

Introduced by

Senators Fischer, Flakoll, Klein

Representatives Koppelman, B. Thoreson

1 A BILL for an Act to create and enact a new section to chapter 43-15 of the North Dakota
2 Century Code, relating to parenteral pharmacists; and to amend and reenact section 43-15-01
3 of the North Dakota Century Code, relating to pharmacy definitions.

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

5 **SECTION 1. AMENDMENT.** Section 43-15-01 of the 1997 Supplement to the North
6 Dakota Century Code is amended and reenacted as follows:

7 **43-15-01. Definitions.** In this chapter, unless the context or subject matter otherwise
8 requires:

- 9 1. "Administration" means the direct application of a drug to the body of a patient.
10 ~~The term includes the emergency maintenance of a drug delivery device used in~~
11 ~~home infusion therapy by a qualified home pharmacist when nursing service is not~~
12 ~~available. The term excludes the regular ongoing delivery of a drug to the patient~~
13 ~~in a health care setting and other parenteral administration of a drug.~~
- 14 2. "Authorization to administer parenteral drugs" means an order from a practitioner
15 to a qualified parenteral pharmacist which authorizes administration of specific
16 parenteral drugs to specific individuals.
- 17 3. "Board" means the state board of pharmacy.
- 18 4. "Compounding" means the preparation, mixing, assembling, packaging, or labeling
19 of a drug or device:
- 20 a. As the result of a practitioner's prescription drug order or initiative based on
21 the practitioner, patient, and pharmacist relationship in the course of
22 professional practice; or
- 23 b. For the purpose of, or as an incident to, research, teaching, or chemical
24 analysis and not for sale or dispensing.

1 ~~Compounding also~~ The term includes the preparation of drugs or devices in
2 anticipation of prescription drug orders based on routine, regularly observed
3 prescribing patterns.

4 4- 5. "Confidential information" means information maintained by the pharmacist in the
5 patient's records or which is communicated to the patient as part of a patient
6 counseling, which is privileged and may be released only to the patient or, as the
7 patient directs, to those practitioners and other pharmacists where, in the
8 pharmacist's professional judgment, such release is necessary to protect the
9 patient's health and well-being, and to such other persons or governmental
10 agencies authorized by law to receive such confidential information.

11 5- 6. "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a
12 drug or device from one person to another, whether or not for a consideration.

13 6- 7. "Device" means an instrument, apparatus, implement, machine, contrivance,
14 implant, in vitro reagent or other similar or related article, including any component
15 part or accessory, which is required under federal or North Dakota law to be
16 prescribed by a petitioner and dispensed by a pharmacist.

17 7- 8. "Dispense" or "dispensing" means the preparation and delivery of a prescription
18 drug, pursuant to a lawful order of a practitioner or a nurse licensed under chapter
19 43-12.1 who is authorized by the practitioner to orally transmit the order that has
20 been reduced to writing in the patient's record, in a suitable container appropriately
21 labeled for subsequent administration to or use by a patient or other individual
22 entitled to receive the prescription drug.

23 8- 9. "Distribute" means the delivery of a drug other than by dispensing or administering.

24 9- 10. "Drug" or "drugs" means:

- 25 a. Articles recognized as drugs in the official United States pharmacopeia,
26 official national formulary, official homeopathic pharmacopeia, other drug
27 compendium, or any supplement to any of them;
- 28 b. Articles intended for use in the diagnosis, cure, mitigation, treatment, or
29 prevention of disease in man or other animal;
- 30 c. Articles (other than food) intended to affect the structure or any function of the
31 body of man or other animals; and

- 1 d. Articles intended for use as a component of any articles specified in
2 subdivision a, b, or c.
- 3 ~~40.~~ 11. "Drug regimen review" includes the following activities:
- 4 a. Evaluation of the prescription drug orders and patient records for:
- 5 (1) Known allergies;
- 6 (2) Rational therapy-contraindications;
- 7 (3) Reasonable dose and route of administration; and
- 8 (4) Reasonable directions for use.
- 9 b. Evaluation of the prescription drug orders and patient records for duplication
10 of therapy.
- 11 c. Evaluation of the prescription drug orders and patient records for interactions:
- 12 (1) Drug-drug;
- 13 (2) Drug-food;
- 14 (3) Drug-disease; and
- 15 (4) Adverse drug reactions.
- 16 d. Evaluation of the prescription drug orders and patient records for proper
17 utilization, including overutilization or underutilization, and optimum
18 therapeutic outcomes.
- 19 ~~44.~~ 12. "Emergency pharmacy practice" means in the event a pharmacist receives a
20 request for a prescription refill and the pharmacist is unable to obtain refill
21 authorization from the prescriber, the pharmacist may dispense a one-time
22 emergency refill of up to a seventy-two hour supply of the prescribed medication,
23 provided that:
- 24 a. The prescription is not for a controlled substance listed in Schedule II;
- 25 b. The pharmaceutical is essential to the maintenance of life or to the
26 continuation of therapy;
- 27 c. In the pharmacist's professional judgment, the interruption of therapy might
28 reasonably produce undesirable health consequences or may cause physical
29 or mental discomfort;
- 30 d. The pharmacist properly records the dispensing; and

