

Sixty-ninth
Legislative Assembly
of North Dakota

PROPOSED AMENDMENTS TO

SENATE BILL NO. 2402

Introduced by

Legislative Management

(Joint Policy Committee)

1 A BILL for an Act to create and enact two new sections to chapter 43-15 and a new subsection
2 to section 43-48-03 of the North Dakota Century Code, relating to the prescriptive authority of
3 pharmacists and therapeutic substitution; to amend and reenact subsection 1 of section
4 26.1-36.11-01 and section 43-15-01 of the North Dakota Century Code, relating to the scope of
5 practice of pharmacists; to repeal section 43-15-25.3 of the North Dakota Century Code,
6 relating to approved laboratory tests; and to provide an effective date.

7 BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

8 **SECTION 1. AMENDMENT.** Subsection 1 of section 26.1-36.11-01 of the North Dakota
9 Century Code is amended and reenacted as follows:

- 10 1. a. "Comprehensive medication management" means medication management
11 pursuant to a standard of care that ensures each enrollee's medications, both
12 prescription and nonprescription, are individually assessed to determine each
13 medication is appropriate for the enrollee, effective for the medical condition, and
14 safe, given the comorbidities and other medications being taken and able to be
15 taken by the enrollee as intended. Services provided in comprehensive
16 medication management are, as follows:
- 17 (1) Performing or obtaining necessary assessments of the enrollee's health
18 status;
- 19 (2) Formulating a medication treatment plan;

- (3) Monitoring and evaluating the enrollee's response to therapy, including safety and effectiveness;
- (4) Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events;
- (5) Providing verbal or written, or both, counseling, education, and training designed to enhance enrollee understanding and appropriate use of the enrollee's medications;
- (6) Providing information, support services, and resources designed to enhance enrollee adherence with the enrollee's therapeutic regimens;
- (7) Coordinating and integrating medication therapy management services within the broader health care management services being provided to the enrollee;
- (8) Initiating or modifying drug therapy under a collaborative agreement with a practitioner in accordance with section 43-15-31.4;
- (9) Prescribing medications pursuant to protocols approved by the state board of pharmacy in accordance with subsection 24 of section 43-15-10;
- (10) Administering medications in accordance with requirements in section 43-15-31.5; and
- (11) Ordering, performing, and interpreting laboratory tests authorized by ~~section 43-15-25.3~~ under chapter 43-15 and North Dakota Administrative Code section 61-04-10-06.

- b. This subsection may not be construed to expand or modify pharmacist scope of practice.

SECTION 2. AMENDMENT. Section 43-15-01 of the North Dakota Century Code is amended and reenacted as follows:

43-15-01. Definitions.

In this chapter, unless the context or subject matter otherwise requires:

1. "Administration" means the direct application of a drug to the body of a patient. The term includes:
 - a. The emergency maintenance of a drug delivery device used in home infusion therapy by a qualified home pharmacist if nursing service is not available;

- b. Immunization and vaccination by injection of an individual who is at least three years of age upon an order by a practitioner authorized to prescribe such a drug or by written protocol with a physician or nurse practitioner and subsequently reported as a childhood immunization and other information if required to the state's immunization information system pursuant to section 23-01-05.3;
 - c. Provision of other drugs to an individual who is at least three years of age upon the order of a practitioner authorized to prescribe such a drug; and
 - d. Provision of drugs to an individual receiving emergency services in a health care facility upon an order or by established written protocol.
2. "Automated dispensing system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications and which collects, controls, and monitors all transaction information.
3. "Board" means the state board of pharmacy.
4. "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:
 - a. As the result of a practitioner's prescription drug order or initiative based on the practitioner, patient, and pharmacist relationship in the course of professional practice; or
 - b. For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing.Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.
5. "Confidential information" means individually identifiable health information maintained by the pharmacist in the patient's records or which is communicated to the patient as part of a patient counseling.
6. "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for a consideration.
7. "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or

