

# North Dakota State Board of Pharmacy

<b>KEY:</b>	43-15	North Dakota Century Code (Law)
	19	Statute (Law)
	61	Administrative Code (Rules/Regulations)

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## ARTICLE 61-01 GENERAL ADMINISTRATION

### Chapter 61-01-01

#### Organization of Board

##### Section

#### 61-01-01-01 Organization of Board of Pharmacy

1. **History and functions.** The 1890 legislative assembly passed pharmacy practice legislation codified as North Dakota Century Code chapter 43-15. This chapter requires the governor to appoint a state board of pharmacy. The board is responsible for examining and licensing applicants for licensure as pharmacists, for issuing permits to operate pharmacies, and for regulating and controlling the dispensing of prescription drugs and the practice of pharmacy for the protection of the health, welfare, and safety of the citizens of the state.
2. **Board membership.** The board consists of seven members appointed by the governor. Five members of the board must be licensed pharmacists, one member must be a registered pharmacy technician, and one member must represent the public and may not be affiliated with any group or profession that provides or regulates any type of health care. Board members serve five-year terms, with one of the pharmacist's terms expiring each year. The term of the public member and registered pharmacy technician member will expire five years from May eighth in the year of their appointment.
3. **Executive director.** The executive director of the board is appointed by the board and is responsible for administration of the activities of the board.
4. **Inquiries.** Inquiries regarding the board may be addressed to the executive director:

State Board of Pharmacy

P.O. Box 1354

Bismarck, ND 58502-1354

**Street address** - 1906 East Broadway Avenue **Web address** - [www.nodakpharmacy.com](http://www.nodakpharmacy.com)

**E-mail address** - [www.ndboph@btinet.net](mailto:www.ndboph@btinet.net)

**Telephone** - 701-328-9535

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**History:** Amended effective August 1, 1983; November 1, 1985; October 1, 1987; February 1, 1993; April 1, 1994; January 1, 2000; January 1, 2004; April 1, 2010.

**General Authority:** NDCC 28-32-02.1

**Law Implemented:** NDCC 28-32-02.1

## ARTICLE 61-02 PHARMACIES

### Chapter

- 61-02-01 Pharmacy Permits
- 61-02-02 Building Standards for Pharmacies
- 61-02-03 Security Standards for Pharmacies
- 61-02-04 Sanitary Standards for Pharmacies
- 61-02-05 Existing Pharmacies
- 61-02-06 Computer Pharmacy Regulations

61-02-07 Clerical Personnel [Repealed]  
61-02-07.1 Pharmacy Technician  
61-02-08 Telepharmacy Pilot Project Rules

## **CHAPTER 61-02-01 PHARMACY PERMITS**

### Section

61-02-01-01 Permit Required  
61-02-01-02 Application for Permit  
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61-02-01-04 Permit Not Transferable  
61-02-01-05 Change of Ownership  
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61-02-01-10 Pharmacist-in-Charge - Requirement - Definition - Duties  
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61-02-01-13 Pharmacist on Duty  
61-02-01-14 Limitation on Rent  
61-02-01-15 Closing a Pharmacy  
61-02-01-16 Transfer of Controlled Substances When Selling a Business  
61-02-01-17 Identification  
61-02-01-18 Policy and Procedure Manual Required

**61-02-01-01. Permit required.** No person, partnership, association, or corporation shall conduct a pharmacy in North Dakota without first obtaining a permit to do so from the board. A fee, set by the board but not to exceed that prescribed by statute, shall be charged for each permit.

1. Each physical location of a pharmacy shall have a separate pharmacy permit. A location is defined as being in the same building at the same physical address. Buildings connected by tunnels, skywalks, or other similar methods must be deemed separate physical locations.
2. Any pharmacy receiving a permit shall advise the board, when applying for the permit and when changes occur, of the name of the employees of the pharmacy who are:
  - a. The pharmacist-in-charge of the pharmacy, who shall be a licensed pharmacist in North Dakota in good standing;
  - b. All other licensed pharmacists who shall be licensed pharmacists in North Dakota in good standing;
  - c. All licensed pharmacy interns who shall be licensed pharmacy interns in North Dakota in good standing;
  - d. All registered pharmacy technicians who shall be registered pharmacy technicians in North Dakota in good standing; and
  - e. All supportive personnel permitted in the pharmacy area.
3. Nothing in this section prohibits a pharmacy with other than class F permit from delivering drugs or devices through the United States postal service or other parcel delivery service or hand delivery.
4. Classes of pharmacy permits are as follows:
  - a. Class A - Permit to conduct an outpatient pharmacy. These permits are issued to a pharmacy dispensing drugs or devices to the general public pursuant to a valid prescription.
  - b. Class B - Permit to conduct a hospital pharmacy. These permits are issued to a pharmacy dispensing drugs or devices to persons who are patients in a hospital, patients who are being discharged, or patients in emergency situations, pursuant to a valid prescription. These permits shall be issued to facilities licensed under North Dakota Century Code chapter 23-16 and shall be issued in the name of the facility.



- c. Class C - Permit to conduct a sterile compounding pharmacy. These permits are issued to a pharmacy dispensing sterile injectable drug products and devices to the general public who are not patients within a facility with a class B pharmacy permit pursuant to a valid prescription.
  - d. Class D - Permit to conduct a long-term care pharmacy. These permits are issued to a pharmacy dispensing drugs and devices to residents of facilities licensed under North Dakota Century Code chapters 23-09.3 and 23-16 pursuant to a valid prescription which are not physically accessed by the general public.
  - e. Class E - Permit to conduct a nuclear pharmacy. These permits are issued to a pharmacy dispensing or providing diagnostic or therapeutic radioactive drugs or devices for administration to an ultimate user.
  - f. Class F - Permit to conduct a mail-order pharmacy. These permits are issued to a pharmacy dispensing drugs and devices to the general public exclusively through the United States postal service or other parcel delivery service pursuant to a valid prescription but which are not physically accessed by the general public.
  - g. Class G - Permit to conduct an out-of-state pharmacy. These permits are issued to any pharmacy operating outside the state of North Dakota which ships, mails, or delivers in any manner a dispensed prescription drug or legend device into North Dakota, which shall obtain and hold a pharmacy permit issued by the North Dakota state board of pharmacy and that part of the pharmacy operation dispensing the prescription for a North Dakota resident shall abide by state laws and rules of the board.
  - h. Class H - Permit to conduct a governmental agency pharmacy. This permit is issued to a pharmacy operated by the state of North Dakota, dispensing drugs and devices only to patients within correctional facilities or rehabilitation facilities, or for the purpose of teaching at institutions of higher learning, pursuant to a valid prescription.
  - i. Class I - Permit to conduct a research pharmacy. This permit is issued to a pharmacy in which scientific research is conducted under protocols established by an institutional review board meeting federal drug administration guidelines. Pharmaceuticals on hand are incident to the research being conducted. Security and storage for pharmaceuticals must meet United States Pharmacopeia and board of pharmacy requirements. A specific application for a pharmacy permit must be made delineating the specific physical facility to be utilized.
  - j. Class J - Permit to conduct an office practice pharmacy. Any licensed pharmacist may practice in an office pharmacy setting where prescriptions are not routinely dispensed. If legend drugs or devices are maintained, a permit must be obtained by making application to the board of pharmacy delineating specific practice intentions and assuring the board that security and storage requirements are met for any legend drugs or pharmaceuticals on hand.
  - k. Class K - Permit to conduct telepharmacy. A pharmacy staffed by a registered pharmacy technician with access to its main pharmacy and registered pharmacists by computer link, videolink, and audiolink while open.
  - l. Class L – Permit for a dispensing device in a long-term care facility, retirement care, mental care, or other facility or institution which provides extended health care to residents. The dispensing device must be located in a facility defined in NDCC Chapter 50-10.1, as any assisted living facility, any skilled nursing facility, basic care facility, nursing home as defined in subsection 3 of the NDCC section 43-34-01, or swing bed hospital approved to furnish long-term care services. The device must be under the control of a licensed Pharmacist in the state of North Dakota.
- 5. Any applicable rule governing the practice of pharmacy shall apply to all permits under this section.
  - 6. Operating in one class does not preclude permitting in another class. Pharmacies wishing to operate in more than one class shall apply on forms prescribed by the board, pay a fee set by the board, and comply with all rules for each class.

**History:** Effective October 1, 1999; amended effective January 1, 2004; July 1, 2011; October 1, 2014.

**General Authority:** NDCC 43-15-34

**Law Implemented:** NDCC 43-15-34

**61-02-01-02. Application for permit.** Applications for permits and renewal of permits to conduct a pharmacy or drugstore shall be made in writing on such form or forms as the board may from time to time prescribe, and shall set forth information required by the board to enable it to determine if the pharmacy or drugstore will be conducted in full compliance with existing laws and with regulations established thereunder by the board of pharmacy. This information shall include:

1. Name and address of proposed pharmacy.
2. Name of current owner.
3. If applicant is a sole proprietor, evidence that owner is a registered pharmacist in good standing.
4. If applicant is a partnership, evidence that each active partner is a registered pharmacist in good standing, names of all partners and ownership interests of each, and copy of partnership agreement.
5. If applicant is a corporation, names of corporate officers, list of shareholders and shares of stock held by each, affidavit of stock ownership showing that a majority of the stock is owned by registered pharmacists in good standing, actively and regularly employed in and responsible for the management, supervision, and operation of applicant pharmacy, copies where applicable of agreement to form corporation, articles of incorporation, certificate of incorporation, bylaws, employment agreements, financial records as they may pertain to stock ownership requirements, and any other corporate documents relating to ownership or control of applicant pharmacy or corporation, or both.
6. Leases on space to be occupied by applicant or permitholder.
7. Blueprints or drawings of floor plans and physical layout of pharmacy and space to be occupied by applicant.
8. Franchise or license agreements where applicable.
9. Names of registered pharmacists employed.
10. Name of pharmacist in charge.
11. Information showing that adequate technical equipment is maintained.

Documents to be provided herein shall include all changes and amendments. All changes and amendments in documents previously furnished to the board shall be promptly submitted to the board. An application for a renewal of a permit need not include documents previously furnished to the board except where the facts, information, or documents have been changed or amended and not previously furnished to the board. The board shall have the right to require that an applicant or permitholder furnish to the board current documents required hereunder, including all changes or amendments, at any time.

**History:** Amended effective August 1, 1983.

**General Authority:** NDCC 28-32-02, 43-15-10(9), 43-15-10(12), 43-15-10(14), 43-15-34, 43-15-35

**Law Implemented:** NDCC 28-32-03, 43-15-10(9), 43-15-10(12), 43-15-10(14), 43-15-34, 43-15-35

**61-02-01-03. Pharmaceutical compounding standards.** The minimum standards and technical equipment to be considered as adequate shall include:

1. Definitions.
  - a. "Active chemical or ingredient" refers to chemicals, substances, or other components of articles intended for use in the diagnostics, cure, mitigation, treatment, or prevention of diseases.
  - b. "Aseptic processing" is the method of preparing pharmaceutical and medical products that involves the separate sterilization of the product and of the package, the transfer of the product into the container and closure of the container under ISO class 5 or superior conditions, and using procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by micro-organisms during the process.
  - c. "Beyond-use date" refers to the date placed on preparation label that is intended to indicate to the patient or caregiver a time beyond which the contents of the preparation are not recommended to be used. The beyond-use date is determined from the date and time compounding of the preparation is completed.
  - d. "Component" is any ingredient used in the compounding of a drug product, including any that are used in its preparation, but may not appear on the labeling of such a product.
  - e. "Compounded sterile preparation" (CSP) will include all of the following:
    - (1) Preparations prepared according to the manufacturer's labeled instructions and other manipulations when manufacturing sterile products that expose the original contents to potential contamination.

- (2) Preparations containing nonsterile ingredients or employing nonsterile components or devices that must be sterilized before administration.
- (3) Biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that possess either of the above two characteristics, and which include baths and soaks for live organs and tissues, implants, inhalations, injections, powders for injection, irrigations, metered sprays, and ophthalmic preparations.
- f. "Compounder or compounding personnel" is the pharmacist or other licensed or registered health care professional responsible for preparing the compounded preparations.
- g. "Compounding" is the preparation, mixing, assembling, packaging, and labeling of a drug or device in accordance to a licensed practitioner's prescription or medication order. Compounding does not include tablet splitting, reconstitution of oral or topical products as intended by the manufacturer, or repackaging of nonsterile dosage forms for redistribution, dispensing, or administration.  
Compounding includes:
  - (1) Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.
  - (2) The addition of one or more ingredients to a commercial product as a result of a licensed practitioner's prescription drug order.
  - (3) Preparation of drugs or devices for the purposes of, or as an incident to, research, teaching, or chemical analysis.
  - (4) Categories of compounding.
    - (a) Category 1 - Nonsterile simple.
      - [1] Simple Mixing of two or more commercial products.
      - [2] Complex - Compounding with the bulk drug substances or when calculations are required.
    - (b) Category 2 - Sterile compounds. Risk levels of compounded sterile preparations. Risk levels are assigned according to the corresponding probability of contaminating a preparation with microbial organisms, spores, and endotoxins, or chemical and physical contamination such as foreign chemicals and physical matter.
      - [1] Immediate-use compounded sterile preparations. Immediate-use preparations must not be medium-risk level or high-risk level compounded sterile preparations. Immediate-use preparations must be designed for immediate administration and are exempt from the requirements described for low-risk level compounded sterile preparations only when all the following criteria are met:
        - [a] The compounding process involves simple transfer of no more than three commercially manufactured packages of sterile nonhazardous products from the manufacturer's original containers and no more than two entries into any one container.
        - [b] Unless required for the preparation, such as a long dissolution time, the compounding procedure is a continuous process not to exceed one hour.
        - [c] During preparation and prior to administration, aseptic technique must be followed. At no point may critical sites and ingredients of the compounded sterile preparation be directly exposed to contact contamination. If not immediately administered, the finished compounded sterile preparation must be under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter, or biological fluids, mixups with other products, and direct contact of outside surfaces.
        - [d] Administration must begin no later than one hour following the start of the preparation and must be completed within twelve hours.
        - [e] Must be immediately and completely administered by the person who prepared it, or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact one-hour BUD and time.

