Fifty-sixth
Legislative Assembly
of North Dakota

SENATE BILL NO. 2364

Introduced by

Senators Fischer, Flakoll, Klein

Representatives Koppelman, B. Thoreson

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

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. AMENDMENT. Section 43-15-01 of the 1997 Supplement to 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 the emergency maintenance of a drug delivery device used in home infusion therapy by a qualified home pharmacist when nursing service is not available. The term excludes the regular ongoing delivery of a drug to the patient in a health care setting and other parenteral administration of a drug.~~
2. "Authorization to administer parenteral drugs" means an order from a practitioner to a qualified parenteral pharmacist which authorizes administration of specific parenteral drugs to specific individuals.
3. "Board" means the state board of pharmacy.
~~3.~~ 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~~ The term includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

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

~~5.~~ 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.

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

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

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

~~9.~~ 10. "Drug" or "drugs" means:

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

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

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

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

~~10.~~ 11. "Drug regimen review" includes the following activities:

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

(1) Known allergies;

(2) Rational therapy-contraindications;

(3) Reasonable dose and route of administration; and

(4) Reasonable directions for use.

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

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

(1) Drug-drug;

(2) Drug-food;

(3) Drug-disease; and

(4) Adverse drug reactions.

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

~~11.~~ 12. "Emergency pharmacy practice" means in the event a pharmacist receives a request for a prescription refill and the pharmacist is unable to obtain refill authorization from the prescriber, the pharmacist may dispense a one-time emergency refill of up to a seventy-two hour supply of the prescribed medication, provided that:

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

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

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

d. The pharmacist properly records the dispensing; and

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

~~12.~~ 13. "Labeling" means the process of preparing and affixing of a label to any drug container exclusive, however, of the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packaged legend drug or device. Any label ~~shall~~ must include all information required by federal and North Dakota law or regulation.

~~13.~~ 14. "Manufacture" means the production, preparation, propagation, compounding, conversion, or processing of a device or a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis and includes any packaging or repackaging of the substances or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging, or labeling of a drug:

a. By a pharmacist or practitioner as an incident to his dispensing or administering of a drug in the course of his professional practice; or

b. By a practitioner or by his authorization under supervision for the purpose of or as an incident to research, teaching, or chemical analysis and not for sale.

~~14.~~ 15. "Manufacturer" means a person engaged in the manufacture of drugs in facilities located within ~~North Dakota~~ this state.

~~15.~~ 16. "Medicine" means a drug or combination of drugs, used in treating disease in man or other animals.

~~16.~~ 17. "Nonprescription drugs" means medicines or drugs ~~which~~ that may be sold without a prescription and which are prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of this state and the federal government.

~~17.~~ 18. "Original package" means the original carton, case, can, box, vial, bottle, or other receptacle, put up by the manufacturer or wholesaler or distributor, with label attached, making one complete package of the drug article.

19. "Parenteral" means a sterile product prepared for injection through one or more layers of the skin.

~~18.~~ 20. "Person" means an individual, corporation, limited liability company, partnership, association, or any other legal entity.

~~19.~~ 21. "Pharmaceutical care" is the provision of drug therapy and other pharmaceutical patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process as defined in the rules of the board.

~~20.~~ 22. "Pharmacist" means a person to whom the board has issued a license to practice the profession of pharmacy whose license has not expired, or been suspended.

~~21.~~ 23. "Pharmacy" or "drugstore" means every store or shop where drugs, medicines, or chemicals are dispensed, displayed for sale, or sold, at retail for medicinal purposes, or where prescriptions are compounded, and which is duly registered by the board.

~~22.~~ 24. "Pharmacy technician" means a person registered by the board who is employed by a pharmacy to assist licensed pharmacists in the practice of pharmacy by performing specific tasks delegated by and under the immediate personal supervision and control of a licensed pharmacist, as permitted by the board.

~~23.~~ 25. "Practice of pharmacy" means the interpretation, evaluation, and monitoring of prescription orders and patient drug therapy; the compounding, dispensing, labeling of drugs and devices except labeling by a manufacturer, packer, or distributor of nonprescription drugs and commercially packaged legend drugs and devices; the participation in drug selection, drug monitoring, drug administration, drug regimen review, the provision of these acts or services necessary as a primary health care provider of pharmaceutical care, and drug utilization evaluations; the proper and safe storage of drugs and devices and the maintenance of proper records therefor; the responsibility for advising, consulting, and educating where necessary or where regulated, patients, public, and other health care providers on the rational, safe, and cost-effective use of drugs including therapeutic values, content, hazards, and appropriate use of drugs and devices; the participation in interpreting and applying pharmacokinetic data and other

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

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

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

~~26.~~ 28. "Prescription drug or legend drug" means ~~a~~:

a. A drug ~~which,~~ that under federal law is required, ~~prior to~~ before being dispensed or delivered, to be labeled with ~~either of the following~~:

~~a.~~ (1) "Caution: Federal law prohibits dispensing without prescription"; or

~~b.~~ (2) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; or

b. ~~or a~~ A drug ~~which~~ that is required by any applicable federal or North Dakota law or regulation to be dispensed on prescription only or is restricted to use by practitioners only.

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

~~27.~~ 30. "Radiopharmaceutical service" ~~means, but is not limited to,~~ includes the compounding, dispensing, labeling, and delivery of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, where 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.

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

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

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