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Sixtieth
Legislative Assembly
of North Dakota

FIRST ENGROSSMENT

ENGROSSED HOUSE BILL NO. 1054

Introduced by

Human Services Committee

(At the request of the State Board of Pharmacy)

A BILL for an Act to create and enact sections 43-15-38.1 and 43-15-42.3 of the North Dakota Century Code, relating to pharmacy closings and reporting requirements; to amend and reenact sections 43-15-01, 43-15-05, 43-15-10, and 43-15-25.2 of the North Dakota Century Code, relating to the practice of pharmacy; and to provide a penalty.

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.
   a. The term includes:
      (1) The emergency maintenance of a drug delivery device used in home infusion therapy by a qualified home pharmacist when nursing service is not available;
      (2) Immunization and vaccination by injection of an individual who is more than eighteen years of age, upon an order by a physician or nurse practitioner authorized to prescribe such a drug or by written protocol with a physician or nurse practitioner; and
      (3) Provision of drugs by subcutaneous, intradermal, and intramuscular injection to an individual who is more than eighteen years of age upon the order of a physician or nurse practitioner authorized to prescribe such a drug.
   b. The term does not include the regular ongoing delivery of a drug to the patient in a health care setting and other parenteral administration of a drug.

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.

~~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 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 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.

~~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 practitioner 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 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 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.

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

~~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 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.

~~18.~~ 19. "Person" means an individual, corporation, limited liability company, partnership, association, or any other legal entity.

~~19.~~ 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.

~~20.~~ 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.

~~21.~~ 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.

~~22.~~ 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.

~~23.~~ 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.

~~24.~~ 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.

~~25.~~ 26. "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.~~ 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.

~~27.~~ 28. "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.

~~28.~~ 29. "Wholesaler" means a person with facilities located in this state who buys for resale and distribution to persons other than consumers.

SECTION 2. AMENDMENT. Section 43-15-05 of the North Dakota Century Code is amended and reenacted as follows:

43-15-05. Compensation of board - Disposition of fees. Each member of the board shall receive a per diem of ~~twenty~~ two hundred dollars for attendance at board meetings, and all actual and necessary expenses incurred in attending such meetings and in performing other official duties. The mileage and travel expense allowed may not exceed the amount provided for in section 54-06-09. All funds collected or received by the board must be deposited and disbursed in accordance with section 54-44-12.

SECTION 3. AMENDMENT. Section 43-15-10 of the North Dakota Century Code is amended and reenacted as follows:

43-15-10. Powers of board. In addition to other powers provided by law, the board shall have the following powers and duties, which shall be exercised in conformity with chapter 28-32 in order to protect the public health, welfare, and safety:

1. To place on probation, reprimand, or fine any pharmacy, pharmacist, or ~~licensed pharmacist~~ pharmacy intern or pharmacy technician; or refuse to issue or renew,

or suspend, revoke, restrict, or cancel, the license, permit, or ~~license~~ registration of any pharmacy, pharmacist, or ~~licensed pharmacist~~ pharmacy intern or pharmacy technician, if any of the following grounds apply and the pharmacy, pharmacist, or ~~licensed pharmacist~~ pharmacy intern or pharmacy technician:

a. Is addicted to any alcohol or drug habit.

b. Uses any advertising statements of a character tending to deceive or mislead the public.

c. Is subject to drug or alcohol dependency or abuse.

d. Permits or engages in the unauthorized sale of narcotic drugs or controlled substances.

e. Permits or engages an unauthorized person to practice pharmacy.

f. Is mentally or physically incompetent to handle pharmaceutical duties.

g. Is guilty of fraud, deception, or misrepresentation in passing the pharmacist examination.

h. Is found by the board in violation of any of the provisions of the laws regulating drugs, pharmacies, and pharmacists or interns and technicians or the rules and regulations established by the board.

i. Is found to have engaged in unprofessional conduct as that term is defined by the rules of the board.

j. Is subject to incapacity of a nature that prevents a pharmacist from engaging in the practice of pharmacy with reasonable skill, competence, and safety to the public.

k. Is found guilty by a court of competent jurisdiction of one or more of the following:

(1) A felony, as defined by the statutes of North Dakota.

(2) Any act involving moral turpitude or gross immorality.