- [f] If administration has not begun within one hour following the start of preparing the compounded sterile preparation, it must be promptly, properly, and safely discarded and not stored for later use.
- [2] Low-risk level compounded sterile preparations. Low-risk preparations are compounded sterile preparations under the following conditions:
- [a] Compounded with aseptic manipulations entirely with ISO class 5 or superior air quality using only sterile ingredients, products, components, and devices.
  - [b] The compounding involves only transferring, measuring, and mixing using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container.
  - [c] Manipulations must be limited to aseptically opening ampules, penetrating disinfected stoppers with sterile needles and syringes, and transferring sterile liquids into sterile administration devices or containers for storage.
  - [d] In the absence of passing a sterility test, the storage periods cannot exceed forty-eight hours at controlled room temperature, for not more than fourteen days at a refrigerated temperature, or forty-five days in solid frozen state, from minus twenty-five degrees Celsius and minus ten degrees Celsius, unless supported by manufacturer or medical literature.
  - [e] Examples of low-risk compounded sterile preparations include:
    - {1} Single volume transfers of sterile dosage forms from ampules, bottles, bags, and vials with sterile needles.
    - {2} Simple aseptic measuring and transferring with not more than three packages of manufactured sterile products, including infusion and diluents solutions. The solution content of ampules must be passed through a sterile filter to remove any particles.
  - [f] Low-risk quality assurance programs must include routine disinfection, air quality testing, visual confirmation that compounding personnel are properly gowned and garbed, review of all orders and packages of ingredients, and visual inspection of the compounded sterile preparation to ensure the absence of particulate matter or leakage, and thoroughness of labeling in addition to annual media fill tests by each of the compounding personnel specific for low-risk preparation.
- [3] Medium-risk level compounded sterile preparations. Medium-risk preparations are compounded sterile preparations prepared aseptically under low-risk level conditions and one or more of the following conditions exist:
- [a] Multiple small doses of sterile products are combined or pooled to prepare the sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions.
  - [b] The compounding process includes complex aseptic manipulations other than the single volume transfer.
  - [c] The compounding process requires unusually long duration such as that required to complete dissolution.
  - [d] In the absence of passing a sterility test, the storage periods cannot exceed thirty hours at controlled room temperature, for not more than nine days at refrigerated temperature and for forty-five days in solid frozen state, between minus twenty-five degrees Celsius and minus ten degrees Celsius, unless supported by manufacturer or medical literature.
  - [e] Examples of medium-risk compounded sterile preparations include:
    - {1} Total parenteral nutrient fluids using manual or automated devices.
    - {2} Filling reservoirs of injection and infusion devices with more than three sterile drug products.
    - {3} Transfer volumes from multiple ampules or vials into one or more final sterile containers.

- [f] Medium-risk quality assurance includes all elements of low-risk compounded sterile preparations in addition to annual media fill tests by each of the compounding personnel specific for medium-risk preparations.
- [4] High-risk level compounded sterile preparations. High-risk preparations are compounded sterile preparations that are either contaminated or at a high risk to become contaminated.
  - [a] When the following criteria take place, the preparations will be considered high risk:
    - {1} If nonsterile ingredients, including manufactured products not intended for sterile routes of administration (e.g., oral) are incorporated or a nonsterile device is employed before terminal sterilization.
    - {2} If there has been exposure to air quality inferior to ISO class 5 for more than one hour by the sterile contents, sterile surfaces of devices and containers, or a lack of effective antimicrobial preservatives.
    - {3} If personnel are improperly garbed and gloved.
    - {4} If nonsterile water-containing preparations are stored for more than six hours before being sterilized.
  - [b] Storage periods cannot exceed twenty-four hours at controlled room temperature; three days at refrigerated temperature or forty-five days in sold frozen state, between minus twenty-five degrees Celsius and minus ten degrees Celsius, unless supported by manufacturer or medical literature.
  - [c] All nonsterile measuring, mixing, and purifying devices must be rinsed thoroughly with sterile pyrogen-free water, then thoroughly drained or dried immediately before use for high-risk compounding.
  - [d] All high-risk solutions subjected to terminal sterilization are prefiltered by passing through a filter not larger than 1.2 microns. Sterilization of high-risk level solutions by filtration should be performed with a sterile 0.2 micron normal pore size filter entirely within an ISO class 5 or superior air quality environment.
  - [e] An example of high-risk compounded sterile preparations is dissolving nonsterile bulk drug and nutrient powders to make solutions that will be terminally sterilized.
  - [f] High-risk quality assurance includes all elements of low-risk compounded sterile preparations in addition to semiannual media fill tests by each of the compounding personnel specific for high-risk preparations.
- (c) Category 3 - Radiopharmaceuticals. See article 61-05.
- (d) Category 4 - Veterinary pharmaceuticals. Standards for veterinary pharmaceuticals are consistent with all parts of section 61-02-01-03.
- h. "Compounding supervisor" is a person who supervises and is responsible for the compounding and dispensing of a nonsterile or sterile preparation. This may be the pharmacist on duty or the pharmacist-in-charge.
- i. "Critical site" is a location that includes any component or fluid pathway surfaces (such as injection ports) or openings (such as opened ampules or needle hubs) exposed and at risk of direct contact with air, moisture, or touch contamination.
- j. "Direct and contiguous compounding area" refers to the specific area where a compound is prepared.
- k. "Disinfection" is the process by which the total number of micro-organisms is reduced to a safe level or eliminated by applying an agent to inanimate objects that destroys disease-causing pathogens or other harmful micro-organisms but may not kill bacterial and fungal spores.
- l. "Hazardous drug" is one of those which studies in animals or humans indicate that exposures to them have a potential for causing cancer, development, or reproductive toxicity or harm to organs.
- m. "ISO class" is a description of an atmospheric environment characterized by the number of particles of 0.5 microns or larger, within a cubic foot of air. "ISO class 5" atmospheric environment contains less than 100 particles, 0.5 microns or larger in diameter, per cubic foot of air.
- n. "Media fill test" refers to tests used to validate aseptic techniques of compounding personnel and of processes that ensure the personnel and processes used are able to produce sterile products

without microbial contamination. Testing uses a microbiological growth medium to substitute for actual drug product to simulate admixture compounding in determining the quality of a person's technique.

- o. "NDC number" is the national drug code given to each drug separately and specifically approved by the food and drug administration for identification and reporting.
  - p. "Preparation" is a drug dosage form, dietary supplement, or a finished device. It contains one or more substances formulated for use on or for the patient or consumer.
  - q. "Primary engineering control (PEC)" refers to a device or room that provides an ISO class 5 or superior environment during the compounding process, including laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACIs).
  - r. "Product" is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the food and drug administration, accompanied by full prescribing information.
  - s. "Repackaging" is the transfer of an ingredient from one container to another.
  - t. "Risk levels" of CSPs determine the level assigned that represent the probability that it will be contaminated with microbial organisms, spores, endotoxins, foreign chemicals, or other physical matter.
  - u. "Seventy percent sterile isopropyl" or IPA is an antimicrobial used to clean surfaces used in sterile preparations.
  - v. "Stability" means the extent to which a preparation retains, with specified limits, and throughout its period of storage and use, the same properties and characteristics it possessed at the time of compounding.
  - w. "US pharmacopeia (USP)" is the book of official compendia of standards for the United States.
2. General compounding.
- a. Responsibility of the compounder.
    - (1) Personnel engaging in compounding must be proficient, capable, and qualified to perform assigned duties in the compounding area while expanding the individual's knowledge of compounding through seminars or appropriate literature.
    - (2) Compounding personnel must be familiar with USP standards and North Dakota regulations, including:
      - (a) Certifying all prescriptions orders.
      - (b) Approving or rejecting all components, drug product containers, closures, in-process materials, and labeling ensuring preparations and ingredients are of acceptable strength, quality, and purity, with appropriate packaging.
      - (c) Preparing and reviewing all compounding records to assure that errors have not occurred in the compounding process and the finished product has expected qualities as well as implementing procedures to prevent cross-contamination.
      - (d) Assuring the proper maintenance, cleanliness, sanitization, and use of all equipment used in prescription compounding practice, including the direct and contiguous compounding area allowing for the compounding environment to be suitable for its intended purpose.
      - (e) Assuring that the drug product and components of drug products are not on the list of federally recognized drug products that have been withdrawn or removed from the market for public health reasons.
    - (3) Policies and procedures must be established concerning washing and donning the appropriate clothing specific to the type of process performed to protect the personnel from chemical exposures and prevent drug contamination.
  - b. Training. All compounding supervisors and all personnel involved in compounding must be well trained and must participate in current, relevant training programs. All training activities will be covered by standard operating procedures and must be properly documented. Steps in the training procedure include:
    - (1) Be familiar with pharmaceutical compounding and nonsterile compounding (USP 795), pharmaceutical compounding and sterile compounding (USP 797), and pharmaceutical calculations in prescription compounding (USP 1160).

- (2) Be familiar with all procedures relating to compounding specific to the individual's facility, equipment, personnel, compounding process, evaluation, packaging, storage, and dispensing.
  - (3) Compounding supervisors must be responsible to follow the instructions below to show that personnel are appropriately trained:
    - (a) Demonstrate compounding procedures to compounding personnel.
    - (b) Guide personnel through the compounding process with assistance.
    - (c) Observe personnel performing a compound without assistance but under supervision.
    - (d) Review the compound, correct mistakes, and answer questions concerning compounding and associated processes.
    - (e) Confirm verbal and functional knowledge of the personnel concerning compounding.
    - (f) Have personnel perform a compounding procedure without supervision, yet checking off the final preparation.
    - (g) If properly compounded and when satisfied, sign the documentation records confirming appropriate training.
    - (h) Continually monitor the work of the personnel, including calculations.
  - (4) The pharmacist on duty and the pharmacist-in-charge are ultimately responsible for the finished product.
- c. Procedures and documentation. Procedures must be developed for the facility, equipment, personnel, preparation, packaging, and storage of the compounded preparation to ensure accountability, accuracy, quality, safety, and uniformity in compounding. This allows for a compounder, whenever necessary, to systematically trace, evaluate, and replicate the steps included throughout the preparation process of a compounded preparation.
- d. Nonsterile drug compounding facilities must include all of the following:
- (1) Compounding facilities and equipment that are clean, accurate, of appropriate size and construction, and properly inspected and the compounding environment is properly maintained, isolated, and inspected. Personnel must have a written plan and schedule while maintaining records of cleaning and disinfecting.
  - (2) Aseptic processes must be conducted in an area separate from the area used for nonsterile preparations.
  - (3) Areas designated for compounding, including space for storage, must have adequate space, designed and well-lighted to prevent mixups, errors, or adventitious cross-contamination.
  - (4) Heating, ventilation, and air-conditioning systems are controlled to avoid decomposition of chemicals.
  - (5) A supply of potable water is available for washing with adequate washing facilities that are easily accessible, including hot and cold water, soap or detergent, and an air dryer or single-use towels. The plumbing system should be free of defects that could contribute to contamination of the compounded product.
  - (6) All areas maintained in a clean and sanitary condition and trash, sewage, and other refuse should be disposed of in a safe and timely manner.
  - (7) Bulk drugs, chemicals, or materials must be properly labeled and stored in an area that is clean, dry, at appropriate temperature (i.e., controlled room, refrigerator, or freezer), and protected from contamination.
- e. Nonsterile drug compounding equipment.
- (1) Equipment and utensils must be of appropriate design and capacity and properly stored to avoid contamination while located in a place appropriate for facility operations for its use, maintenance, and cleaning.
  - (2) All equipment must be constructed so that surfaces that contact components, in-process materials, or finished preparations are not reactive, additive, or absorptive to avoid altering the preparation.

- (3) Equipment, apparatus, and devices used to compound a preparation must be calibrated, maintained, and monitored for proper function. Records must be kept for the lifetime of the equipment.
- f. Packaging, drug preparation containers, storage, and beyond-use dating for nonsterile preparations.
  - (1) Containers and container closures.
    - (a) Must meet USP requirements found under containers - glass (USP 660), containers - plastic (USP 661), and containers - performance testing (USP 671).
    - (b) Those intended for compounding of sterile and nonsterile preparations must be handled, sterilized (if appropriate), and stored according to pharmaceutical compounding - sterile preparations (USP 797) and pharmaceutical compounding - nonsterile preparations (USP 795).
    - (c) Must be stored off the floor and handled and stored to prevent contamination.
    - (d) Must be stored in a way to facilitate inspection and cleaning.
    - (e) Must be constructed in such a way that surfaces are not reactive, additive, or absorptive.
    - (f) The containers and closures shall be of suitable material so as not to alter the quality, strength, or purity of the compounded drug.
  - (2) Storage area.
    - (a) Compounded preparations must be stored strictly in accordance with the conditions stated on the label of ingredient products and finished preparations.
    - (b) Monitoring of appropriate temperatures must occur daily for controlled storage areas and temperatures recorded in the temperature log.
      - [1] Controlled room temperature areas, twenty degrees Celsius to twenty-five degrees Celsius.
      - [2] Controlled cold temperature, two degrees Celsius to eight degrees Celsius.
      - [3] Controlled freezing temperature, minus twenty-five degrees Celsius to minus ten degrees Celsius.
  - (3) Beyond-use dates for nonsterile preparations.
    - (a) The compounder must establish an appropriate beyond-use date determined by drug-specific chemical and physical stability parameters of the components in conjunction with the manufacturer's product label, appropriate literature, and USP standards.
    - (b) The compounder must establish a beyond-use date considering the nature of the drug, degradation mechanism, purposed container, expected storage conditions, and intended duration of therapy.
    - (c) Beyond-use dating is assigned conservatively to all compounded preparations. Immediate-use preparations do not require a beyond-use date.
      - [1] For nonaqueous liquids and solid formulations where the manufactured drug product is the source of the active ingredient, the beyond-use date is no later than twenty-five percent of the time remaining until the product's expiration date or six months, whichever is earlier.
      - [2] For water-containing, liquid formulations prepared from ingredients in solid form, the beyond-use date is no later than fourteen days when stored at cold temperatures from two to eight degrees Celsius.
      - [3] For all other formulations the beyond-use date is no later than the intended duration of therapy or thirty days, whichever is earlier, unless supporting valid scientific stability information can be applied.
- g. Compounding controls for nonsterile preparations.
  - (1) The compounder must ensure that the written procedures for compounding are available electronically or in hard copy and assure the finished products have the correct identity, strength, quality, and purity.
  - (2) Procedures must be established that give a description of the following:
    - (a) Components and their amounts.
    - (b) Order of component additives.
    - (c) Compounding process.
    - (d) Drug product.