- 1 e. The dispensing pharmacist notifies the prescriber of the emergency
2 dispensing within a reasonable time after the one-time emergency refill
3 dispensing.
- 4 ~~42.~~ 13. "Labeling" means the process of preparing and affixing of a label to any drug
5 container exclusive, however, of the labeling by a manufacturer, packer, or
6 distributor of a nonprescription drug or commercially packaged legend drug or
7 device. Any label ~~shall~~ must include all information required by federal and North
8 Dakota law or regulation.
- 9 ~~43.~~ 14. "Manufacture" means the production, preparation, propagation, compounding,
10 conversion, or processing of a device or a drug, either directly or indirectly by
11 extraction from substances of natural origin or independently by means of chemical
12 synthesis or by a combination of extraction and chemical synthesis and includes
13 any packaging or repackaging of the substances or labeling or relabeling of its
14 container, except that this term does not include the preparation or compounding of
15 a drug by an individual for the individual's own use or the preparation,
16 compounding, packaging, or labeling of a drug:
- 17 a. By a pharmacist or practitioner as an incident to his dispensing or
18 administering of a drug in the course of his professional practice; or
19 b. By a practitioner or by his authorization under supervision for the purpose of
20 or as an incident to research, teaching, or chemical analysis and not for sale.
- 21 ~~44.~~ 15. "Manufacturer" means a person engaged in the manufacture of drugs in facilities
22 located within ~~North Dakota~~ this state.
- 23 ~~45.~~ 16. "Medicine" means a drug or combination of drugs, used in treating disease in man
24 or other animals.
- 25 ~~46.~~ 17. "Nonprescription drugs" means medicines or drugs ~~which~~ that may be sold without
26 a prescription and which are prepackaged for use by the consumer and labeled in
27 accordance with the requirements of the statutes and regulations of this state and
28 the federal government.
- 29 ~~47.~~ 18. "Original package" means the original carton, case, can, box, vial, bottle, or other
30 receptacle, put up by the manufacturer or wholesaler or distributor, with label
31 attached, making one complete package of the drug article.

1 pertinent laboratory data to design safe and effective drug dosage regimens; where
2 appropriate and where regulated, the participation in drug research either scientific
3 or clinical as investigator or in collaboration with other investigators for the
4 purposes of studying the effects of drugs on animals or human subjects, with other
5 drugs or chemicals, and with drug delivery devices; emergency pharmacy practice;
6 prescriptive practices as limited herein; and the offering or performing of those
7 acts, services, operations, or transactions necessary in the conduct, operation,
8 management, and control of pharmacy.

9 ~~24.~~ 26. "Practitioner" means a physician, dentist, veterinarian, scientific investigator, or
10 other person (other than pharmacists) licensed by ~~North Dakota~~ this state and
11 permitted by ~~such~~ the license to dispense, conduct research with respect to or
12 administer drugs in the course of professional practice or research in ~~North Dakota~~
13 this state.

14 ~~25.~~ 27. "Prescription" means any order for drugs or medical supplies, where such order is
15 written or signed or transmitted by word of mouth, telephone, telegram, or other
16 means of communication by a duly licensed physician, optometrist, dentist,
17 veterinarian, or other practitioner, licensed by law to prescribe and administer such
18 drugs or medical supplies intended to be filled, compounded, or dispensed by a
19 pharmacist or any order for drugs or medical supplies transmitted orally by a nurse
20 licensed under chapter 43-12.1 as written and signed by such a duly licensed
21 physician, optometrist, dentist, veterinarian, or other practitioner.

22 ~~26.~~ 28. "Prescription drug or legend drug" means a:
23 a. ~~A drug which, that~~ that under federal law is required, ~~prior to~~ before being
24 dispensed or delivered, to be labeled with ~~either of the following~~:
25 a. (1) "Caution: Federal law prohibits dispensing without prescription"; or
26 b. (2) "Caution: Federal law restricts this drug to use by or on the order of a
27 licensed veterinarian"; or
28 b. ~~or a~~ A drug which that is required by any applicable federal or North Dakota
29 law or regulation to be dispensed on prescription only or is restricted to use by
30 practitioners only.

1 29. "Qualified parenteral pharmacist" means a pharmacist who successfully completed
2 a board-approved course of study pertaining to the parenteral administration of
3 drugs and maintains continuing education requirements according to rules adopted
4 by the board.

5 ~~27.~~ 30. "Radiopharmaceutical service" ~~means, but is not limited to,~~ includes the
6 compounding, dispensing, labeling, and delivery of radiopharmaceuticals; the
7 participation in radiopharmaceutical selection and radiopharmaceutical utilization
8 reviews; the proper and safe storage and distribution of radiopharmaceuticals; the
9 maintenance of radiopharmaceutical quality assurance; the responsibility for
10 advising, where necessary or where regulated, of therapeutic values, hazards, and
11 use of radiopharmaceuticals; and the offering or performing of those acts, services,
12 operations, or transactions necessary in the conduct, operation, management, and
13 control of radiopharmaceuticals.

14 ~~28.~~ 31. "Wholesaler" means a person with facilities located in this state who buys for
15 resale and distribution to persons other than consumers.

16 **SECTION 2.** A new section to chapter 43-15 of the North Dakota Century Code is
17 created and enacted as follows:

18 **Qualified parenteral pharmacists.** A qualified parenteral pharmacist may administer
19 parenteral drugs upon receipt of an authorization to administer parenteral drugs from a
20 practitioner authorized to prescribe the drugs under rules adopted by the board.