

SENATE BILL NO. 2221

Introduced by

Senators Meyer, Anderson, Bekkedahl

Representatives Kasper, Keiser, O'Brien

1 A BILL for an Act to create and enact a new subsection to section 43-15-10 of the North Dakota
2 Century Code, relating to the powers of the state board of pharmacy, ~~and~~; to amend and
3 reenact section 43-15-01 of the North Dakota Century Code, relating to the practice of
4 pharmacy; and to declare an emergency.

5 **BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:**

6 **SECTION 1. AMENDMENT.** Section 43-15-01 of the North Dakota Century Code is
7 amended and reenacted as follows:

8 **43-15-01. Definitions.**

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

- 10 1. "Administration" means the direct application of a drug to the body of a patient. The
11 term includes:
- 12 a. The emergency maintenance of a drug delivery device used in home infusion
13 therapy by a qualified home pharmacist if nursing service is not available;
 - 14 b. ~~Upon~~ Immunization and vaccination by injection of an individual who is at least
15 three years of age upon an order by a practitioner authorized to prescribe such a
16 drug or by written protocol with a physician or nurse practitioner and
17 subsequently reported as a childhood immunization and other information if
18 required to the state's immunization information system pursuant to section
19 23-01-05.3;:
 - 20 ~~(1) Immunization and vaccination by injection of an individual who is at least~~
21 ~~eleven years of age; and~~
 - 22 ~~(2) Influenza vaccination by injection or by live, attenuated influenza vaccine of~~
23 ~~an individual who is at least five years of age;~~

- 1 c. Provision of other drugs to an individual who is at least ~~eighteen~~three years of
2 age upon the order of a practitioner authorized to prescribe such a drug; and
3 d. Provision of drugs to an individual receiving emergency services in a health care
4 facility upon an order or by established written protocol.
- 5 2. "Automated dispensing system" means a mechanical system that performs operations
6 or activities, other than compounding or administration, relative to the storage,
7 packaging, counting, labeling, and dispensing of medications and which collects,
8 controls, and monitors all transaction information.
- 9 3. "Board" means the state board of pharmacy.
- 10 4. "Compounding" means the preparation, mixing, assembling, packaging, or labeling of
11 a drug or device:
12 a. As the result of a practitioner's prescription drug order or initiative based on the
13 practitioner, patient, and pharmacist relationship in the course of professional
14 practice; or
15 b. For the purpose of, or as an incident to, research, teaching, or chemical analysis
16 and not for sale or dispensing.
- 17 Compounding also includes the preparation of drugs or devices in anticipation of
18 prescription drug orders based on routine, regularly observed prescribing patterns.
- 19 5. "Confidential information" means individually identifiable health information maintained
20 by the pharmacist in the patient's records or which is communicated to the patient as
21 part of a patient counseling.
- 22 6. "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a drug
23 or device from one person to another, whether or not for a consideration.
- 24 7. "Device" means an instrument, apparatus, implement, machine, contrivance, implant,
25 in vitro reagent, or other similar or related article, including any component part or
26 accessory, which is required under federal or North Dakota law to be prescribed by a
27 practitioner and dispensed by a pharmacist.
- 28 8. "Dispense" or "dispensing" means the preparation and delivery of a prescription drug,
29 pursuant to a lawful order of a practitioner or a nurse licensed under chapter 43-12.1
30 who is authorized by the practitioner to orally transmit the order that has been reduced
31 to writing in the patient's record, in a suitable container appropriately labeled for

1 subsequent administration to or use by a patient or other individual entitled to receive
2 the prescription drug.

3 9. "Distribute" means the delivery of a drug other than by dispensing or administering.

4 10. "Drug" or "drugs" means:

5 a. Articles recognized as drugs in the official United States pharmacopeia, official
6 national formulary, official homeopathic pharmacopeia, other drug compendium,
7 or any supplement to any of them;

8 b. Articles intended for use in the diagnosis, cure, mitigation, treatment, or
9 prevention of disease in man or other animal;

10 c. Articles other than food intended to affect the structure or any function of the
11 body of man or other animals; and

12 d. Articles intended for use as a component of any articles specified in
13 subdivision a, b, or c.