- (e) Required equipment and utensils, including container and closure systems.
- (3) The compounder will accurately weigh, measure, and subdivide all components as appropriate.
  - (a) The compounder must check and recheck each procedure at each point of the process to ensure that each weight or measure is correct.
  - (b) If a component is transferred from the original container to another, the new container must be identified with the component, name, weight or measure, the lot or control number, the expiration or beyond-use date, and the transfer date.
- (4) The compounder must write procedures that describe the tests or examinations that prove uniformity and integrity of the compounded preparations.
- (5) Control procedures must be established to monitor the output and validate the performance of compounding personnel that affect variability of final preparations, such as:
  - (a) Capsule weight variation.
  - (b) Adequacy of mixing to assure uniformity and homogeneity.
  - (c) Clarity, completeness, or pH of solutions.
- (6) The compounder must establish an appropriate beyond-use date for each compounded preparation.
- (7) Facilities engaging in compounding must have a specifically designated and adequate space for orderly compounding, including the placement and storage of equipment and materials.
- h. Labeling of nonsterile preparations.
  - (1) The compounder's preparation label must contain all information required by North Dakota state law and accepted standards of practice found under chapter 61-04-06, prescription label requirements, plus the beyond-use date and assigned lot number.
  - (2) The compounder must label any excess compounded products so as to refer to the formula used.
  - (3) Preparations compounded in anticipation of a prescription prior to receiving a valid prescription should be made in a regularly used amount based on the history of prescriptions filled and they should be labeled with:
    - (a) Complete list of ingredients or preparation time and reference or established chemical name or generic name.
    - (b) Dosage form.
    - (c) Strength.
    - (d) Preparation date and time.
    - (e) Inactive ingredients.
    - (f) Batch or lot number.
    - (g) Assigned beyond-use date.
    - (h) Storage conditions.
  - (4) The compounder must examine the preparation for correct labeling after completion.
- i. Records and reports for nonsterile preparations.
  - (1) Records must be maintained, including a hard copy of the prescription with formulation and compounding records.
  - (2) Adequate records of controlled substances used in compounds.
  - (3) All records must be kept for five years according to North Dakota state law and be available for inspection.
  - (4) Formulation record provides a consistent source document for preparing the preparation to allow another compounder to reproduce the identical prescription at a future date and must list:
    - (a) Name, strength, and dosage form of the preparation compounded.
    - (b) All ingredients and their quantities.
    - (c) Equipment needed to prepare the preparation, when appropriate.
    - (d) Mixing instructions including order of mixing, mixing temperatures, and other valid instructions, such as duration of mixing.

- (e) Assigned beyond-use date.
- (f) Container used in dispensing.
- (g) Storage requirements.
- (h) Any quality control procedures.
- (5) Compounding record documents the actual ingredients in the preparation and the person responsible for the compounding activity and includes:
  - (a) Name and strength of the compounded preparation.
  - (b) The formulation record reference.
  - (c) Sources and lot numbers of the ingredients.
  - (d) Total number of dosage units compounded.
  - (e) Name of compounding personnel who prepared the preparation.
  - (f) The date of preparation.
  - (g) The assigned internal identification number, lot number, and prescription numbers.
  - (h) Assigned beyond-use date.
  - (i) Results of all quality control procedures.
- (6) Temperature log records the daily monitoring of temperatures in the storage area specifically for the controlled room temperature, refrigerator, freezer, or incubator.
- 3. Nonsterile compounding. Compounders are to use the following steps to minimize error and maximize the prescriber's intent, specifics can be found in pharmaceutical compounding - nonsterile compounding (USP 795):
  - a. Judge the suitability of the prescription of the preparation in terms of safety and intended use.
  - b. Perform necessary calculations to establish the amounts of ingredients needed.
  - c. Identify equipment and utensils needed.
  - d. Don the proper attire and properly wash hands and arms.
  - e. Clean the compounding area and needed equipment.
  - f. Only one prescription can be compounded at a time in the specified compounding area.
  - g. Assess weight variation, adequacy of mixing, clarity, odor, color consistency, and pH as appropriate of the completed preparation.
  - h. Annotate the compounding and formulation records.
  - i. Label the prescription containers appropriately.
  - j. Sign and date the prescription or compounding record affirming that all procedures were carried out to ensure uniformity, identity, strength, quantity, and purity.
  - k. Thoroughly clean all equipment immediately when finished.
- 4. Compounding process for compounded sterile preparations. Compounders are to use the following steps to minimize error and maximize the prescriber's intent, specifics can be found in pharmaceutical compounding sterile compounds (USP 797):
  - a. Judge the suitability of the prescription for the compounded sterile preparation in terms of safety and intended use.
  - b. Perform necessary calculations to establish the amounts of ingredients needed.
  - c. Identify equipment and utensils needed for the preparation of the compounded sterile preparation.
  - d. Sterile compounding areas and critical areas must be structurally isolated from other areas designated to avoid unnecessary traffic and airflow disturbances, separate from nonsterile compounding areas, and restricted to qualified compounding personnel.
  - e. Policies and procedures must be established for personnel cleaning and garbing for protection and avoidance of containment, including:
    - (1) Remove all jewelry from hands and arms, no artificial nails allowed.
    - (2) Don proper garb, including shoe covers, head and facial hair covers, face mask, and nonshedding gown, if the manufacturer of the primary engineering control has research and documentation demonstrating that specific things are not necessary, they are not required.
    - (3) Wash hands and arms prior to donning powder-free gloves.
    - (4) Abstain from gum chewing, candy, or food items in or near the compounding area.

f. Clean and sanitize the compounding area and needed equipment.

- (1) At the beginning of each work shift and after spills, the surface of the compounding area should be cleaned with sterile water to remove water soluble residues, then immediately with seventy percent sterile isopropyl alcohol, or another antimicrobial agent, using nonlinting wipe.
- (2) All rubber stops of vials and bottles and the neck of ampules must be sanitized with seventy percent sterile isopropyl alcohol prior to introduction of a needle or spike for the removal of a product.
- (3) After procedures are completed, used syringes, bottles, vials, and other supplies must be moved.
- (4) Only one preparation can be compounded at a time in the specified compounding area.
- (5) Assess weight variation, adequacy of mixing, clarity, odor, color consistency, and pH as appropriate of the completed compounded sterile preparation.
- (6) If preparing in anticipation of future orders, annotate the compounding and formulation records with date of preparation, ingredients and their lot numbers, total number of dosage units prepared, initials of preparer and pharmacist who checked the batch, assigned beyond-use date, and assigned internal batch or lot number.
- (7) Label the preparation containers with name and strength of preparation, internal batch or lot number, and appropriate beyond-use date.
- (8) Sign and date the compounding record affirming that all procedures were carried out to ensure uniformity, identity, strength, quantity, purity, and sterility.

5. Facilities for sterile compounding.

a. The facilities that engage in low-risk and medium-risk preparations must meet the standards, including:

- (1) Limits access and activities to qualified personnel, materials, and processes that are directly related to productions of sterile compounded products.
- (2) Structurally isolated from other areas, including other nonsterile compounding areas.
- (3) Designed to avoid unnecessary traffic and airflow disturbances.
- (4) Of sufficient size to accommodate all primary engineering control devices, as required by the compounding risk level.
- (5) Able to provide storage and preparation of drugs, supplies, and finished products under appropriate temperature, light, moisture, sanitation, ventilation, and security conditions.
  - (a) Ventilation must maintain appropriate ISO class designations of each separate working area and avoid disruption and cross-room currents.
  - (b) Walls, floors, and ceilings, along with fixtures, counters, shelves, and cabinets must be resistant to damage that could occur from routine disinfection with cleaning agents.
  - (c) Policies and procedures must be established for personnel in the sterile compounding area regarding proper hand washing, proper donning of appropriate attire, and restrictions on items and practices within the compounding area.
  - (d) Policies and procedures must be established for cleaning and sanitizing.
    - [1] All cleaning and sanitizing must not occur simultaneously with aseptic operations.
    - [2] Counters and easily cleanable work surfaces cleaned and sanitized daily.
    - [3] Storage shelving cleaned and sanitized monthly.
    - [4] Floors must be mopped daily. Trash must be collected and removed daily.

b. The facilities that engage in high-risk preparations must meet the standards, including:

- (1) All of the facilities listed for low-risk and medium-risk preparations.
- (2) Buffer areas must have the following standards:
  - (a) Maintain ISO class 7 or superior air quality during compounding activity.
  - (b) Be physically divided or have designated boundaries that separate it from the anteroom with appropriate ventilation that assures contamination from the anteroom does not enter the buffer area through utilization of filtered unidirectional flow and principles of air displacement.

- (c) Must not have unsealed windows or doors that connect to the outdoors, or be located adjacent to a construction site, warehouse, or food preparation area.
- (d) Must not contain sinks or drains and shall be void of all materials, equipment, and fixtures that are not directly involved in the current processing of compounded sterile preparations.
- (e) The construction, arrangement, and ventilation must not allow conditions that could adversely affect compounding, such as aberrant heating, cooling, door drafts, and personnel traffic air currents.
- (f) Policies and procedures must be established for cleaning and sanitizing.
  - [1] Cleaning and sanitizing must occur in the buffer area first, then move to the anteroom and other areas.
  - [2] All cleaning and sanitizing must occur simultaneously with aseptic operations.
  - [3] Storage shelving cleaned and sanitized weekly.
  - [4] Floors must be mopped daily. Trash must be collected and removed daily.
- (3) Anteroom must have the following standards:
  - (a) Located adjacent to the buffer area and maintained at ISO class 8 or superior air quality during compounding activity.
  - (b) Must be established with the purpose of unpacking and disinfecting supplies for storage and areas to support hand and arm washing and donning of appropriate attire.
  - (c) Hands-free sinks and closed system soap dispenser must be used for hand and arm washing.
  - (d) Procedures must be established for cleaning and sanitizing.
    - [1] Compounding must occur secondary to cleaning and sanitizing.
    - [2] All cleaning and sanitizing must not occur simultaneously with aseptic operations.
    - [3] Counters and easily cleanable work areas must be cleaned daily.
    - [4] Supplies and equipment must be removed and wiped with a sanitizing agent weekly.
    - [5] Floors must be mopped daily.
    - [6] Storage shelving and walls must be emptied and cleaned and sanitized monthly.
- (4) Storage areas for sterile preparations. When ingredients and finished preparations are exposed to temperatures warmer than the warmest labeled limit, but not exceeding forty degrees Celsius for more than four hours, they must be discarded.
- 6. Equipment specific for sterile compounding.
  - a. Primary engineering controls:
    - (1) Are not required for immediate-use compounding.
    - (2) One primary engineering control is required for compounding low-risk and medium-risk preparations.
    - (3) For compounding high-risk preparations the primary engineering control must be placed in a buffer area, if required, where HEPA filters are employed and the air quality is maintained at ISO class 7 or superior. If the manufacturer has research and documentation demonstrating that the primary engineering control does not need to be in a buffer area, this is not required. If used, the primary engineering control must be maintained as continuously powered on, if turned off, however, the blowers must be allowed to run continuously for at least thirty minutes before using.
  - b. Environmental monitoring.
    - (1) Barrier certification for proper functioning and ISO class 5 airflow requirements must be tested every six months and after relocation of the primary engineering control.
    - (2) Maintain the air quality of the buffer area and anteroom, if required, at ISO class 7 and ISO class 8, respectively must be tested every six months and after any renovation of the compounding area.
    - (3) Where high-risk sterile preparations are being compounded, air sampling via sterile nutrient agar plates or suitable electric air samplers must be performed semiannually at locations

judged by compounding personnel to be the most prone to contamination during compounding activities.

- (4) Instructions and verification of air sampling devices must be located with the equipment.
- (5) Passive exposure processes of sterile nutrient agar settling plates can be found in USP standards.
7. Poison record book and suitable prescription files.
8. Suitable current reference sources either in book or electronic data form (available in the pharmacy or online) which might include the United States Pharmacopeia and National Formulary, the United States Pharmacopeia Dispensing Information, Facts & Comparisons, Micro Medex, the ASHP Formulary, or other suitable references determined by the board which are pertinent to the practice carried on in the licensed pharmacy.
9. It is acceptable to compound drug products to be used by practitioners in their office for administration to patients. These products cannot be dispensed or sold to others. Sales to other pharmacies, clinics, or hospitals are manufacturing and are not allowed.
10. Hazardous drugs as compounded sterile products (CSPs).
  - a. Hazardous drugs, when prepared for administration only, shall be prepared under conditions that protect the health care worker and other personnel in the preparation and storage areas.
  - b. Hazardous drugs shall be stored and prepared separately from other nonhazardous drugs in a manner to prevent contamination and personnel exposure.
  - c. Hazardous drugs shall be handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration, and disposal.
  - d. Hazardous drugs shall be prepared in an ISO class 5 environment with protective engineering controls in place and following aseptic practices specified for the appropriate contamination risk levels specified in this chapter.
  - e. All hazardous drugs shall be prepared in a biological safety cabinet (BSC) or a compounding aseptic containment isolator (CACI). The BSC or CACI shall be placed in an ISO class 7 area that is physically separated (i.e., a different area from other preparation areas) and with negative pressure to adjacent positive pressure ISO class 7 or better anterooms. If the CACI is used outside of a buffer area, the compounding area shall maintain a minimum negative pressure of 0.01 inch water column and have a minimum of twelve air challenges per hour.
    - (1) When closed-system vial-transfer devices (CSTDs) are used, they shall be used within the ISO class 5 environment of a BSC or CACI. This may be done in a nonnegative pressure room when this two-tier containment method is used.
    - (2) Appropriate personnel protective equipment shall be worn when compounding hazardous drugs.
  - f. All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur prior to preparing or handling hazardous drugs and this training shall be by testing specific hazardous drug-handling techniques. Such training shall be documented for each person at least annually.

The state board of pharmacy recognizes that the equipment needed will depend on the type of pharmaceutical services offered, and therefore, variations for required equipment may be granted by the state board of pharmacy.

All compounders of sterile and nonsterile products must be in compliance with this rule by January 1, 2015.

**History:** Amended effective August 1, 1983; April 1, 1988; October 1, 1999; December 1, 2003; April 1, 2012.

**General Authority:** NDCC 28-32-02, 43-15-10(9), 43-15-10(12), 43-15-10(14), 43-15-35(2), 43-15-35(3), 43-15-36

**Law Implemented:** NDCC 28-32-03, 43-15-10(9), 43-15-10(12), 43-15-10(14), 43-15-35(2), 43-15-35(3), 43-15-36

**61-02-01-04. Permit not transferable.** A permit registers the pharmacy to which it is issued at the location specified in the permit, and is not transferable. It is issued on the application of the owner, or the registered pharmacist in charge, on the sworn statement that the pharmacy will be conducted in accordance with the

provisions of law. If it is desired to operate, maintain, open, or establish more than one pharmacy, separate applications shall be made and separate permits issued for each.

**General Authority:** NDCC 43-15-10(9), 43-15-34, 43-15-39

**Law Implemented:** NDCC 43-15-10(9), 43-15-34, 43-15-39

**61-02-01-05. Change of ownership.** When a pharmacy changes ownership, the original permit becomes void and must be surrendered to the board, and a new permit secured by the new owner or owners. This is required even in case there is no change in the name of the pharmacy or in the registered pharmacist in charge of the pharmacy. The board shall be promptly notified of any change in ownership of a pharmacy. In the case of a corporation holding a pharmacy permit, the board shall be immediately notified at any time when a majority of the stock is not owned by registered pharmacists in good standing, actively and regularly employed in and responsible for the management, supervision, and operation of the pharmacy. In the case of a partnership holding a pharmacy permit, the board shall be notified as to the addition or removal of one or more partners in the partnership.