- 1 accessory, which is required under federal or North Dakota law to be prescribed by a
2 practitioner and dispensed by a pharmacist.
- 3 8. "Dispense" or "dispensing" means the preparation and delivery of a prescription drug,
4 pursuant to a lawful order of a practitioner or a nurse licensed under chapter 43-12.1
5 who is authorized by the practitioner to orally transmit the order that has been reduced
6 to writing in the patient's record, in a suitable container appropriately labeled for
7 subsequent administration to or use by a patient or other individual entitled to receive
8 the prescription drug.
- 9 9. "Distribute" means the delivery of a drug other than by dispensing or administering.
- 10 10. "Drug" or "drugs" means:
- 11 a. Articles recognized as drugs in the official United States pharmacopeia, official
12 national formulary, official homeopathic pharmacopeia, other drug compendium,
13 or any supplement to any of them;
- 14 b. Articles intended for use in the diagnosis, cure, mitigation, treatment, or
15 prevention of disease in man or other animal;
- 16 c. Articles other than food intended to affect the structure or any function of the
17 body of man or other animals; and
- 18 d. Articles intended for use as a component of any articles specified in
19 subdivision a, b, or c.
- 20 11. "Drug regimen review" includes the following activities:
- 21 a. Evaluation of the prescription drug orders and patient records for:
- 22 (1) Known allergies;
- 23 (2) Rational therapy-contraindications;
- 24 (3) Reasonable dose and route of administration; and
- 25 (4) Reasonable directions for use.
- 26 b. Evaluation of the prescription drug orders and patient records for duplication of
27 therapy.
- 28 c. Evaluation of the prescription drug orders and patient records for interactions:
- 29 (1) Drug-drug;
- 30 (2) Drug-food;
- 31 (3) Drug-disease; and

1 (4) Adverse drug reactions.

2 d. Evaluation of the prescription drug orders and patient records for proper
3 utilization, including overutilization or underutilization, and optimum therapeutic
4 outcomes.

5 12. "Emergency pharmacy practice" means in the event a pharmacist receives a request
6 for a prescription refill and the pharmacist is unable to obtain refill authorization from
7 the prescriber, the pharmacist may dispense and bill using a pharmacist national
8 provider identifier a one-time emergency refill of up to a thirty-day supply of the
9 prescribed medication, provided that:

10 a. The prescription is not for a controlled substance listed in schedule II;

11 b. The pharmaceutical is essential to the maintenance of life or to the continuation
12 of therapy;

13 c. In the pharmacist's professional judgment, the interruption of therapy might
14 reasonably produce undesirable health consequences or may cause physical or
15 mental discomfort;

16 d. The pharmacist properly records the dispensing; and

17 e. The dispensing pharmacist notifies the prescriber of the emergency dispensing
18 within a reasonable time after the one-time emergency refill dispensing.

19 13. "Labeling" means the process of preparing and affixing of a label to any drug container
20 exclusive, however, of the labeling by a manufacturer, packer, or distributor of a
21 nonprescription drug or commercially packaged legend drug or device. Any label shall
22 include all information required by federal and North Dakota law or regulation.

23 14. "Manufacture" means the production, preparation, propagation, compounding,
24 conversion, or processing of a device or a drug, either directly or indirectly by
25 extraction from substances of natural origin or independently by means of chemical
26 synthesis or by a combination of extraction and chemical synthesis and includes any
27 packaging or repackaging of the substances or labeling or relabeling of its container,
28 except that this term does not include the preparation or compounding of a drug by an
29 individual for the individual's own use or the preparation, compounding, packaging, or
30 labeling of a drug:

- 1 a. By a pharmacist or practitioner as an incident to dispensing or administering of a
2 drug in the course of the person's professional practice; or
3 b. By a practitioner or by the practitioner's authorization under supervision for the
4 purpose of or as an incident to research, teaching, or chemical analysis and not
5 for sale.
- 6 15. "Manufacturer" means a person engaged in the manufacture of drugs in facilities
7 located within North Dakota.
- 8 16. "Medicine" means a drug or combination of drugs, used in treating disease in man or
9 other animals.
- 10 17. "Nonprescription drugs" means medicines or drugs which may be sold without a
11 prescription and which are prepackaged for use by the consumer and labeled in
12 accordance with the requirements of the statutes and regulations of this state and the
13 federal government.
- 14 18. "Original package" means the original carton, case, can, box, vial, bottle, or other
15 receptacle, put up by the manufacturer or wholesaler or distributor, with label attached,
16 making one complete package of the drug article.
- 17 19. "Patient-pharmacist relationship" means the required relationship between a patient
18 and a pharmacist as defined under the rules of the board which authorizes the
19 pharmacist to independently prescribe drugs, drug categories, and devices as limited
20 by this chapter.
- 21 20. "Person" means an individual, corporation, limited liability company, partnership,
22 association, or any other legal entity.
- 23 20-21. "Pharmaceutical care" is the provision of drug therapy and other pharmaceutical
24 patient care services intended to achieve outcomes related to the cure or prevention of
25 a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a
26 disease process as defined in the rules of the board.
- 27 21-22. "Pharmacist" means a person to whom the board has issued a license to practice the
28 profession of pharmacy whose license has not expired or been suspended.
- 29 22-23. "Pharmacy" or "drugstore" means every store or shop where drugs, medicines, or
30 chemicals are dispensed, displayed for sale, or sold, at retail for medicinal purposes,
31 or where prescriptions are compounded, and which is duly registered by the board.

1 ~~23.24.~~ "Pharmacy technician" means a person registered by the board who is employed by a
2 pharmacy to assist licensed pharmacists in the practice of pharmacy by performing
3 specific tasks delegated by and under the immediate personal supervision and control
4 of a licensed pharmacist, as permitted by the board.

5 ~~24.25.~~ "Practice of pharmacy" means ~~the~~:

6 a. ~~The~~ interpretation, evaluation, and monitoring of prescription orders and patient
7 drug therapy; ~~the~~

8 b. ~~The~~ compounding, dispensing, and labeling of drugs and devices except labeling
9 by a manufacturer, packer, or distributor of nonprescription drugs and
10 commercially packaged legend drugs and devices; ~~the~~

11 c. ~~The~~ participation in drug selection, drug monitoring, drug administration, drug
12 regimen review, the provision of these acts or services necessary as a primary
13 health care provider of pharmaceutical care, and drug utilization evaluations; ~~the~~

14 d. ~~The~~ proper and safe storage of drugs and devices and the maintenance of proper
15 records for this storage; ~~the~~

16 e. ~~The~~ responsibility for advising, consulting, and educating if necessary or if
17 regulated, patients, ~~the~~ public, and other health care providers on the rational,
18 safe, and cost-effective use of drugs including therapeutic values, content,
19 hazards, and appropriate use of drugs and devices; ~~the~~

20 f. ~~The~~ participation in interpreting and applying pharmacokinetic data and other
21 pertinent laboratory data to design safe and effective drug dosage regimens; if

22 g. If appropriate and if regulated, the participation in scientific or clinical drug
23 ~~research either scientific or clinical as an investigator or in collaboration with~~
24 ~~other investigators for the purposes of studying the effects of drugs on animals or~~
25 ~~human subjects, with other drugs or chemicals, and with drug delivery devices;~~
26 ~~emergency~~

27 h. Emergency pharmacy practice; ~~prescriptive~~

28 i. Prescriptive practices as limited under this chapter; ~~the~~

29 j. The ordering of laboratory tests:

30 k. ~~The~~ performance of laboratory tests to provide pharmaceutical care services

31 which are waived under the Federal Clinical Laboratory Improvement Act of 1988

1 [Pub. L. 100-578, section 2; 102 Stat. 2903; 42 U.S.C. 263a et seq.], as
2 amended; and the

3 I. The offering or performing of those acts, services, operations, or transactions
4 necessary in the conduct, operation, management, and control of pharmacy.

5 ~~25-26.~~ "Practitioner" means an individual licensed, registered, or otherwise authorized by the
6 jurisdiction in which the individual is practicing to prescribe drugs in the course of
7 professional practice.

8 ~~26-27.~~ "Prescription" means any order for drugs or medical supplies, if such order is written or
9 signed or transmitted by word of mouth, telephone, telegram, or other means of
10 communication by a duly licensed physician, optometrist, dentist, veterinarian, or other
11 practitioner, licensed by law to prescribe and administer such drugs or medical
12 supplies intended to be filled, compounded, or dispensed by a pharmacist or any order
13 for drugs or medical supplies transmitted orally by a nurse licensed under chapter
14 43-12.1 as written and signed by such a duly licensed physician, optometrist, dentist,
15 veterinarian, or other practitioner.