(3) Violations of the pharmacy or the drug laws of North Dakota or rules and regulations pertaining thereto, or of statutes, rules or regulations of any other state, or of the federal government.

l. Commits fraud or intentional misrepresentation in securing the issuance or renewal of a license or pharmacy permit.

m. Sells, dispenses, or compounds any drug while on duty and while under the influence of alcohol or while under the influence of a controlled substance without a practitioner's prescription.

n. Discloses confidential information to any person, except as authorized by law.

2. To prescribe rules and regulations not inconsistent with this chapter governing the cancellation or suspension of a license.

3. To examine and license as pharmacist any applicant found entitled to such license.

4. To prescribe rules and regulations for the guidance of its members, officers, and employees, and to ensure the proper and orderly dispatch of its business.

5. To employ and pay such persons as it may deem necessary to inspect pharmacies in this state, investigate pharmacies for the information of the board, procure evidence in any proceeding pending before the board, or procure evidence in aid of any prosecution or action in any court commenced or about to be commenced by or against the board in relation to any matter in which the board has any duty to perform.

6. To employ and pay counsel to advise the board or to prosecute or defend any action or proceeding commenced by or against the board or pending before it.

7. To grant permits and renewals thereof for the establishment and operation of pharmacies.

8. Only for good cause to cancel, revoke, or suspend permits and renewals thereof for the establishment and operation of pharmacies.

9. To prescribe reasonable and nondiscriminatory rules and regulations in regard to granting, renewing, canceling, revoking, or suspending permits and renewals for establishing and operating pharmacies.

10. Action by the board canceling, revoking, suspending, or refusing to renew a permit to establish or operate a pharmacy shall not be enforced for thirty days after notice has been given an aggrieved party by the board, nor during the time that an appeal by such aggrieved party is pending and until such appeal is finally determined.

11. To prescribe reasonable rules and regulations relating to the physical design of space occupied by a pharmacy to ensure appropriate control of and safeguards over the contents of such pharmacy.

12. To regulate and control the practice of pharmacy in North Dakota.

13. To adopt, amend, and repeal rules for the regulation of pharmacies and pharmacists providing radiopharmaceutical services, including special training, education, and experience for pharmacists and physical design of space, safeguards, and equipment for pharmacies.

14. To adopt, amend, and repeal rules determined necessary by the board for the proper administration and enforcement of this chapter, chapter 19-02.1 as that chapter pertains to drugs, subject to approval of the director of the state department of health, and chapter 19-03.1.

15. The board or its authorized representatives may investigate and gather evidence concerning alleged violations of the provisions of chapter 43-15, chapter 19-02.1 that pertains to drugs, chapters 19-03.1, 19-03.2, and 19-04, or of the rules of the board. Board investigative files are confidential and may not be considered public records or open records for purposes of section 44-04-18, until a complaint is filed or a decision made by the board not to file a complaint.

16. In addition to other remedies, the board may apply to the district court in the jurisdiction of an alleged violation, and that court has jurisdiction upon hearing and for cause shown, to grant a temporary or permanent injunction restraining any person from violating any provision of chapter 43-15, chapter 19-02.1 pertaining to drugs, and chapter 19-03.1, whether or not there exists an adequate remedy at law. Whenever a duly authorized representative of the board finds or has probable cause to believe that any drug or device is adulterated, misbranded, mislabeled, or improperly identified, within the meaning of chapter 19-02.1, the representative shall affix to that drug or device a tag or other appropriate marking giving notice that the article is or is suspected of being adulterated, misbranded, mislabeled, or improperly identified, has been detained or embargoed and warning all persons not to remove or dispose of such article by sale or otherwise until provision for removal or disposal is given by the board or its agents or the court. No person may remove or dispose of such embargoed drug or device by sale or otherwise without the permission of the board or its agent, or, after summary proceedings have been instituted, without permission from the court.