**General Authority:** NDCC 43-15-10(9), 43-15-35(5)

**Law Implemented:** NDCC 43-15-10(9), 43-15-35(5)

**61-02-01-06. Affidavit of ownership.** An affidavit shall be filed each year with the application for renewal of a pharmacy permit, indicating in the case of a partnership, that each active member is a registered pharmacist, or in the case of a corporation, that the majority stock is owned by registered pharmacists in good standing, actively and regularly employed in and responsible for the management, supervision, and operation of the pharmacy.

**General Authority:** NDCC 43-15-10(9), 43-15-35(5)

**Law Implemented:** NDCC 43-15-10(9), 43-15-35(5)

**61-02-01-07. Renewal of permits.** Each pharmacy permit shall expire on June thirtieth of each year, and shall be renewed annually by filing an application therefor, on or before June first of each year, together with a fee set by the board, but not to exceed that prescribed by statute.

**General Authority:** NDCC 43-15-10(9), 43-15-38

**Law Implemented:** NDCC 43-15-10(9), 43-15-38

**61-02-01-08. Change of location.** Before a pharmacy changes the location of its business, it shall first submit to the board a new application for a permit, setting forth such changes, and shall submit therewith the information and documents required in an initial application for a permit. If the board approves the application, no additional fee shall be made for the new permit.

**General Authority:** NDCC 43-15-10(9), 43-15-10(11)

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(11)

**61-02-01-09. Permit for heirs at law of pharmacist.** The issuance of a permit to the heirs at law of a pharmacist shall not be refused on the grounds that such heirs at law are not registered pharmacists, provided assurance will be given that when the pharmacy is disposed of by the heirs at law of the registered pharmacist owner, it shall be sold only to a registered pharmacist or a corporation or partnership controlled by a registered pharmacist in North Dakota.

**General Authority:** NDCC 43-15-10(9)

**Law Implemented:** NDCC 43-15-10(9)

**61-02-01-10. Pharmacist-in-charge - Requirement - Definition - Duties.** No permitholder shall conduct a pharmacy without a pharmacist-in-charge who shall be designated in the application for a pharmacy permit and each renewal of pharmacy permit. The term "pharmacist-in-charge" means a duly licensed pharmacist in North Dakota who has been so designated, and it shall be the pharmacist's duty and responsibility consistent with the accepted standards of professional conduct and practice and in compliance with all applicable laws and regulations to:

1. Establish for the employees of the pharmacy policies and procedures for the procurement, storage, compounding, and dispensing of drugs
2. Supervise all of the professional employees of the pharmacy.

3. Supervise all of the nonprofessional employees of the pharmacy insofar as their duties relate to the sale or storage, or both, of drugs.
4. Establish and supervise the recordkeeping system for the purchase, sale, possession, storage, safekeeping, and return of drugs.
5. Notify the board immediately upon the pharmacist's knowledge that the pharmacist's services as pharmacist-in-charge have been or will be terminated.

**General Authority:** NDCC 43-15-10(9), 43-15-35(4)

**Law Implemented:** NDCC 43-15-10(9), 43-15-35(4)

**61-02-01-11. Pharmacist-in-charge** - Termination of service. Each pharmacy shall notify the state board of pharmacy immediately upon knowledge of the termination of the services of the pharmacist-in-charge and further, shall immediately designate a successor pharmacist-in-charge and immediately notify the state board of pharmacy of such designation. The state board of pharmacy upon receiving such notice shall furnish the successor pharmacist-in-charge such form or forms as it may from time to time prescribe which form or forms must be completed by the successor pharmacist-in-charge and filed with the board within ten days after receipt.

**General Authority:** NDCC 43-15-10(9), 43-15-35(4)

**Law Implemented:** NDCC 43-15-10(9), 43-15-35(4)

**61-02-01-12. Posting of permit.** Each pharmacy permit shall be posted and exposed in a conspicuous place in the pharmacy for which the permit has been issued.

**General Authority:** NDCC 43-15-10(9), 43-15-39

**Law Implemented:** NDCC 43-15-10(9), 43-15-39

**61-02-01-13. Pharmacist on duty.** Each pharmacy shall have at least one registered pharmacist on duty and physically present in the pharmacy area at all times that the prescription area is open for the transaction of business.

**History:** Amended effective May 1, 1984.

**General Authority:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

**61-02-01-14. Limitation on rent.** Before a pharmacy permit is issued, in the case of a pharmacy leasing space, a copy of the lease agreement must be furnished to the board which must include rental terms and information. The lease rental amounts, less in-house sales and wholesale sales, may not exceed five percent of the total gross sales of the pharmacy, with the further provision that the landlord shall furnish all utilities including heat, electrical, and janitorial services, but not including telephone service. The board recognizes that the lease terms and rent will depend on the type of pharmaceutical services offered, and therefore, variations for rent may be granted by the state board of pharmacy.

**History:** Effective April 1, 1988; amended effective July 1, 1996.

**General Authority:** NDCC 28-32-02, 43-15-10(7)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36

**Law Implemented:** NDCC 28-32-03

**61-02-01-15. Closing a pharmacy.** A permitholder shall follow these procedures to close a North Dakota licensed pharmacy:

1. Notify the state board of pharmacy at least thirty days in advance of the closing date.
2. Notify customers at least fifteen days in advance of the closing date and advise them where their records will be maintained.
3. Notify the drug enforcement administration (DEA) at least fourteen days in advance of the closing date.
4. At the closing date:
  - a. Take an inventory of the pharmacy's controlled substances and maintain it for two years.
  - b. Return the North Dakota pharmacy permit to the board.
  - c. Cover all signage indicating "drugstore" or "pharmacy" until removed in a timely manner.
  - d. Send the DEA certificate of registration and any used official order forms (DEA form-222) to the nearest DEA registration field office. The pharmacist should write or stamp the word "VOID" across the face of each official order form before returning them to the DEA.

- e. Notify the state board of pharmacy and the DEA as to where the controlled substances inventory and records will be kept and how the controlled substances were transferred or destroyed. Records involving controlled substances must be kept available for two years for inspection and copying. This requirement applies, even though the business has been discontinued.

**History:** Effective October 1, 2007.

**General Authority:** NDCC 43-15-10

**Law Implemented:** NDCC 43-15-10, 43-15-35

**61-02-01-16. Transfer of controlled substances when selling a business.** The permitholder of a pharmacy discontinuing business shall notify the state board of pharmacy and the nearest DEA registration field office at least fourteen days before the date of the proposed transfer of controlled substances in connection with discontinuing the business, and provide the following information:

1. The name, address, and registration number of the pharmacy discontinuing business.
2. The name, address, and registration number of the pharmacy acquiring the business.
3. The date on which the controlled substances will be transferred.

**History:** Effective October 1, 2007.

**General Authority:** NDCC 43-15-10

**Law Implemented:** NDCC 43-15-10, 43-15-35

**61-02-01-17. Identification.** All pharmacy employees shall wear a name badge while in the pharmacy, which clearly identifies the person's title.

**History:** Effective July 1, 2011.

**General Authority:** NDCC 43-15-10

**Law Implemented:** NDCC 43-15-10, 43-15-35

**61-02-01-18. Policy and procedure manual required.** Each pharmacy must have a written or electronic and easily accessible policy and procedure manual to address all aspects of the pharmacy's operations. The policy and procedure manual must be available for inspection. The policy and procedure manual must set forth in detail the objectives and operational guidelines of the pharmacy. The policy and procedure manual must be reviewed and revised or reaffirmed on an annual basis.

Inspection procedures, including:

1. Location of controlled substance records, including:
  - a. Location of current biennial inventory;
  - b. Wholesale records of receipt and sale of controlled substances;
  - c. DEA 222 forms, both paper and electronic, executed or not;
  - d. Information for running reports from the pharmacy computer system relative to dispensing of specific controlled substances; and
  - e. Power of attorney forms if granted and termination forms if executed.
2. Location of most recent inspection forms by the state board of pharmacy, accreditation agencies, or the food and drug administration, if applicable.

**History:** Effective October 1, 2014.

**General Authority:** NDCC 28-32-02, 43-15-10(9), 43-15-10(12), 43-15-10(14)

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

## **CHAPTER 61-02-02 BUILDING STANDARDS FOR PHARMACIES**

Section

61-02-02-01 Building Standards for Pharmacies

**61-02-02-01. Building standards for pharmacies.** Any new pharmacy, or any existing pharmacy which is being remodeled, except in the cases of institutional practice, must comply with the following provisions:

1. **Approval of plans.** The prescription area, merchandising area, waiting area, storeroom, restroom, and all partitions, doors, windows, and fixtures shall be indicated on floor plans showing appropriate elevations submitted to the board at the time the application for a new pharmacy is filed, or prior to remodeling. Such plans shall be submitted to the board prior to proceeding with the new construction. Before a pharmacy permit is issued, the plans submitted must meet the approval of the board.



2. **Minimum size of the prescription area.** The minimum size of the prescription area, including adjacent patient consultation and information area and drug storage areas shall be not less than one thousand square feet [92.90 square meters], with an additional two hundred fifty square feet [23.23 square meters], to be used but not restricted to prescription receiving, checkout, and entrance area, but in all cases shall be large enough to carry out efficiently the elements of the practice of pharmacy at the level of activity of that operation. All of the allotted square footage space, including adequate shelving, shall lend itself to efficient pharmaceutical practice so as to permit free movement and visual surveillance. A patient consultation and information center must be provided. This patient consultation and information center may not be located in the prescription area or drug storage area. The patient consultation and information center must afford the patient privacy from visual or auditory detection or surveillance by any unauthorized person or persons. The patient consultation and information center must be accessible by a patient by provision of an entrance and exit that does not require the patient to enter or traverse the prescription area or drug storage areas.
3. **Prescription compounding counter.** There shall be a prescription compounding counter which shall provide a minimum of sixteen square feet [1.49 square meters] of unobstructed working space for one pharmacist, and a minimum of twenty-four square feet [2.23 square meters] of unobstructed working space where two or more pharmacists are on duty at any one time. The floor area to be occupied by the dispensing pharmacists shall extend the full length of the prescription compounding counter, and shall be clear and unobstructed for a minimum distance of thirty inches [76.2 centimeters] from the counter.
4. **Prescription area.** The prescription area shall be separated from other areas in such a manner that prescription or nonproprietary drugs or devices are inaccessible to the reach of any unauthorized person.
5. **Light and ventilation.** The prescription area and all storerooms shall be well-lighted, ventilated, and kept free of obnoxious odors.
6. **Refrigerator.** The restricted area shall contain a refrigerator for its exclusive use.
7. **Change in location of a pharmacy.** Before a licensed pharmacy changes the location of its business, or its physical dimensions or elements of physical security, it shall first submit the changes to the board for its approval that the changes do conform with all rules of the board.
8. **Storage of other merchandise - Telephone.** The prescription department shall not be used for storage of merchandise other than that used in the preparation or dispensing of medical needs. If such stored material is present, such area shall not be included as part of the prescription department. A telephone shall be immediately accessible in the prescription area, and the telephone number shall coincide with the telephone number on prescription labels.
9. **Building standards variations.** The board of pharmacy recognizes that the building standards for pharmacies will depend on the type of pharmaceutical services offered, and therefore, variations for required building standards may be granted by the board of pharmacy.
10. **Remodeling or improvement variations.** When the pharmacy is remodeling within existing permitted space or when a pharmacy is attempting to improve toward the standards in section 61-02-02-01 or chapters 61-02-03 or 61-02-04, the board may grant approval to move toward the standards even though the amount of space available does not allow complete compliance with the standards.

**History:** Amended effective August 1, 1983; April 1, 1988; June 1, 1992; January 1, 2003.

**General Authority:** NDCC 28-32-02, 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(14)

**Law Implemented:** NDCC 28-32-03, 43-15-01(16), 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(14)

## CHAPTER 61-02-03

### SECURITY STANDARDS FOR PHARMACIES

#### Section

#### 61-02-03-01 Security Standards for Pharmacies

**61-02-03-01. Security standards for pharmacies.** A pharmacy must comply with the following security standards:

1. **Pharmacist in charge.** Every pharmacy must have a pharmacist designated as the pharmacist-in-charge who shall be responsible to the board for a pharmacy's compliance with the laws and regulations, both state and federal, pertaining to the practice of pharmacy. The pharmacist-in-charge shall see that directives from the board are communicated to, and complied with by, the management, other pharmacists, and interns of the pharmacy.
2. **Personnel permitted in prescription area.** Personnel permitted in the prescription area are pharmacists, interns, drug inspectors, peace officers when acting in their official capacity, drug salesmen, and supporting personnel of the pharmacy. Interns, drug salesmen, and supporting personnel shall be permitted in the prescription area only when a pharmacist is on duty, except in an extreme emergency. No more than one clerical person shall be permitted in the prescription area per pharmacist.
3. **Prescription area and storage shall be kept locked.** The prescription area and any additional storage area for drugs restricted to a pharmacist, except in an extreme emergency, shall be kept locked when a pharmacist is not on duty. The pharmacist shall keep each portion of the prescription area secured and locked at all times the pharmacist does not have full vision or control of such portions of the prescription area. The prescription area shall be open for business to the public at all times that the retail establishment is open for business to the public, or for a minimum of eight hours a day should the retail establishment be open longer than eight hours per day. The board of pharmacy recognizes that the hours that the prescription area of a pharmacy is open for business to the public will depend on the type of pharmaceutical services offered, as well as other factors, and therefore, variations in the required hours that a prescription area shall be open for business to the public may be granted by the board of pharmacy.
4. **Only pharmacist permitted to unlock prescription area or storage area.** The pharmacist shall be the only person permitted to unlock the prescription area or any additional storage area for drugs restricted to a pharmacist, except in an extreme emergency. Only the pharmacist shall maintain possession of the key to the prescription area. The pharmacist shall be responsible for assuring that only authorized personnel have access to the legend and nonproprietary drugs stored in the prescription area or additional storage area.
5. **Extreme emergency.** An extreme emergency shall be in case of fire, water leak, electrical failure, public disaster, or other catastrophe, whereby the public is better served by overlooking the safety security restrictions on drugs.
6. **Receiving and checking area for drugs.** The area where prescription drugs are received, opened, and marked shall be under the immediate supervision of a pharmacist, and immediately thereafter the prescription drugs shall be kept or moved into the secured area of the pharmacy.
7. **Security of prescription area.** In order for the prescription area to be left without a pharmacist on duty when other people are in the store, after business hours, the prescription area shall be enclosed by a permanent barrier or partition from floor to ceiling, with entry doors that can be securely locked. If a prescription area is continually attended by a pharmacist when other people are in the store, the prescription area need not be enclosed by the permanent barrier. The barrier shall be so designed that only a pharmacist with a key, except in an extreme emergency, shall have access to the area where prescription only drugs, dangerous drugs, narcotics, and other drugs and devices restricted to sales by pharmacists are stored, compounded, and dispensed.
8. **Types of permanent barrier.** The permanent barrier may be constructed of other than a solid material. If constructed of a material other than a solid, the openings or interstices in the material shall not be large enough to permit removal of items in the prescription area by any means. Any material used in the construction of the permanent barrier must be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated, or bent. The plans and specifications of the permanent barrier shall be submitted to the board for approval that it affords adequate security.
9. **Additional storage area.** When additional storage area is required for drugs that are restricted to pharmacists, the area shall be contained by a permanent barrier from floor to ceiling. All doors or gates to the storage area shall be able to be locked, and only a pharmacist with a key shall be permitted to enter the storage area, except in an extreme emergency.