16 ~~27-28.~~ "Prescription drug or legend drug" means a drug which, under federal law is required,
17 prior to being dispensed or delivered, to be labeled with one of the following:

- 18 a. "Caution: Federal law prohibits dispensing without prescription";
19 b. "Caution: Federal law restricts this drug to use by or on the order of a licensed
20 veterinarian"; or
21 c. Rx only;

22 or a drug which is required by any applicable federal or North Dakota law or rule to be
23 dispensed on prescription only or is restricted to use by practitioners only.

24 ~~28-29.~~ "Public health issues" include immunizations, tobacco cessation, and other issues
25 deemed appropriate by the board.

26 ~~29-30.~~ "Radiopharmaceutical service" means, but is not limited to, the compounding,
27 dispensing, labeling, and delivery of radiopharmaceuticals; the participation in
28 radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper
29 and safe storage and distribution of radiopharmaceuticals; the maintenance of
30 radiopharmaceutical quality assurance; the responsibility for advising, where
31 necessary or where regulated, of therapeutic values, hazards, and use of

radiopharmaceuticals; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of radiopharmaceuticals.

~~30:31.~~ "Wholesaler" means a person with facilities located in this state who buys for resale and distribution to persons other than consumers.

SECTION 3. A new section to chapter 43-15 of the North Dakota Century Code is created and enacted as follows:

Prescriptive authority.

1. A pharmacist whose practice is physically located within this state, acting in good faith and exercising reasonable care, may independently prescribe drugs, drug categories, and devices as provided in this section if each of the following requirements are met:
 - a. A pharmacist may prescribe drugs or devices only for conditions for which the pharmacist is educationally prepared and competence has been achieved and maintained.
 - b. A pharmacist may issue a prescription only for a legitimate medical purpose arising from a patient-pharmacist relationship.
 - c. A pharmacist shall obtain adequate information about the patient's health status to make appropriate decisions based on the applicable standard of care.
 - d. For each drug or drug category a pharmacist intends to prescribe, the pharmacist shall maintain a patient assessment protocol based on current clinical guidelines, when available, or evidence-based research findings that specify the following:
 - (1) Patient inclusion and exclusion criteria; and
 - (2) Explicit medical referral criteria.
 - e. A pharmacist shall revise the patient assessment protocol when necessary to ensure continued compliance with clinical guidelines or evidence-based research findings. The pharmacist's patient assessment protocol, and any related forms, must be made available to the board upon request.
 - f. A pharmacist shall consult with and refer to other health care professionals as appropriate, including in situations where the pharmacist's knowledge or experience is limited.

- 1 g. A pharmacist shall develop and implement an appropriate follow-up care plan,
2 including any monitoring parameters, in accordance with clinical guidelines. The
3 plan may include follow-up care with the patient and communication with the
4 patient's primary care provider.
- 5 h. A pharmacist shall inquire about the identity of the patient's primary care provider
6 or provider of record. If a primary care provider or provider of record is identified,
7 the pharmacist shall provide notification to the primary care provider or provider
8 of record within three business days following the prescription of a drug. The
9 notification must include the results of any test that required the prescription and,
10 upon the provider's request, any relevant documentation required under
11 subdivision i.
- 12 i. A pharmacist shall maintain documentation adequate to justify the care provided,
13 including information collected as part of the patient assessment, the prescription
14 record, any notification provided under this section, and the follow-up care plan.
- 15 2. A pharmacist may prescribe any drug approved by the federal food and drug
16 administration which is indicated for the following conditions:
- 17 a. Lice;
18 b. Cold sores;
19 c. Motion sickness, including the prevention of motion sickness; and
20 d. Hypoglycemia; and
21 ~~e. Uncomplicated urinary tract infections.~~
- 22 3. A pharmacist may prescribe any of the following devices approved by the federal food
23 and drug administration:
- 24 a. Inhalation spacer;
25 b. Nebulizer;
26 c. ~~Diabetes~~Disposable diabetes blood sugar testing supplies; and
27 d. Pen needles; and
28 ~~e. Auto-injectors containing drugs for patients with a documented history of allergies~~
29 or anaphylaxis.
- 30 4. A pharmacist may prescribe any drug approved by the federal food and drug
31 administration which is indicated for the following conditions, provided the

1 symptomatic patient first tests positive to a test that is waived under the Federal
2 Clinical Laboratory Improvement Act of 1988 [Pub. L. 100-578, section 2: 102 Stat.
3 2903; 42 U.S.C. 263a et seq.], as amended:

4 a. Influenza;

5 b. Group A streptococcal pharyngitis; and

6 c. Severe acute respiratory syndrome coronavirus 2 identified as SARS-CoV-2.

