](http://www.pharmacy.ohio.gov/NRTapproval)

Currently, there are no Board approved courses or screening procedures. However, there are a number of courses and screening procedures listed on the CDC website that meet the requirements of the rule:

- **\*Training Courses:** <https://www.cdc.gov/tobacco/patient-care/education-training/index.html>
- **Screening Tools:** <https://www.cdc.gov/tobacco/patient-care/clinical-tools/index.html>

\*Unless otherwise approved by the Board, training courses must be taught by a provider accredited by the [Accreditation Council for Pharmacy Education \(ACPE\)](#).