10. **Security standards variations.** The board of pharmacy recognizes that the security standards for pharmacies will depend on the type of pharmaceutical services offered, and therefore, variations for required security standards may be granted by the board of pharmacy.

**History:** Amended effective May 1, 1984; April 1, 1988.

**General Authority:** NDCC 43-15-10(11)

**Law Implemented:** NDCC 43-15-10(11)

## CHAPTER 61-02-04 SANITARY STANDARDS FOR PHARMACIES

Section

61-02-04-01 Sanitary Standards for Pharmacies

**61-02-04-01. Sanitary standards for pharmacies.** A pharmacy must comply with the following sanitary standards:

1. **Pharmacies and equipment.** All pharmacies and equipment therein shall be maintained in a clean condition and in good repair.
2. **Sanitary facilities.** All sanitary facilities shall be constructed in accordance with the laws and ordinances applying thereto.
3. **Trash.** Adequate trash receptacles shall be provided. No waste material shall be permitted to collect in the prescription area.
4. **Toilet.** A toilet available to the prescription area shall be maintained in a sanitary condition and in good repair at all times. All new pharmacies shall maintain a restroom immediately adjacent to the prescription area.
5. **Personnel's apparel.** All authorized persons working in relation to the pharmacy shall be required to keep themselves and their apparel neat and clean while in the pharmacy.
6. **Hot and cold running water.** There shall be a sink with hot and cold running water within the prescription area for pharmaceutical purposes only.
7. **Storerooms.** Storerooms shall be dry and well-ventilated, free from rodents and insects, and equipped with adequate lighting facilities.
8. **Sanitary standards variations.** The board of pharmacy recognizes that the sanitary standards for pharmacies will depend on the type of pharmaceutical services offered, and therefore, variations for required sanitary standards may be granted by the board of pharmacy.

**History:** Amended effective April 1, 1988.

**General Authority:** NDCC 43-15-10(11), 43-15-35(3)

**Law Implemented:** NDCC 43-15-10(11), 43-15-35(3)

## CHAPTER 61-02-05 EXISTING PHARMACIES

Section

61-02-05-01 Existing Pharmacies

**61-02-05-01. Existing pharmacies.** Existing pharmacies licensed by the board prior to March 8, 1972, the effective date of chapters 61-02-02, 61-02-03, and 61-02-04, may have their use continued if they reasonably conform, or are made to reasonably conform, to the intent of those chapters.

**General Authority:** NDCC 43-15-10(9), 43-15-10(11)

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(11)

## CHAPTER 61-02-06 COMPUTER PHARMACY REGULATIONS

Section

61-02-06-01 Input of Drug Information Into Electronic Data Processing Equipment to Be by Pharmacist or Under the Supervision of a Pharmacist

61-02-06-02 Requirements for Storage and Retrieval of Prescription Information

61-02-06-03 Original Prescription Shall Be Retained on File

61-02-06-04 Written Policy and Procedures

**61-02-06-01 Input of drug information into electronic data processing equipment to be by pharmacist or under the supervision of a pharmacist.** When electronic data processing equipment is employed by a pharmacy, input of drug information shall be performed only by a pharmacist or under the immediate and personal supervision of a pharmacist. If orders are entered by other personnel, the pharmacist must certify the accuracy of the information entered and verify the prescription order prior to the dispensing of the medication. The identity of the pharmacist must be retained in the record.

**History:** Effective August 1, 1983.

**General Authority:** NDCC 28-32-02, 43-15-10(9)(12)(14)

**Law Implemented:** NDCC 28-32-02, 43-15-10(9)(12)(14)

**61-02-06-02 Requirements for storage and retrieval of prescription information.** Electronic data processing equipment or media, when used to store or process prescription information, shall meet the following requirements:

1. Must guarantee the confidentiality of the information contained in the database. Must require that the transmission of electronic prescriptions from prescriber to pharmacist not be compromised by interventions, control, or manipulation of said prescriptions by any other party.
2. An electronic system must provide online retrieval via computer screen or hard-copy printout of original prescription order information for those prescription orders which are currently authorized for refilling. If more refills are authorized, it must be noted on the computer screen or on the hard copy of the prescription or a new prescription must be produced.
3. Must produce a hard-copy daily summary of controlled substance transactions. Monthly summaries must be produced and filed with the biennial inventory.
4. Be capable of recording and carrying in the record all dates of refills of any prescription and the initials of the pharmacist.
5. Be capable of producing a patient profile indicating all drugs being taken and the date of refills of these prescriptions, as required by North Dakota Century Code section 43-15-31.1.
6. Be capable of reconstructing information, by daily backups in the event of a computer malfunction or accident resulting in destruction of the database.

**History:** Effective August 1, 1983; amended effective July 1, 1990; December 1, 1996; July 1, 2011.

**General Authority:** NDCC 28-32-02, 43-15-10(9)(12)(14)

**Law Implemented:** NDCC 43-15-10(9)(12)(14)

**61-02-06-03 Original prescription shall be retained on file.** In all cases where electronic data processing equipment is used, the original prescription (hard copy or saved in an unalterable electronic data filing system that has been approved by the board) shall be retained on file according to law to assure access to the information contained on the prescription in the event of a computer malfunction.

**History:** Effective August 1, 1983; amended effective July 1, 1990; December 1, 1996.

**General Authority:** NDCC 28-32-02, 43-15-10(9)(12)(14)

**Law Implemented:** NDCC 43-15-10(9)(12)(14)

**61-02-06-04 Written policy and procedures.** Written policy and procedures must be available electronically or in hard copy format, detailing responsibilities of each pharmacist relative to the operation of the computer and its records.

**History:** Effective July 1, 1990, amended October 1, 2014.

**General Authority:** NDCC 28-32-02, 43-15-10(9)(12)(14)

**Law Implemented:** NDCC 43-15-10(9)(12)(14)

## **CHAPTER 61-02-07 CLERICAL PERSONNEL**

[Repealed effective October 1, 1993]

## CHAPTER 61-02-07.1 PHARMACY TECHNICIAN

### Section

61-02-07.1-01 Purpose and Scope

61-02-07.1-02 Definitions

61-02-07.1-03 Educational Preparation

61-02-07.1-04 Ratio of Pharmacists to Pharmacy Technicians

61-02-07.1-05 Tasks Pharmacy Technicians May Perform

61-02-07.1-06 Tasks Pharmacy Technicians May Not Perform

61-02-07.1-07 Pharmacy Technician Registration Requirements

61-02-07.1-08 Supportive Personnel

61-02-07.1-09 Penalties for Violation of Rule Regulating Pharmacy Technicians

61-02-07.1-10 Pharmacy Technician Continuing Education

61-02-07.1-11 Pharmacy Technician in Training

61-02-07.1-12 Technicians Checking Technicians

61-02-07.1-13 Pharmacy Technician Reinstatement

### **61-02-07.1-01. Purpose and scope.**

1. The board of pharmacy is responsible for maintaining, continuing, and enhancing the development of the educational and professional role of the pharmacists for the protection of the health, welfare, and safety of the citizens of the state.
2. Current practice requires an expanding knowledge base for pharmacists to serve patients with appropriate counseling, advising, evaluating, and cost-effective pharmaceuticals.
3. To assist a pharmacist in technical services related to pharmaceutical product preparation and distribution, the need for a pharmacy technician is appropriate.

**History:** Effective October 1, 1993.

**General Authority:** NDCC 28-32-02, 43-15-10(12)(14)

**Law Implemented:** NDCC 28-32-03, 43-15-10(12)(14)

### **61-02-07.1-02. Definitions.**

1. "Pharmacy technician" means a person registered by the board of pharmacy who is employed by a pharmacy under the responsibility of the pharmacist-in-charge or a staff pharmacist so designated by the pharmacist-in-charge, to assist in the technical services of preparing pharmaceuticals for final dispensing by a licensed pharmacist in compliance with subsection 4 of North Dakota Century Code section 43-15-01 and subsection 16 of North Dakota Century Code section 43-15-01.
2. "Pharmacy technician in training" is a person who is enrolled in an academic experiential rotation program of North Dakota state college of science or in an on-the-job self-instructioned pharmacy technician study program under the supervision of a licensed pharmacist.
3. "Supportive personnel" means a person other than a licensed pharmacist, pharmacy intern, or pharmacy technician who may be performing duties assigned by the pharmacist under direct supervision.

**History:** Effective October 1, 1993; amended effective July 1, 1996.

**General Authority:** NDCC 28-32-02, 43-15-10(12)(14)(19)

**Law Implemented:** NDCC 28-32-03

### **61-02-07.1-03. Educational preparation.**

1. To be eligible to be registered by the board of pharmacy as a pharmacy technician the person must have completed one of the following requirements:
  - a. Successful completion of an American society of health systems pharmacists accredited academic program;
  - b. An American society of health systems pharmacists accredited on-the-job training program.
2. Technician certification:
  - a. An applicant for registration as a pharmacy technician must have obtained certification by a national certification body approved by the board of pharmacy.

- b. A technician registered after August 1, 1995, must obtain and maintain certification by a national certification body approved by the board of pharmacy.
- c. A registered technician who does not hold certification on April 1, 2011, will have until March 1, 2014, to obtain that certification.
- d. A copy of a current certification certificate will serve as proof of the technician's continuing education requirement upon renewal or a continuing education audit.
- e. The pharmacy technician certification board is an approved certification body.

**History:** Effective October 1, 1993; amended effective October 1, 2012.

**General Authority:** NDCC 28-32-02, 43-15-10(12)(14)(19)

**Law Implemented:** NDCC 43-15-10(12)(14)(19)

**61-02-07.1-04. Ratio of pharmacists to pharmacy technicians.** The ratio of pharmacists to pharmacy technicians may not be greater than one to three (one pharmacist to three pharmacy technicians) in a retail setting. The ratio of pharmacists to pharmacy technicians may not be greater than one to four (one pharmacist to four pharmacy technicians) in a hospital or closed-door pharmacy that does not deal directly with patients. A pharmacist may not supervise more than four telepharmacy sites. This ratio does not include other supportive personnel.

**History:** Effective October 1, 1993; amended effective January 1, 2005.

**General Authority:** NDCC 28-32-02, 43-15-10(12)(14)

**Law Implemented:** NDCC 28-32-03, 43-15-10(12)(14)

**61-02-07.1-05. Tasks pharmacy technicians may perform.**

1. Under the responsibility of the pharmacist-in-charge or designated staff pharmacist the pharmacy technician may perform any service assigned by the pharmacist-in-charge in the preparation of pharmaceuticals to be dispensed by the pharmacist to a patient except as specified in section 61-02-07.1-06.
2. The pharmacist is legally responsible for all the pharmacy technician's activities and services performed.

**History:** Effective October 1, 1993.

**General Authority:** NDCC 28-32-02, 43-15-10(12)(14)

**Law Implemented:** NDCC 28-32-03, 43-15-10(12)(14)

**61-02-07.1-06. Tasks pharmacy technicians may not perform.** The pharmacy technician may not:

1. Evaluate the patient's profile relative to the pharmaceuticals that have or will be dispensed.
2. Consult with the patient concerning the utilization of their pharmaceuticals.
3. Make decisions that require a pharmacist's professional education, such as interpreting and applying pharmacokinetic data and other pertinent laboratory data or therapeutic values to design safe and effective drug dosage regimens.
4. Engage in the practice of pharmacy, except as authorized by a licensed pharmacist, as permitted by North Dakota law and rules adopted by the board.

**History:** Effective October 1, 1993; amended effective July 1, 1996; October 1, 1999.

**General Authority:** NDCC 28-32-02, 43-15-10(12)(14)(19)

**Law Implemented:** NDCC 28-32-03

**61-02-07.1-07. Pharmacy technician registration requirements.**

1. A pharmacy technician must register with the board of pharmacy on an annual basis.
2. The pharmacy technician will be assigned a registration number.
3. The board of pharmacy must provide the pharmacy technician with an annual registration card and pocket identification card.
4. The pharmacy technician certificate and annual registration card must be displayed and visible to the public in the pharmacy where the pharmacy technician is employed.
5. The pharmacy technician must wear a name badge while in the pharmacy which clearly identifies the person as a "pharmacy technician".
6. Pharmacy technicians shall identify themselves as pharmacy technicians on all telephone conversations while on duty in the pharmacy.

7. The northland association of pharmacy technicians shall appoint annually three of their members as an advisory committee to the board of pharmacy.
8. Every registered pharmacy technician, within fifteen days after changing address or place of employment, shall notify the board of the change. The board shall make the necessary changes in the board's records.
9. A pharmacy technician having passed the reciprocity examination of the national association of boards of pharmacy, or any other examination approved by the board, shall be granted reciprocity and shall be entitled to registration as a registered pharmacy technician in North Dakota.
10. A pharmacy technician registered by the board may use the designations "registered pharmacy technician" and "R. Ph. Tech.".
11. A pharmacy technician holding a certificate of registration as a pharmacy technician in North Dakota may go on inactive status, and continue to hold a certificate of registration in North Dakota, provided that the technician on inactive status may not practice within North Dakota. A pharmacy technician on inactive status will not be required to meet the continuing education requirements of the board under chapter 61-02-07.1. In order for a pharmacy technician to change an inactive status registration to an active status of registration, the pharmacy technician must complete ten hours of approved pharmacy technician continuing education and thereafter comply with the continuing education requirements of the board.
12. In the case of loss or destruction of a certificate of registration, a duplicate can be obtained by forwarding the board an affidavit setting forth the facts.

**History:** Effective October 1, 1993; amended effective July 1, 1996.

**General Authority:** NDCC 28-32-02, 43-15-10(12)(14)(19)

**Law Implemented:** NDCC 28-32-03

**61-02-07.1-08. Supportive personnel.** Any duty that is not required to be performed by a registered pharmacist, registered pharmacy intern, or by a pharmacy technician may be performed by other employees of the pharmacy.

**History:** Effective October 1, 1993.

**General Authority:** NDCC 28-32-02, 43-15-10(12)(14)

**Law Implemented:** NDCC 28-32-03, 43-15-10(12)(14)

**61-02-07.1-09. Penalties for violation of rule regulating pharmacy technicians.** The registration of any pharmacy technician violating drug laws or rules may be revoked by the board of pharmacy. Pharmacists or pharmacies violating drug laws or rules may be subject to the penalties of North Dakota Century Code section 43-15-42.1.