14 11. "Drug regimen review" includes the following activities:

15 a. Evaluation of the prescription drug orders and patient records for:

16 (1) Known allergies;

17 (2) Rational therapy-contraindications;

18 (3) Reasonable dose and route of administration; and

19 (4) Reasonable directions for use.

20 b. Evaluation of the prescription drug orders and patient records for duplication of
21 therapy.

22 c. Evaluation of the prescription drug orders and patient records for interactions:

23 (1) Drug-drug;

24 (2) Drug-food;

25 (3) Drug-disease; and

26 (4) Adverse drug reactions.

27 d. Evaluation of the prescription drug orders and patient records for proper
28 utilization, including overutilization or underutilization, and optimum therapeutic
29 outcomes.

30 12. "Emergency pharmacy practice" means in the event a pharmacist receives a request
31 for a prescription refill and the pharmacist is unable to obtain refill authorization from

- 1 the prescriber, the pharmacist may dispense and bill using a pharmacist national
2 provider identifier a one-time emergency refill of up to a ~~seventy-two-hour~~thirty-day
3 supply of the prescribed medication, provided that:
- 4 a. The prescription is not for a controlled substance listed in schedule II;
- 5 b. The pharmaceutical is essential to the maintenance of life or to the continuation
6 of therapy;
- 7 c. In the pharmacist's professional judgment, the interruption of therapy might
8 reasonably produce undesirable health consequences or may cause physical or
9 mental discomfort;
- 10 d. The pharmacist properly records the dispensing; and
- 11 e. The dispensing pharmacist notifies the prescriber of the emergency dispensing
12 within a reasonable time after the one-time emergency refill dispensing.
- 13 13. "Labeling" means the process of preparing and affixing of a label to any drug container
14 exclusive, however, of the labeling by a manufacturer, packer, or distributor of a
15 nonprescription drug or commercially packaged legend drug or device. Any label shall
16 include all information required by federal and North Dakota law or regulation.
- 17 14. "Manufacture" means the production, preparation, propagation, compounding,
18 conversion, or processing of a device or a drug, either directly or indirectly by
19 extraction from substances of natural origin or independently by means of chemical
20 synthesis or by a combination of extraction and chemical synthesis and includes any
21 packaging or repackaging of the substances or labeling or relabeling of its container,
22 except that this term does not include the preparation or compounding of a drug by an
23 individual for the individual's own use or the preparation, compounding, packaging, or
24 labeling of a drug:
- 25 a. By a pharmacist or practitioner as an incident to dispensing or administering of a
26 drug in the course of the person's professional practice; or
- 27 b. By a practitioner or by the practitioner's authorization under supervision for the
28 purpose of or as an incident to research, teaching, or chemical analysis and not
29 for sale.
- 30 15. "Manufacturer" means a person engaged in the manufacture of drugs in facilities
31 located within North Dakota.

- 1 16. "Medicine" means a drug or combination of drugs, used in treating disease in man or
2 other animals.
- 3 17. "Nonprescription drugs" means medicines or drugs which may be sold without a
4 prescription and which are prepackaged for use by the consumer and labeled in
5 accordance with the requirements of the statutes and regulations of this state and the
6 federal government.
- 7 18. "Original package" means the original carton, case, can, box, vial, bottle, or other
8 receptacle, put up by the manufacturer or wholesaler or distributor, with label attached,
9 making one complete package of the drug article.
- 10 19. "Person" means an individual, corporation, limited liability company, partnership,
11 association, or any other legal entity.
- 12 20. "Pharmaceutical care" is the provision of drug therapy and other pharmaceutical
13 patient care services intended to achieve outcomes related to the cure or prevention of
14 a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a
15 disease process as defined in the rules of the board.
- 16 21. "Pharmacist" means a person to whom the board has issued a license to practice the
17 profession of pharmacy whose license has not expired or been suspended.
- 18 22. "Pharmacy" or "drugstore" means every store or shop where drugs, medicines, or
19 chemicals are dispensed, displayed for sale, or sold, at retail for medicinal purposes,
20 or where prescriptions are compounded, and which is duly registered by the board.
- 21 23. "Pharmacy technician" means a person registered by the board who is employed by a
22 pharmacy to assist licensed pharmacists in the practice of pharmacy by performing
23 specific tasks delegated by and under the immediate personal supervision and control
24 of a licensed pharmacist, as permitted by the board.
- 25 24. "Practice of pharmacy" means the interpretation, evaluation, and monitoring of
26 prescription orders and patient drug therapy; the compounding, dispensing, labeling of
27 drugs and devices except labeling by a manufacturer, packer, or distributor of
28 nonprescription drugs and commercially packaged legend drugs and devices; the
29 participation in drug selection, drug monitoring, drug administration, drug regimen
30 review, the provision of these acts or services necessary as a primary health care
31 provider of pharmaceutical care, and drug utilization evaluations; the proper and safe

