Pharmacist Prescribing Protocol
Nicotine Replacement Medication

Background

Minn. Stats. §151.37, subd. 15, states the following:

“A pharmacist is authorized to prescribe nicotine replacement medications approved by the United States Food and Drug Administration in accordance with this subdivision . . . the board shall develop a standardized protocol for the pharmacist to follow in prescribing nicotine replacement medications. In developing the protocol, the board shall consult with the Minnesota Board of Medical Practice; the Minnesota Board of Nursing; the commissioner of health; professional pharmacy associations; and professional associations of physicians, physician assistants, and advanced practice registered nurses.”

This protocol was developed by Board staff after consulting with the above-mentioned agencies and professional associations. It was approved at the Board’s [Month Date], 2020 meeting. Pharmacists who independently prescribe nicotine replacement medications must follow this protocol. When prescribing per this protocol, the pharmacist is the prescriber-of-record.

Pharmacists can also issue legally valid prescriptions for nicotine replacement medications through the use of other protocols that they enter into with a physician, advanced practice registered nurse (APRN), or physician assistant (PA) as allowed by Minn. Stats. §151.01, subd. 27(6) and Minn. Stats. §151.37, subd. 2. When working under those protocols, the practitioner, not the pharmacist, is the prescriber-of-record.

Pharmacists may continue to recommend and sell FDA-approved, non-prescription nicotine replacement medications without receiving or issuing a prescription.

1. Definition.

   a. Nicotine replacement medication (NRM). "Nicotine replacement medication" means a product approved by the United States Food and Drug Administration that gives small, steady doses of nicotine to help stop cravings and relieve symptoms that occur when a person is trying to quit smoking. Such products include nicotine gums, inhalers, nasal sprays, lozenges, and patches. Only products approved by the FDA are included; compounded products are not included. Both over-the-counter and prescription products are included.
2. **General considerations**

   a. Pharmacists who use this protocol must keep a written copy of it at each location at which they issue prescriptions for an NRM. They must make a copy of the protocol available upon the request of a representative of the Board of Pharmacy. This protocol must list the names of each pharmacist who is issuing prescriptions for NRMs at the location.

   b. Before a pharmacist is authorized to prescribe NRMs to a patient under this protocol, the pharmacist must successfully complete a training program on *prescribing* NRMs that is offered by a college of pharmacy or by a continuing education provider that is accredited by the Accreditation Council for Pharmacy Education, or a program approved by the board.
      i. Upon the request of a representative of the Board, pharmacists must provide proof that they have completed the training.
      ii. Pharmacists may request Board approval of a program by downloading the Continuing Education Program Approval Form for Non-ACPE Program Attendees, filling it out, and submitting it to the Board, along with information about the program. This form does *not* need to be submitted for a program offered by a college of pharmacy or by a continuing education provider that is accredited by ACPE.
      iii. Note that the program must be developed for the *prescribing* of NRMs. For example, a continuing education program that only provides education about the pharmacology of NRMs would not be sufficient.

   c. Pharmacists may prescribe an NRM only for FDA approved indications.

3. **Procedure**

   a. When a patient requests an NRM, or when a pharmacist (using sound professional judgment) decides to offer to prescribe an NRM, the pharmacist shall complete the following steps:

      1) Review the patient’s current tobacco use and past quit attempts.
      2) Have the patient fill out the *Minnesota Board of Pharmacy Tobacco Cessation Self-Screening Patient Intake Form*
      3) Review the *Intake Form* with the patient and ask any necessary follow-up questions.
      4) **Prescribing and referral.** Once the first three steps are completed, the pharmacist should refer to the *Tobacco Cessation Assessment & Treatment Care Algorithm* to determine if prescribing an NRM is appropriate.

         a) If it is appropriate, the pharmacist may prescribe an NRM per the *Algorithm* and the *Nicotine Replacement Dosing* chart.
         b) When necessary, and as noted in the *Algorithm*, the pharmacist should refer the patient to a primary care provider.
         c) The pharmacist should always provide information to the patient about Quit Partner (see below for additional information).

      5) When prescribing a nicotine replacement medication, the pharmacist must ensure that the patient is appropriately trained in the administration of the requested or recommended medication.
6) When a nicotine replacement medication is prescribed, the pharmacist must provide the patient with appropriate counseling and information for the product prescribed, as required by Minn. Rules 6800.0910. In addition to verbal counseling, the pharmacist must also supply a fact sheet to the patient that is specific to the drug prescribed. The information that must be provided includes the following:

   a) the name and description of the drug;
   b) the dosage form, dose, route of administration, and duration of drug therapy;
   c) intended use of the drug and expected action;
   d) directions and precautions for preparation, administration, and appropriate use by the patient;
   e) common severe side effects, adverse effects, or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
   f) techniques for self-monitoring of drug therapy;
   g) proper storage; and
   h) any other information relevant to the patient's drug therapy.

7) When a nicotine replacement medication is prescribed, the pharmacist must provide the patient with a written record of the medication prescribed. At a minimum, the record must include:

   a) the patient’s name and date-of-birth;
   b) the name, practice address, and telephone number for the prescribing pharmacist;
   c) the date on which the prescription was issued;
   d) the name and strength of the nicotine replacement medication that was prescribed; and
   e) the quantity prescribed and how many refills were authorized (if any)

8) Whether or not a nicotine replacement medication is prescribed, the pharmacist must recommend that the patient seek additional assistance for smoking cessation, including but not limited to Quit Partner (http://www.quitpartnermn.com/), Minnesota’s family of programs to help people who want to quit smoking, vaping, chewing or using other commercial tobacco products. Quit Partner toll-free telephone number: 1-800-QUIT-NOW (784-8669)

4. **Delegation prohibited; involvement of pharmacist interns.** A pharmacist who is authorized to prescribe a nicotine replacement medication is prohibited from delegating the prescribing to any other person. A pharmacist intern registered pursuant to section 151.101 may prepare a prescription for a nicotine replacement medication, but before the prescription is processed or dispensed, a pharmacist authorized to prescribe under this subdivision must review, approve, and sign the prescription.

5. **Records.** The pharmacist must generate a written or electronic prescription for nicotine replacement medication that is prescribed and dispensed. The prescription must include all of the information
required by Minn. Stats. §151.01, subd. 16a. The prescription must be processed in the same manner that any other prescription is processed, pursuant to the applicable statutes and rules for the dispensing of prescription drugs. The prescription shall be kept on file and maintained for a minimum of two years. Pharmacists are reminded that prescriptions paid for by Medicare and Medicaid must be kept on file for even longer periods of time.

**Names of Pharmacists Who Will Be Prescribing Pursuant to this Protocol**

**Location at which prescribing will occur**

*Pharmacy or facility name:__________________________________________________________*

*Pharmacy of facility address:________________________________________________________*

**Names of Prescribing pharmacists:**

1) ________________________________________________________________

2) ________________________________________________________________

3) ________________________________________________________________

4) ________________________________________________________________

5) ________________________________________________________________

6) ________________________________________________________________

7) ________________________________________________________________

8) ________________________________________________________________

9) ________________________________________________________________

10) ________________________________________________________________