**History:** Effective October 1, 1993.

**General Authority:** NDCC 28-32-02, 43-15-10(12)(14)

**Law Implemented:** NDCC 28-32-03, 43-15-10(12)(14)

**61-02-07.1-10. Pharmacy technician continuing education.**

1. Each pharmacy technician shall complete at least ten hours of approved pharmacy technician continuing education every year as a condition of renewal of a registration as a pharmacy technician in North Dakota.
2. There may be no carryover or extension of continuing education units with the exception that continuing education units obtained twelve months prior to the beginning of each annual reporting period may be used in the current annual reporting period which begins March first of each year and ends the last day of February, or the previous reporting period. However, they may not be counted as credit in both reporting periods. The failure to obtain the required ten hours of continuing education by the renewal date may result in a suspension for a minimum of thirty days, or a maximum of the period ending the date the continuing education is completed.
3. Pharmacy technicians shall maintain their own records on forms supplied by the board. The records must be maintained for a two-year period.
4. The requirements of this section do not apply to a pharmacy technician applying for a first renewal of a registration.

5. A pharmacy technician registered with the board may make application to the board for a waiver of compliance with the pharmacy technician continuing education requirements and may be granted an exemption by the board.
6. Upon request of the board, proof of compliance must be furnished to the board.
7. Approved pharmacy technician continuing education means those pharmacy technician continuing education programs approved by the board. The board shall maintain a record of approved programs, including the hours of credit assigned to each program which shall be available upon request.

**History:** Effective July 1, 1996; amended effective January 1, 2005; January 1, 2010.

**General Authority:** NDCC 28-32-02, 43-15-10(12)(14)(19)

**Law Implemented:** NDCC 28-32-03

**61-02-07.1-11. Pharmacy technician in training.** A pharmacy technician in training must be designated as a pharmacy technician in training and will be allowed to practice the professional duties of a registered pharmacy technician as determined by the pharmacist-in-charge and the supervising licensed pharmacist. Upon receipt of a request to have a person designated a pharmacy technician in training from a pharmacist-in-charge, the board, if appropriate, shall register the person so enrolled as a pharmacy technician in training. The maximum amount of time to be registered as a technician in training is two years unless an extension is granted.

**History:** Effective July 1, 1996; amended effective January 1, 2005.

**General Authority:** NDCC 28-32-02, 43-15-10(12)(14)(19)

**Law Implemented:** NDCC 28-32-03

**61-02-07.1-12. Technicians checking technicians.** Activities allowed by law to be performed within a licensed pharmacy by a registered pharmacy technician in the preparation of a prescription or order for dispensing or administration may be performed by one registered pharmacy technician and verified by another registered pharmacy technician working in the same licensed pharmacy, under the following conditions:

1. The licensed pharmacy where the work is being conducted has policies and procedures specifically describing the scope of the activities to be verified through this practice, included in the policy and procedure manual required under section 61-02-01-18.
  - a. Training for the specific activity is reflected in a written policy.
  - b. A record of the individuals trained is maintained in the pharmacy for two years.
2. The pharmacy has a continuous quality improvement system in place to periodically verify the accuracy of the final product, including:
  - a. Recording any quality related events leading up to the final dispensing or administration of the drug prepared.
  - b. Recording any errors which actually reach the patient as a result of these activities.
  - c. Specific limits of acceptable quality related event levels before reassessment is required.
  - d. Consideration must be made for high-risk medications on the institute for safe medication practices (ISMP) list and specific monitoring, review, and quality assurance parameters must be instituted if any of these products are included in the pharmacy's technicians-checking-technicians program.
3. Any error must trigger pharmacist review of the process. This review and subsequent recommendations must be documented.
4. The pharmacy has a system in place to review all quality related events and errors recorded and takes corrective action based on the information to reduce quality related events and eliminate errors reaching the patient.
5. As always, the pharmacist-in-charge and the permitholder are jointly responsible for the final product dispensed or released for administration from the pharmacy.

**History:** Effective January 1, 2009; amended effective October 1, 2014.

**General Authority:** NDCC 28-32-02

**Law Implemented:** NDCC 28-32-03



**61-02-07.1-13. Pharmacy technician reinstatement.** If a registered pharmacy technician fails to pay the fee for a renewal registration within the time required, the executive director of the board shall cancel the registration for nonpayment. Upon application, the delinquent registrant may procure a renewed registration once the payment of all back registration fees and proof of ten hours of continuing pharmaceutical education obtained within the past year are submitted, provided there have been no disciplinary actions involved with the registration and the board is satisfied that the applicant is a proper person to receive the same.

**History:** Effective January 1, 2011.

**General Authority:** NDCC 28-32-02, 43-15-10(12)(14)(19)

**Law Implemented:** NDCC 28-32-03, 43-15-10(12)(14)(19)

## **CHAPTER 61-02-08 TELEPHARMACY RULES**

### **Section**

61-02-08-01 Purpose and Scope

61-02-08-02 Definitions

61-02-08-03 Operations

61-02-08-04 Rule Exceptions

61-02-08-05 Suspension and Termination

61-02-08-06 Expiration [Repealed]

61-02-08-07 Telepharmacy Satellite Consultation Sites

61-02-08-08 Telepharmacy in Hospitals

61-02-08-09 Telepharmacy Satellite Remote Dispensing Machine Sites

### **61-02-08-01. Purpose and scope.**

1. The state board of pharmacy is responsible for maintaining, continuing, and enhancing the development of the education and professional role of the pharmacist for the protection of the health, welfare, and safety of the citizens of North Dakota.
2. Rural North Dakota is facing an accessibility problem due to closing pharmacies.
3. In order to maintain or make pharmacy services available in areas that have lost their pharmacies or are in jeopardy of losing their pharmacies, rules are necessary to permit telepharmacies.
4. This chapter applies to central pharmacies, each with one or more remote sites. Both the central pharmacy and remote site may be located within North Dakota, either the remote site or the central pharmacy, may be located in a contiguous state.

**History:** Effective October 1, 2001; amended effective December 1, 2003; January 1, 2005.

**General Authority:** NDCC 43-15-10(7)(9)(11)(12)(14)(19)

**Law Implemented:** NDCC 43-15-10, 43-15-32, 43-15-34, 43-15-35

### **61-02-08-02. Definitions.**

1. "Remote site" means a pharmacy staffed by a registered pharmacy technician with access to its main pharmacy and registered pharmacists by computer link, videolink, and audiolink while open.
2. "Satellite consultation site" means a telepharmacy where any filled prescription ready for dispensing is prepared at another pharmacy and delivered to the satellite for dispensing via computer, videolink, and audiolink to the main pharmacy and a licensed pharmacist.
3. "Telepharmacy" means a central pharmacy with one or more remote sites in which all sites are connected via computer link, videolink, and audiolink.
4. "Telepharmacy in hospitals" means a central hospital pharmacy with one or more remote sites in which all sites are connected via computer, videolink, and audiolink.

**History:** Effective October 1, 2001; amended effective December 1, 2003.

**General Authority:** NDCC 43-15-10(7)(9)(11)(12)(14)(19)

**Law Implemented:** NDCC 43-15-10, 43-15-32, 43-15-34, 43-15-35

### 61-02-08-03. Operations.

1. A remote site shall comply with North Dakota Century Code section 43-15-35 governing requirements for a permit to operate a pharmacy. The remote site is considered to be under the personal charge of the pharmacist at the central pharmacy.
2. A remote site shall be connected to its central pharmacy via computer link, videolink, and audiolink.
3. A remote site shall use its central pharmacy's central processing unit.
  - a. Consecutive prescription numbers and all prescription records must be maintained at the central pharmacy.
  - b. Prescriptions filled at the remote site must be distinguishable on records from those filled at the central pharmacy.
  - c. Daily reports must be separated for the central pharmacy and the remote site but must be maintained at the central pharmacy.
  - d. Pharmacies must be able to generate labels from the central pharmacy or at the remote site.
  - e. All prescriptions distributed at the remote site must have a label that meets requirements set forth in chapter 61-04-06 attached to the final drug container before the pharmacist verifies the dispensing process.
4. A pharmacist at the central pharmacy must approve each prescription before it leaves the remote site.
  - a. Dispensing is considered to be done at the central pharmacy.
  - b. Both the pharmacist's and the technician's initials must appear on the fill screen, patient profile, and label.
  - c. A pharmacist shall compare via videolink the stock bottle, drug dispensed, and strength. The entire label must be checked for accuracy on the videolink.
5. Counseling must be done by a pharmacist via videolink and audiolink. The pharmacist must counsel the patient or the patient's agent on all new prescriptions and refills.
6. A pharmacist must complete monthly inspections of the remote site. Inspection criteria must be included in the policies and procedures for the site. The inspection reports must be maintained until the next state board of pharmacy inspection.
7. The remote site may have a prescription inventory. Controlled substances shall be kept at the remote site in accordance with North Dakota Century Code chapter 19-03.1, the Uniform Controlled Substances Act.
  - a. If controlled substances are kept, the remote site must be registered with the drug enforcement administration and obtain its own drug enforcement administration number.
  - b. All records must be stored at the central pharmacy, except those required by the drug enforcement administration to be at the drug enforcement administration-registered site.
8. There must be policies and procedures in place to ensure the safe and effective distribution of pharmaceutical products and delivery of required pharmaceutical care. There must be an ongoing review of incident reports and outcomes, with appropriate corrective action taken when necessary, to ensure there is no abnormal frequency of errors in dispensing drugs or devices.
9. The telepharmacy location must be in compliance with chapter 61-02-02, building standards for pharmacies; chapter 61-02-03, security standards for pharmacies; and chapter 61-02-04, sanitary standards for pharmacies; except as otherwise provided in this chapter.
10. Dispensing and consultation may be done when the registered pharmacy technician is not present, under the following circumstances:
  - a. The prescription has been prepared by the registered pharmacy technician and checked by the licensed pharmacist.
  - b. The prescription area is locked.
  - c. A separate locked drawer or cabinet is maintained for prescriptions ready for dispensing.
  - d. A log is maintained by the registered pharmacy technician of prescriptions placed in the locked drawer or cabinet.
  - e. A record must be made by the pharmacist as to the date and time at which dispensing and counseling occurs.

- f. Supportive personnel, trained in the use of the audiolink and videolink, to the licensed pharmacist, are on hand, to assist the patients.
- g. The patients receive their prescriptions as they are being counseled by the licensed pharmacist.
11. The permit holder or the pharmacist in charge of the central pharmacy must apply for a permit for the remote site. A class K permit is established under section 61-02-01-01 for the purpose of conducting a telepharmacy. These permits are issued to a remote site connected to a central pharmacy via computer link, videolink, and audiolink.

**History:** Effective October 1, 2001; amended effective December 1, 2003.

**General Authority:** NDCC 43-15-10(7)(9)(11)(12)(14)(19)

**Law Implemented:** NDCC 43-15-10, 43-15-32, 43-15-34, 43-15-35

**61-02-08-04. Rule exceptions.** To the extent of a conflict with any provision of this title, the provisions of this chapter govern with respect to a telepharmacy and remote site operating in compliance with this chapter. With the following conditions, this chapter is an exception to the following rules:

1. Pharmacist on duty under section 61-02-01-13. The remote site must have a registered pharmacy technician present and a working computer link, videolink, and audiolink to a pharmacist at the central pharmacy to have the prescription area open. The communication link must be checked daily and the remote site pharmacy must be closed if the link malfunctions, unless a pharmacist is at the remote site.
  - a. The technician must be registered with the state board of pharmacy and have at least one year of work experience as a North Dakota-registered pharmacy technician.
  - b. The technician must be a graduate of an approved pharmacy technician education program or must make application to the board, and must demonstrate knowledge and experience in preparation of prescriptions for dispensing and working with patients.
  - c. The technician will be subject to all rules in chapter 61-02-07.1, excluding the ratio of pharmacists to pharmacy technicians. A pharmacist may oversee no more than four remote sites. As dispensing is considered done by the pharmacist, the pharmacist will be responsible for and held accountable for the remote site.
2. Security standards for pharmacies under subsections 3, 4, 6, 7, and 9 of section 61-02-03-01. The pharmacy technician may unlock the prescription and storage areas. While the technician is on duty, the prescription area may remain open.
3. Input of drug information into electronic data processing equipment under section 61-02-06-01. The input of drug information shall be done by a pharmacist at the central pharmacy or, if entered by the technician at the remote site, must be verified by a pharmacist.
  - a. New prescriptions may be received and entered at the central pharmacy with a label printed at the remote site.
  - b. New prescriptions received at the remote site may be entered into the remote computer system with all verification, interaction checking, and profile review the responsibility of the pharmacist at the central pharmacy.

**History:** Effective October 1, 2001.

**General Authority:** NDCC 43-15-10(7)(9)(11)(12)(14)(19)

**Law Implemented:** NDCC 43-15-10, 43-15-32, 43-15-34, 43-15-35

**61-02-08-05. Suspension and termination.**

1. The board may suspend immediately the permit of any class K pharmacy if a danger to the public exists.
2. The board may terminate all of the class K permits pursuant to North Dakota Century Code chapter 28-32. A sixty-day notice will be sent to the pharmacist in charge of each.

**History:** Effective October 1, 2001; amended effective January 1, 2004.

**General Authority:** NDCC 43-15-10(7)(9)(11)(12)(14)(19)

**Law Implemented:** NDCC 43-15-28.1

**61-02-08-06. Expiration.** [Repealed effective July 1, 2005.]

### **61-02-08-07. Telepharmacy satellite consultation sites.**

1. These sites have no prescription inventory.
2. Only filled prescriptions, filled at the central pharmacy, with final patient labeling attached are allowed at these sites.
3. These sites may be controlled by supportive personnel who have been trained in the use of the patient counseling audiolink and videolink necessary for the dispensing and consultation to occur.
4. The supportive personnel assist the patient in accessing the pharmacist via the audiolink and videolink.
5. Prescription refill requests may be communicated to this site by the patient or the patient's agent.
6. Original written prescriptions may be brought to these sites by the patient or the patient's agent for faxing, scanning, and transmitting to the central pharmacy.
7. No prescription or refill communicated from practitioners may be received at these sites.
8. No drug enforcement administration number is necessary as only filled prescriptions will be at the site.
9. Security of filled prescriptions must be maintained by a separate locked drawer or cabinet.
10. A record must be made by the pharmacist as to the date and time at which dispensing and counseling occurred.

**History:** Effective December 1, 2003.

**General Authority:** NDCC 43-15-10(7)(9)(11)(12)(14)(19)

**Law Implemented:** NDCC 43-15-10, 43-15-32, 43-15-34, 43-15-35

### **61-02-08-08. Telepharmacy in hospitals.**

1. The supervision required in subsection 3 of section 61-07-01-04 may be accomplished via audiolink, videolink, and computer link, if the hospital has a registered pharmacy technician on duty meeting the qualifications of subsection 1 of section 61-02-08-04.
2. No prescription order may be released for administration to a patient until approved by a pharmacist via the audiolink, videolink, and computer link.
3. The policy and procedures of the hospital pharmacy must address all aspects of the telepharmacy operation, including control of the pharmacy by the registered pharmacy technician in the absence of the pharmacist.
4. Contractual arrangements must be in place for the supervision of the technician by either the consultant pharmacist, another hospital pharmacy with adequate staffing, or a contracted pharmacist providing coverage when pharmacist staffing is not provided at the hospital.