17. When a drug or device detained or embargoed has been declared by such representative to be adulterated, misbranded, mislabeled, or improperly identified, the board shall, as soon as practical thereafter, petition the district court in whose jurisdiction the article is detained or embargoed for an order for condemnation of such article. If the judge determines that the drug or device so detained or embargoed is not adulterated, misbranded, mislabeled, or improperly identified, the board shall direct the immediate removal of the tag or other marking. If the court finds the detained or embargoed drug or device is adulterated, misbranded, mislabeled, or improperly identified, such drug or device, after entry of the decree, shall be destroyed at the expense of the owner under the supervision of a board representative and all court costs and fees, storage, and other proper expense shall be borne by the owner of such drug or device. When the adulteration, misbranding, mislabeling, or improper identification can be corrected by proper labeling or processing of the drug or device, the court, after entry of the decree and after such costs, fees, and expenses have been paid and a good and sufficient bond has been posted, may direct that such drug or device be delivered to the owner for labeling or processing under the supervision of a board representative. Expense of supervision shall be paid by the owner. Bond posted shall be returned to the owner of the drug or device on representation to the court by the board that the drug or device is no longer in violation of the embargo and the expense of supervision has been paid. Nothing in this section shall be construed to require the board to report violations whenever the board believes the public's interest will be adequately served in the circumstances by a suitable written notice or warning.

18. The board shall establish a bill of rights for patients concerning the health care services a patient may expect in regard to pharmaceutical care.

19. To adopt, amend, and repeal rules as may be deemed necessary by the board to register pharmacy technicians pursuant to qualifications established by the board, to charge a pharmacy technician an annual registration fee not to exceed fifty dollars, to specify tasks associated with and included in the practice of pharmacy which may be delegated by a licensed pharmacist to a registered pharmacy technician, to provide for suspension or revocation of a pharmacy technician's

registration, and to regulate and control pharmacy technicians. The board may allocate up to fifty percent of the amount of the registration fee to an appropriate pharmacy technician association for its general operating expenses, including pharmacy technician education and development standards.

20. To require the self-reporting by an applicant or a licensee of any information the board determines may indicate possible deficiencies in practice, performance, fitness, or qualifications.

SECTION 4. AMENDMENT. Section 43-15-25.2 of the North Dakota Century Code is amended and reenacted as follows:

43-15-25.2. Educational requirements - Rules. The board shall adopt rules establishing the educational requirements and quality control procedures for pharmacists who conduct laboratory tests provided in subsection ~~23~~ 24 of section 43-15-01. These rules must include a requirement that pharmacists receive training for each specific test performed and a requirement that pharmacists demonstrate proficiency for each test performed following nationally recognized proficiency guidelines.

SECTION 5. Section 43-15-38.1 of the North Dakota Century Code is created and enacted as follows:

43-15-38.1. Closing a pharmacy. The permitholder and the pharmacist in charge are jointly responsible to follow the procedures outlined in the rules for closing a pharmacy.

SECTION 6. Section 43-15-42.3 of the North Dakota Century Code is created and enacted as follows:

43-15-42.3. Reporting requirements - Penalty. A pharmacist, pharmacy permitholder, pharmacy intern, pharmacy technician, health care institution in the state, state agency, or law enforcement agency in the state having actual knowledge that a pharmacist, pharmacy intern, or pharmacy technician may have committed any of the grounds for disciplinary action provided by law or rules adopted by the board shall promptly report that information in writing to the state board of pharmacy. A pharmacist, pharmacy technician, or institution from which the pharmacist or pharmacy technician voluntarily resigns, or voluntarily limits that individual's staff privileges, shall report the actions of the licensee or registrant to the state board of pharmacy if that action occurs while the licensee or registrant is under formal or informal investigation by the institution or a committee of the institution for any reason related to

possible professional incompetence, unprofessional conduct, or mental or physical impairment. Upon receiving a report concerning a licensee or registrant, the board's investigative committee may investigate any evidence that appears to show a licensee or registrant is committing, or may have committed, any of the grounds for disciplinary action provided by law or rules adopted by the board. A person required to report under this section who makes a report in good faith is not subject to criminal prosecution or civil liability for making the report. For purposes of any civil proceeding, the good faith of a person who makes the report under this section is presumed. A report to the impaired pharmacist program, the pharm-assist committee, of the North Dakota pharmacists association is considered reporting under this section. For purposes of this section, a person has actual knowledge if that person acquired the information by personal observation or under circumstances that cause that person to believe there exists a substantial likelihood that the information is correct. An agency or health care institution that violates this section is guilty of a class B misdemeanor. A pharmacist, pharmacy permitholder, pharmacy intern, or pharmacy technician who violates this section is guilty of a class B misdemeanor and is subject to administrative action by the state board of pharmacy as specified by law or by rule.