1 storage of drugs and devices and the maintenance of proper records for this storage;
2 the responsibility for advising, consulting, and educating if necessary or if regulated,
3 patients, public, and other health care providers on the rational, safe, and
4 cost-effective use of drugs including therapeutic values, content, hazards, and
5 appropriate use of drugs and devices; the participation in interpreting and applying
6 pharmacokinetic data and other pertinent laboratory data to design safe and effective
7 drug dosage regimens; if appropriate and if regulated, the participation in drug
8 research either scientific or clinical as investigator or in collaboration with other
9 investigators for the purposes of studying the effects of drugs on animals or human
10 subjects, with other drugs or chemicals, and with drug delivery devices; emergency
11 pharmacy practice; prescriptive practices as limited under this chapter; the
12 performance of laboratory tests to provide pharmaceutical care services which are
13 waived under the Federal Clinical Laboratory Improvement Act of 1988 [Pub. L.
14 100-578, section 2; 102 Stat. 2903; 42 U.S.C. 263a et seq.], as amended; and the
15 offering or performing of those acts, services, operations, or transactions necessary in
16 the conduct, operation, management, and control of pharmacy.

- 17 25. "Practitioner" means an individual licensed, registered, or otherwise authorized by the
18 jurisdiction in which the individual is practicing to prescribe drugs in the course of
19 professional practice.
- 20 26. "Prescription" means any order for drugs or medical supplies, if such order is written or
21 signed or transmitted by word of mouth, telephone, telegram, or other means of
22 communication by a duly licensed physician, optometrist, dentist, veterinarian, or other
23 practitioner, licensed by law to prescribe and administer such drugs or medical
24 supplies intended to be filled, compounded, or dispensed by a pharmacist or any order
25 for drugs or medical supplies transmitted orally by a nurse licensed under chapter
26 43-12.1 as written and signed by such a duly licensed physician, optometrist, dentist,
27 veterinarian, or other practitioner.
- 28 27. "Prescription drug or legend drug" means a drug which, under federal law is required,
29 prior to being dispensed or delivered, to be labeled with one of the following:
30 a. "Caution: Federal law prohibits dispensing without prescription";

- 1 b. "Caution: Federal law restricts this drug to use by or on the order of a licensed
2 veterinarian"; or
- 3 c. Rx only;
4 or a drug which is required by any applicable federal or North Dakota law or rule to be
5 dispensed on prescription only or is restricted to use by practitioners only.
- 6 28. "Public health issues" include immunizations, tobacco cessation, and other issues
7 deemed appropriate by the board.
- 8 29. "Radiopharmaceutical service" means, but is not limited to, the compounding,
9 dispensing, labeling, and delivery of radiopharmaceuticals; the participation in
10 radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper
11 and safe storage and distribution of radiopharmaceuticals; the maintenance of
12 radiopharmaceutical quality assurance; the responsibility for advising, where
13 necessary or where regulated, of therapeutic values, hazards, and use of
14 radiopharmaceuticals; and the offering or performing of those acts, services,
15 operations, or transactions necessary in the conduct, operation, management, and
16 control of radiopharmaceuticals.
- 17 29-30. "Wholesaler" means a person with facilities located in this state who buys for resale
18 and distribution to persons other than consumers.

19 **SECTION 2.** A new subsection to section 43-15-10 of the North Dakota Century Code is
20 created and enacted as follows:

21 To establish limited prescriptive authority through a statewide protocol for public health
22 issues within the scope of practice for a pharmacist. The board shall adopt rules to
23 establish standards of care.

24 **SECTION 3. EMERGENCY.** This Act is declared to be an emergency measure.