**History:** Effective December 1, 2003.

**General Authority:** NDCC 43-15-10(7)(9)(11)(12)(14)(19)

**Law Implemented:** NDCC 43-15-10, 43-15-32, 43-15-34, 43-15-35

### **61-02-08-09. Telepharmacy satellite remote dispensing machine sites.**

1. These sites have prescription inventory, which is secured in an automated dispensing device connected to the central processing unit at the central pharmacy.
2. A pharmacist must approve all prescription orders before they are released from the automated dispensing device.
3. Dispensing and counseling are performed by the licensed pharmacist at the central site via audiolink and videolink.

**History:** Effective December 1, 2003.

**General Authority:** NDCC 43-15-10(7)(9)(11)(12)(14)(19)

**Law Implemented:** NDCC 43-15-10, 43-15-32, 43-15-34, 43-15-35

## **CHAPTER 61-02-09 CONTINUOUS QUALITY IMPROVEMENT**

Section

61-02-09-01 Definitions

**61-02-09-01 Continuous Quality Improvement Program** In this chapter, unless the context or subject matter otherwise requires:

1. "Actively reports" means reporting all dispensing errors and analysis of such errors to a patient safety organization as soon as practical or at least within thirty days of identifying the error.
2. "Analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors.
3. "Dispensing error" means one or more of the following discovered after the final verification by the pharmacist:
  4. Variation from the prescriber's prescription drug order, including:
    - a. Incorrect drug;
      - (1) Incorrect drug strength;
      - (2) Incorrect dosage form;
      - (3) Incorrect patient; or
      - (4) Inadequate or incorrect packaging, labeling, or directions.
    - b. Failure to exercise professional judgments in identifying and managing:
      - (1) Therapeutic duplication;
      - (2) Drug-disease contraindications, if known;
      - (3) Drug-drug interactions, if known;
      - (4) Incorrect drug dosage or duration of drug treatment, interactions;
      - (5) A clinically significant, avoidable delay in therapy; or
      - (6) Any other significant, actual or potential problem with a patient's drug therapy.
    - c. Deliver of a drug to incorrect patient.
    - d. Variation in bulk repackaging or filling of automated devices, including:
      - (1) Incorrect drug;
      - (2) Incorrect drug strength;
      - (3) Incorrect dosage form; or
      - (4) Inadequate or incorrect packaging or labeling.
4. "Incident" means a patient safety event that reached the patient, whether or not the patient is harmed.
5. "Near miss" means a patient safety event that did not or could not have reached the patient.
6. "Patient safety organization" means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) and is credentialed by the agency for healthcare research and quality.
7. "Unsafe condition" means any circumstance that increases the probability of a patient safety event.

**History:** Effective April 1, 2016.

**General Authority:** NDCC 28-32-02, 43-15-10, 23-34

**Law Implemented:** NDCC 28-32-03, 43-15-10, 23-34

**61-02-09-02. Continuous quality improvement program.**

1. Each pharmacy permittee shall establish continuous quality improvement program for the purpose of detecting, documenting, assessing, and preventing incidents, near misses, and unsafe conditions.
2. A pharmacy permittee meets the requirements if the permittee meets the following:
  - a. Maintains and complies with the policies and procedures as noted in subsection 4;
  - b. The pharmacy reports incidents, near misses, and unsafe events through either:
    - (1) A contracted patient safety organization that is listed as an agency for health research and quality on [www.ahrq.com](http://www.ahrq.com) whose primary mission is pharmacy continuous quality improvement; or
    - (2) An internal program to the pharmacy which is acceptable to the board where proper documentation and evaluation can be completed.
3. At a minimum, a continuous quality improvement program must include provisions to:
  - a. Designate an individual or individuals responsible for implementing, maintaining, and monitoring the continuous quality improvement program, which is managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form;
  - b. Initiate documentation of incidents, near misses, and unsafe conditions as soon as possible, but no more than seven days, after determining their occurrence;

4. The policies and procedures must be in compliance with this section must include:
  - a. Training all pharmacy personnel in relevant phases of the continuous quality improvement program;
  - b. Identifying and documenting reportable incidents and near misses and unsafe events;
  - c. Minimizing the impact of incidents and near misses and unsafe events on patients;
  - d. Analyzing data collected to assess the causes and any contributing factors relating to incidents and near misses and unsafe events;
  - e. Use the findings to formulate an appropriate response and to develop pharmacy systems and workflow processes designed to prevent and reduce incidents and near misses and unsafe events; and
  - f. Periodically, but at least quarterly, meet with appropriate pharmacy personnel to review findings and inform personnel of changes that have been made to pharmacy policies, procedures, systems, or processes as a result of continuous quality improvement program findings.
5. Quality self-audit. Each pharmacy shall conduct a quality self-audit at least quarterly to determine whether the occurrence of incidents, near misses, and unsafe conditions has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the continuous quality improvement program in the future. Each pharmacy shall conduct a quality self-audit upon change of pharmacist-in-charge to familiarize that person with the pharmacy's continuous quality improvement program.
6. Protection from discovery:
  - a. Records that are generated as a component of a pharmacy's ongoing quality assurance program and which are maintained for that program are peer review documents and are not subject to subpoena or discovery in an arbitration or civil proceeding.
  - b. Records that are generated as a component of a pharmacy's ongoing quality assurance program and which are maintained for that program are confidential and may not be released, distributed, or communicated in any manner, except as provided by these rules or the permittee's policies and procedures. Recognizing the importance of sharing information with staff, experts, consultants, and others is necessary in reducing medication errors, information used as a part of the permittee's quality program in any manner does not compromise the confidentiality and privilege of such information.
  - c. This subsection does not prohibit a patient from accessing the patient's prescription records or affect the discoverability of any records that are not generated solely as a component of a pharmacy's ongoing quality assurance program and maintained solely for that program.
7. The board's regulatory oversight activities regarding a pharmacy's continuous quality improvement program are limited to inspection of the pharmacy's continuous quality improvement policies and procedures and enforcing the pharmacy's compliance with those policies and procedures.
8. An analysis or summary of findings, produced within six months of submission, is evidence of compliance with the records and data collection provisions. A permittee may not be required to produce data, charts, error reports, or findings collected and used in compiling an analysis summary.
9. Notwithstanding subsections 6 and 8, if a pharmacy is reporting to a patient safety organization whose primary mission is continuous quality improvement all data and records are privileged and confidential as provided in the Patient Safety and Quality Improvement Act of 2005 and implementing regulations.

**History:** Effective April 1, 2016.

**General Authority:** NDCC 28-32-02, 43-15-10, 23-34

**Law Implemented:** NDCC 28-32-03, 43-15-10, 23-34

## ARTICLE 61-03 PHARMACISTS

### Chapter

- 61-03-01 Licensure of Pharmacists
- 61-03-02 Consulting Pharmacist Regulations for Long-Term Care Facilities (Skilled, Intermediate, and Basic Care)
- 61-03-03 Preceptor/Intern - Internship/Externship/Clerkship [Repealed]
- 61-03-03.1 Internship
- 61-03-04 Continuing Pharmaceutical Education

### CHAPTER 61-03-01 LICENSURE OF PHARMACISTS

#### Section

- 61-03-01-01 Applications
- 61-03-01-02 Approved Schools
- 61-03-01-03 Score Required
- 61-03-01-04 Licensure Without Examination
- 61-03-01-05 Cancellation of Certificates [Repealed]
- 61-03-01-06 Duplicate Certificate
- 61-03-01-07 Posting of Certificate
- 61-03-01-08 Foreign Graduates
- 61-03-01-09 Inactive Status
- 61-03-01-10 Reinstatement Procedures

**61-03-01-01. Applications.** All applicants for licensure as pharmacists must appear in person before the board of pharmacy at a meeting scheduled for examination of applicants for licensure. Applications must be in the hands of the secretary of the board three days before the examination. All applications must be accompanied by affidavits from former employers, showing that the applicant has had the experience required under a licensed pharmacist, as required by North Dakota Century Code section 43-15-15.

**General Authority:** NDCC 43-15-19

**Law Implemented:** NDCC 43-15-19

**61-03-01-02. Approved schools.** The board of pharmacy designates as approved schools all colleges of pharmacy which are members of the American association of colleges of pharmacy or maintain standards equivalent to those required for membership in that association, and have been accredited by the accreditation council for pharmacy education.

**History:** Amended effective October 1, 2007.

**General Authority:** NDCC 43-15-15

**Law Implemented:** NDCC 43-15-15

**61-03-01-03. Score required.** An applicant for licensure as a pharmacist in North Dakota by examination or reciprocity must obtain a score of seventy-five in any written, oral, or practical laboratory examination required by the board.

**History:** Amended effective August 1, 1983; June 1, 1986.

**General Authority:** NDCC 28-32-02, 43-15-10(3)(12)(14), 43-15-19

**Law Implemented:** NDCC 28-32-03, 43-15-10(3)(12)(14), 43-15-19

**61-03-01-04. Licensure transfer.** An applicant seeking licensure by licensure transfer or reciprocity must secure and file an application blank from the national association of boards of pharmacy. This board will license applicants by reciprocity if they possess the requirements in effect in North Dakota at the time the candidates were licensed by examination in other states. The applicant must pass the North Dakota law examination and pay the appropriate fees to obtain licensure.

**History:** Amended effective April 1, 2016.

**General Authority:** NDCC 43-15-22

**Law Implemented:** NDCC 43-15-22

**61-03-01-05. Cancellation of certificates.** [Repealed effective January 1, 2006.]

**61-03-01-06. Duplicate certificate.** In case of a loss or destruction of a certificate, a duplicate can be obtained by forwarding to the secretary an affidavit setting forth the facts in the case. The fee for a duplicate certificate is five dollars.

**General Authority:** NDCC 43-15-10

**Law Implemented:** NDCC 43-15-21

**61-03-01-07. Posting of certificate.** Each pharmacist shall post the pharmacist's certificate or renewal thereof in a conspicuous place in the pharmacy in which the pharmacist is practicing the pharmacist's profession.

**General Authority:** NDCC 43-15-10(9)

**Law Implemented:** NDCC 43-15-10(9), 43-15-25

**61-03-01-08. Foreign graduates.** Any applicant who is a graduate of a school or college of pharmacy located outside the United States, which has not been recognized and approved by the board, but who is otherwise qualified to apply for a license to practice pharmacy in this state, shall be deemed to have satisfied the requirements of subsection 3 of North Dakota Century Code section 43-15-15 by verification to the board of the applicant's academic record and the applicant's graduation and by meeting such other requirements as this board may establish from time to time. Each such applicant shall have the foreign pharmacy graduate examination committee (FPGEC) certification (which certification is hereby recognized and approved by the board) awarded by the national association of boards of pharmacy. The FPGEC certification includes the test of English as a foreign language and the test of spoken English (which examinations are hereby recognized and approved by the board) given by the educational testing service as a prerequisite to taking the licensure examination provided for in North Dakota Century Code section 43-15-19.

**History:** Effective August 1, 1983; amended effective January 1, 2006.

**General Authority:** NDCC 28-32-02, 43-15-10(2)(3)(12)(14), 43-15-15(4)

**Law Implemented:** NDCC 28-32-03, 43-15-10(2)(3)(12)(14), 43-15-15(4)

**61-03-01-09. Inactive status.** Any pharmacist holding a certificate of licensure as a pharmacist in North Dakota may go on inactive status, and continue to hold a certificate of licensure in North Dakota, provided that the pharmacist on inactive status may not practice pharmacy within North Dakota. A pharmacist on inactive status may not be required to meet the requirements of continuing pharmaceutical education as required by North Dakota Century Code section 43-15-25.1 or rules of the boards under chapter 61-03-04. In order for a pharmacist to change an inactive status certificate of licensure to an active status of licensure, the pharmacist will have to complete internship hours and continuing education hours as determined by the board, based on the length of time of inactive status, and then must comply with continuing pharmaceutical education requirements of the board and state of North Dakota thereafter.

**History:** Effective April 1, 1988; amended effective January 1, 2005.

**General Authority:** NDCC 28-32-02, 43-15-10(2)(12)(14), 43-15-15, 43-15-25.1

**Law Implemented:** NDCC 28-32-02, 43-15-10(2)(12)(14), 43-15-15, 43-15-25.1

**61-03-01-10. Reinstatement procedures.** If a licensed pharmacist in this state fails to pay the fee for a renewal of a license within the time required, the director of the board shall mail the pharmacist a notice, addressed to the pharmacist's last-known place of residence, notifying the pharmacist of failure to obtain a renewal license. The delinquent licenseholder, within sixty days after the notice is mailed, may procure a renewal license upon the payment of a renewal fee to be set by the board not to exceed two hundred dollars. If the licenseholder fails to have a license renewed within sixty days after the notice is mailed, the original or renewal license, as the case may be, becomes void and the registry thereof must be canceled. The board, on application of the delinquent licenseholder and upon the payment of all unpaid fees, may authorize the issuance of a new license without examination, if it is satisfied that the applicant is a proper person to receive the same. The board may require reexamination or completion of internship and continuing education hours as determined by the board.

**History:** Effective January 1, 2005.

**General Authority:** NDCC 28-32-02, 43-15-10(2)(12)(14), 43-15-15, 43-15-25.1



**Law Implemented:** NDCC 43-15-26

**CHAPTER 61-03-02**  
**CONSULTING PHARMACIST REGULATIONS FOR LONG-TERM CARE FACILITIES**  
**(SKILLED, INTERMEDIATE, AND BASIC CARE)**

Section

61-03-02-01 Definitions

61-03-02-02 Absence of Provider or Consulting Pharmacist

61-03-02-03 Physical Requirements of Provider Pharmacy Licensed on Premises or Other Pharmacy

61-03-02-04 Distribution and Control

**61-03-02-01. Definitions.** In this chapter, unless the context or subject matter otherwise requires:

1. "Consulting pharmacist" means a pharmacist in a long-term care facility, who:
  - a. Establishes the procedures and rules for distribution and storage of drugs;
  - b. Supervises the distribution and storage of drugs;
  - c. Visits the facility on a regularly scheduled basis;
  - d. Monitors the therapeutic response and utilization of all medications prescribed for the patients, utilizing as guidelines the indicators of the health care financing administration;
  - e. Provides regular pharmacy educational opportunities to the institution.
2. "Provider pharmacist" means a pharmacist who supplies medication to a patient in a long-term care facility and maintains separate pharmacy patient profiles from the facility.