7 5. If a patient tested positive for influenza, a pharmacist may prescribe an antiviral drug
8 to an individual who has been exposed to the infected patient and for whom the
9 clinical guidelines recommend chemoprophylaxis.

10 6. A pharmacist may prescribe any drug approved by the federal food and drug
11 administration for the purpose of closing a gap in clinical guidelines as follows:

12 a. ~~Statins for a patient who has been diagnosed with diabetes~~Post-exposure
13 prophylaxis for nonoccupational exposure to human immunodeficiency virus
14 infection; and

15 b. Short-acting beta agonists for a patient with asthma who has had a prior
16 prescription for a short-acting beta agonist and who has a current prescription for
17 a long-term asthma control drug.

18 7. A pharmacist who successfully completes an accredited continuing pharmacy
19 education or continuing medical education course on travel medicine may prescribe
20 any noncontrolled drug recommended for individuals traveling outside the United
21 States which is specifically listed in the federal centers for disease control and
22 prevention health information for international travel publication. The pharmacist only
23 may prescribe drugs that are indicated for the patient's intended destination for travel.

24 8. If an emergency situation exists which in the professional judgment of the pharmacist
25 threatens the health or safety of the patient, a pharmacist may prescribe the following
26 drugs approved by the federal food and drug administration in the minimum quantity
27 necessary until the patient is able to be seen by a provider:

28 a. Diphenhydramine;

29 b. Epinephrine; and

30 c. Short-acting beta agonists.

- 1 9. A pharmacist may prescribe antimicrobial prophylaxis for the prevention of lyme
2 disease in accordance with the federal centers for disease control and prevention
3 guidelines.

4 **SECTION 4.** A new section to chapter 43-15 of the North Dakota Century Code is created
5 and enacted as follows:

6 **Therapeutic substitution.**

- 7 1. A pharmacist whose practice is physically located within this state may substitute a
8 drug for a therapeutically equivalent drug, except for antidepressants, antipsychotics,
9 chemotherapy agents, schedule II controlled substances, biological products, and
10 narrow therapeutic index drugs, as limited by this section. Therapeutic equivalence
11 may be established by clinical publications comparing dosages of drugs in a
12 therapeutic class.
- 13 2. A pharmacist may not substitute a drug for a therapeutically equivalent drug if:
14 a. The prescriber indicates no substitution is to be made; or
15 b. The board has determined a therapeutically equivalent drug should not be
16 substituted and notified pharmacists of that determination.
- 17 3. Before dispensing a therapeutically equivalent drug, a pharmacist shall:
18 a. Verbally discuss the suggested substitution with the patient, including informing
19 the patient that the therapeutically equivalent drug does not contain the identical
20 active ingredient present in the prescribed drug and any differences in dosage
21 and frequency between the prescribed drug and the therapeutically equivalent
22 drug; and
23 b. Inform the patient of the patient's right to refuse the substitution; and
24 c. Determine whether the substitution would provide a cost benefit to the patient or
25 provide access if the prescribed drug is not available.
- 26 4. The pharmacist shall send notice of the substitution to the prescriber by electronic
27 communication within twenty-four hours of dispensing the drug to the patient.
- 28 5. The prescribing provider is not liable for a substitution made by a pharmacist.

29 **SECTION 5.** A new subsection to section 43-48-03 of the North Dakota Century Code is
30 created and enacted as follows:

31 Pharmacists duly and currently licensed to practice pharmacy.

- 1 **SECTION 6. REPEAL.** Section 43-15-25.3 of the North Dakota Century Code is repealed.
- 2 **SECTION 7. EFFECTIVE DATE.** This Act becomes effective upon its filing with the
- 3 secretary of state.

