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Sixty-seventh
Legislative Assembly
of North Dakota

FIRST ENGROSSMENT

ENGROSSED SENATE BILL NO. 2221

Introduced by

Senators Meyer, Anderson, Bekkedahl

Representatives Kasper, Keiser, O'Brien

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

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. 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. ~~Upon~~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~~:~~;
      ~~(1) Immunization and vaccination by injection of an individual who is at least eleven years of age; and~~
      ~~(2) Influenza vaccination by injection or by live, attenuated influenza vaccine of an individual who is at least five years of age;~~

c. Provision of other drugs to an individual who is at least ~~eighteen~~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 accessory, which is required under federal or North Dakota law to be prescribed by a practitioner and dispensed by a pharmacist.

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.

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

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.

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.

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 and bill using a pharmacist national provider identifier a one-time emergency refill of up to a ~~seventy-two-hour~~thirty-day 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.

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 include all information required by federal and North Dakota law or regulation.

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 dispensing or administering of a drug in the course of the person's professional practice; or

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

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

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

17. "Nonprescription drugs" means medicines or drugs which 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.

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

20. "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.

21. "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.

22. "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.

23. "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.

24. "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 for this storage; the responsibility for advising, consulting, and educating if necessary or if 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; if appropriate and if 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 under this chapter; the performance of laboratory tests to provide pharmaceutical care services which are waived under the Federal Clinical Laboratory Improvement Act of 1988 [Pub. L. 100-578, section 2; 102 Stat. 2903; 42 U.S.C. 263a et seq.], as amended; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of pharmacy.

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

26. "Prescription" means any order for drugs or medical supplies, if 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.

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

a. "Caution: Federal law prohibits dispensing without prescription";

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

c. Rx only;

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

28. "Public health issues" include immunizations, tobacco cessation, and other issues deemed appropriate by the board.

29. "Radiopharmaceutical service" means, but is not limited to, 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.

~~29.~~30. "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 subsection to section 43-15-10 of the North Dakota Century Code is created and enacted as follows:

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

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