**History:** Effective August 1, 1983.

**General Authority:** NDCC 28-32-02, 43-15-10(12), 43-15-10(14)

**Law Implemented:** NDCC 28-32-02, 43-15-10(12), 43-15-10(14)

**61-03-02-02. Absence of provider or consulting pharmacist.**

1. **General.** During such time at the long-term care facility that the pharmacist is not available, arrangements shall be made in advance by the consulting and provider pharmacist for provision of drugs to the staff of the institutional facility by use of an emergency medication kit located at the facility.
2. **Emergency medication kit.**
  - a. Emergency medications defined. Emergency medications are those medications which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients because of delay resulting from obtaining such medications from such other source.
  - b. Supply pharmacist. All emergency medications shall be provided by a provider pharmacist.
  - c. Medications included. The consulting pharmacist and the physicians representing the facility shall jointly determine and prepare a list of medications, by identity and quantity, to be included in such emergency supply. Such list of medications shall be reviewed quarterly by the pharmaceutical services committee. Only prepackaged drugs shall be available therein, in amounts sufficient for immediate therapeutic requirements.
  - d. Storage. The emergency medication kit shall be stored in areas suitable to prevent unauthorized access and to ensure a proper environment for preservation of the medications within them, as required in official compendia.
  - e. Labeling - Exterior. The exterior of an emergency kit shall be labeled to clearly and unmistakably indicate that it is an emergency drug kit and it is for use in emergencies only; such label shall also contain a listing of the name, strength, and quantity of the drugs contained therein and an expiration date.
  - f. Labeling - Interior. All drugs contained in the emergency medication kit shall be labeled in accordance with subsection 7 of North Dakota Century Code section 43-15-01.
  - g. Removal of medication. Medications shall be removed from the emergency medication kit only pursuant to a valid prescriber order and by authorized personnel, or by the provider pharmacist.
  - h. Notifications. Whenever an emergency medication kit is opened or has expired, the provider pharmacist shall be notified and the pharmacist shall replace the medication within a reasonable time so as to prevent risk of harm to the patients.

- i. Expiration date. The expiration date of an emergency kit shall be the earliest expiration date on any drug supplied in the kit. Upon the occurrence of the expiration date, the provider pharmacist shall open the kit and replace expired drugs.
- j. Procedures. The consulting pharmacist shall, in communication with the appropriate committee, develop and implement written policies and procedures to ensure compliance.

**History:** Effective August 1, 1983.

**General Authority:** NDCC 28-32-02, 43-15-10(12), 43-15-10(14)

**Law Implemented:** NDCC 28-32-02, 43-15-10(12), 43-15-10(14)

**61-03-02-03. Physical requirements of provider pharmacy licensed on premises or other pharmacy.**

1. **Area.** The pharmacy serving a long-term care facility as an institutional drug outlet shall have floor space allocated to it to ensure that drugs are prepared in sanitary, well-lighted and enclosed places, and meet the other requirements of this section. Floor space shall be allotted to conduct the activities involved with the scope of pharmaceutical services provided.
2. **Equipment and materials.** The pharmacy serving a long-term care facility as an institutional drug outlet shall have equipment and physical facilities for proper compounding, dispensing, and storage for drugs, including parenteral preparations. As a minimum, the pharmacy shall have the following:
  - a. Minimum equipment listed in section 61-02-01-03.
  - b. Drugs to meet the needs of the patients of the long-term care facility.
  - c. A pharmacy policy and procedures manual in compliance with section 61-02-01-18.
  - d. Pharmaceutical reference books, which shall include one recent edition (not over five years from publication date) from at least two of the following categories, one of which must include dispensing information:
    - (1) Drug dispensing information from one of the following:
      - (a) United States pharmacopoeia dispensing information.
      - (b) Facts and comparisons.
      - (c) Hospital formulary.
    - (2) Categories to choose from:
 Drug interactions - poison and antidote information chemistry toxicology - pharmacology bacteriology sterilization and disinfection - patient counseling - rational therapy - parenteral admixtures.
3. **Drug room.** The drug room of a long-term care facility may utilize the technical equipment and other requirements of a licensed pharmacy for compliance.
4. **Storage.**
  - a. All drugs shall be stored in designated areas within the pharmacy to ensure proper sanitation, temperature, light, ventilation, moisture control, and security.  
Unattended areas: In the absence of a pharmacist, and whenever any area of a pharmacy serving a long-term facility as an institutional drug outlet is not under the personal and direct supervision of a pharmacist, such areas shall be locked. All areas occupied by a pharmacy serving a long-term care facility as an institutional drug outlet shall be capable of being locked by key or combination, so as to prevent access by unauthorized personnel.
  - b. When drugs to be dispensed are stored in a long-term facility drug room, the consulting pharmacist shall verify that space will be available at each unit for storage, safeguarding, and preparation of medication doses for administration and shall include provision of at least the following:
    - (1) A locked drug cabinet or room shall be equipped to ensure physical separation of individual patient prescribed medications. Medications may be stored in these secured individual patient storage areas, or secured portable storage carts providing separate compartments for individual patients may be used.
    - (2) A container or compartment which is capable of securing controlled substances with a lock or other safeguard system shall be permanently attached to storage carts or medication rooms.

**History:** Effective August 1, 1983; amended effective October 1, 2014.

**General Authority:** NDCC 28-32-02, 43-15-10(12), 43-15-10(14)

**Law Implemented:** NDCC 28-32-02, 43-15-10(12), 43-15-10(14)

**61-03-02-04. Distribution and control.**

1. General. The consulting pharmacist shall establish written procedures for the safe and efficient distribution of pharmaceutical products; which shall be on hand for inspections.
2. Responsibility of consulting pharmacist. The consulting pharmacist shall be responsible for the safe and efficient distribution of, control of, and accountability of medications by developing procedures subject to the approval of the pharmaceutical services committee of the long-term care facility, to include:
  - a. Establishment of specifications for the storage, distribution, and procurement of medications and biologicals.
  - b. Participation in those aspects of the long-term care patient evaluation program which relate to drug utilization and effectiveness.
  - c. Providing information on a twenty-four-hour basis for assistance in emergency situations.
  - d. Assuring all medication shall be stored in a locked area or locked cart.
  - e. Review, evaluate, and make recommendations monthly regarding drug utilization to the pharmaceutical services committee.
  - f. Minimum standards that all provider pharmacists must meet to include the following:
    - (1) Expected delivery times for new orders and reorders.
    - (2) Procedures to ensure accountability during delivery.
    - (3) Methods to document receipt of medications by the facility.
    - (4) Procedure to obtain emergency medications and for the provider pharmacist to receive orders.
    - (5) Procedures used by the facility to reorder medications and for the provider pharmacist to receive reorders.
    - (6) Expected scope of services and medications to be provided by the provider pharmacist. If the provider pharmacist cannot provide the complete scope of services and medications, the provider pharmacist shall designate alternative sources.
  - g. Procedures that allow for use of or repackaging of medications received which are not in the packaging system used by the facility.
  - h. Policy that is included as a part of the patient admissions packet that describes the responsibility of the patient or provider pharmacist to compensate a secondary pharmacist for medications or packaging services that the provider pharmacist chosen by the patient is either unwilling or unable to provide.
3. Responsibility of provider pharmacist. All provider pharmacists shall meet the minimum standards established by the consulting pharmacist.
4. Discontinued drugs.
  - a. The consulting pharmacist shall develop and implement policies and procedures to ensure that all discontinued or outdated drugs or containers with worn, illegible or missing labels are destroyed or disposed of so as to render them unusable. Controlled drugs shall be destroyed by the consulting pharmacist subject to guidelines and approval of the state board of pharmacy.
  - b. Controlled drugs shall be destroyed at the specific institution. Noncontrolled drugs may be destroyed at the institution or returned to the provider pharmacy, for possible credit or destruction. A log must be made when the drugs are discontinued. If drugs are destroyed at the institution, two professionals must sign the destruction log.
5. Practitioner's orders. A pharmacist shall review the medication order, or a copy thereof.
  - a. Authorization. Any licensed practitioner authorized by law to prescribe drugs within the scope of the practitioner's license may prescribe for the practitioner's patient in a long-term facility.
  - b. Abbreviations. Orders employing abbreviations or chemical symbols will be only those which are customarily used in the practice of medicine and pharmacy or those on a list of approved abbreviations developed by the pharmaceutical services committee of the facility.
  - c. Requirements. Orders for drugs for use by patients of the facility shall, at a minimum, contain patient name, drug name and strength, directions for use, date of order, and name of prescriber. On the facility reorder form, include all of the above except for directions.

- d. Emergency medication order. In cases where an emergency medication order is written when pharmacy services are unavailable, the medication order shall be reviewed by the pharmacist as soon as reasonably possible.
- e. Verification. Verification of the accuracy of any medication dispensed and of any transcriptions made of that order shall be done by handwritten initials of the pharmacist so certifying.
- f. Duration. The prescribed medications should be for a specific time.
6. An automated dispensing system is authorized for use in long-term care facilities to store controlled bulk drugs.
  - a. Drugs in the automated dispensing system are not considered dispensed until taken out by authorized personnel at the long-term care facility, once released by the pharmacy pursuant to a prescription.
  - b. Only single doses may be removed from the automated dispensing system at one time.
  - c. The pharmacy must have a separate drug enforcement administration number for the automated dispensing system at each location.
  - d. All records of dispensing must be kept at the central pharmacy.
  - e. The automated dispensing system shall permit access to only one controlled substance at each authorized entry.
  - f. Only retail pharmacies are authorized to use an automated dispensing system.
  - g. Pharmacies cannot share an automated dispensing system at a long-term care facility.
  - h. North Dakota controlled substance registration is required.
7. Controlled drug accountability. The consulting pharmacist shall establish and implement effective procedures and assure that adequate records be maintained regarding use and accountability of controlled substances which meet federal and state laws and regulations, and which shall at least specify the following:
  - a. Name of drug.
  - b. Dose.
  - c. Prescriber.
  - d. Patient.
  - e. Date and time of administration.
  - f. Person administering the drug.
8. Recall. The consulting pharmacist shall develop and implement a recall procedure that can readily be activated to assure the medical staff of the facility, the provider pharmacy, and the consulting pharmacist that all drugs included in the recall, located within the facility, are returned to the provider pharmacy for proper disposition.
9. Records and reports. The consulting pharmacist shall supervise the maintenance of such records and reports as are required to ensure patient health, safety, and welfare and, at a minimum, the following:
  - a. Pharmacy patient profiles and medication administration records.
  - b. Reports of suspected adverse drug reactions.
  - c. Inspections of drug storage areas.
  - d. Controlled drug and accountability reports, including board of pharmacy destroyed medication forms for controlled and noncontrolled medications.
  - e. Such other and further records and reports as may be required by law and this chapter.
10. Labeling.
  - a. All stock drugs intended for use within the facility shall be in appropriate containers and adequately labeled as to identify at a minimum: brand name or generic name and manufacturer, and strength. An internal code which centrally references manufacturer and lot number can be utilized.
  - b. Whenever any drugs are added to parenteral solutions, whether within or outside the direct and personal supervision of a pharmacist, such admixtures shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, date and time of addition, expiration date, administration time and infusion rate when applicable, and name or initials of person so adding. This excludes any single dose medication prepared and totally administered immediately.

**History:** Effective August 1, 1983; amended effective October 1, 1999; December 1, 2003; October 1, 2007.

**General Authority:** NDCC 28-32-02, 43-15-10(12), 43-15-10(14)

**Law Implemented:** NDCC 28-32-02, 43-15-10(12), 43-15-10(14)

### **CHAPTER 61-03-03**

### **PRECEPTOR/INTERN - INTERNSHIP/EXTERNSHIP/CLERKSHIP**

[Repealed effective October 1, 1999]

### **CHAPTER 61-03-03.1**

### **INTERNSHIP**

#### Section

61-03-03.1-01 Definitions

61-03-03.1-02 Licensure

61-03-03.1-03 Identification

61-03-03.1-04 Supervision

61-03-03.1-05 Evidence of Completion

61-03-03.1-06 Board and College Responsibilities

61-03-03.1-07 Change of Address or Practice Site

#### **61-03-03.1-01. Definitions. In this chapter, unless the context or subject matter otherwise requires:**

1. "Approved pharmacy experiential program" means structured courses in the pharmacy professional curriculum that are administered by a college of pharmacy, and approved by the state board of pharmacy, via accreditation by the American council on pharmaceutical education.
2. "Approved pharmacy intern program" means pharmacy practice in a board-approved experiential program after a student has been accepted into a board-approved accredited college or school of pharmacy. The entire one thousand five hundred hours of credit shall be included in the four-year doctor of pharmacy program as an intern.
3. "Hour" means the standard sixty minutes division of time.
4. "Intern" means a person licensed by the state board of pharmacy for the purpose of receiving instruction in the practice of pharmacy from a preceptor. The state board of pharmacy may license as an intern any candidate who has successfully completed no less than one academic year of full-time college or university enrollment and has satisfied the state board of pharmacy that the candidate is of good moral character or as required when a student has been accepted into the doctor of pharmacy program.
5. "Location" means any establishment other than a preceptor pharmacy approved by the state board of pharmacy.
6. "Preceptor" means an educator and a licensed pharmacist in good standing with the state board of pharmacy who will devote sufficient time to educate a student in the practice of pharmacy as described in subsection 22 of North Dakota Century Code section 43-15-01.
7. "Preceptor pharmacy" means the pharmacy where the preceptor is practicing the profession. This pharmacy must have a clear record with respect to adherence to federal, state, and municipal laws governing any phase of activity in which it is engaged and must be licensed by the state board of pharmacy, or other duly authorized licensing agency, where located and must have a private patient consultation area.
8. "Supervision" means that in the approved preceptor pharmacy or other location where the intern is being taught, a licensed pharmacist designated as preceptor or another licensed pharmacist shall be in continuous contact with and actually giving instructions to the intern during all professional activities.

**History:** Effective October 1, 1999.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 28-32-02, 43-15-10, 43-15-18

### **61-03-03.1-02. Licensure.**

1. A pharmacy intern must license with the board of pharmacy when accepted into the doctor of pharmacy professional program at any board-approved college or school of pharmacy and annually while successfully completing all four years of the doctor of pharmacy program.
2. Upon receipt of the completed application for internship licensure form, the state board of pharmacy will issue to the intern a certificate, an annual wallet-sized identification card, and an annual renewal card and instruct the intern that the identification card must be carried on the intern's person at all times while on duty in the preceptor pharmacy or other location of instruction. The annual renewal card must be posted in the preceptor pharmacy or other location of instruction.

**History:** Effective October 1, 1999.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 28-32-02, 43-15-10, 43-15-18

**61-03-03.1-03. Identification.** The intern shall be so designated in the intern's professional relationships and shall in no manner falsely assume, directly or by inference, to be a pharmacist. The board shall issue to the intern a license for purposes of identification and verification of the intern's role as an intern, which license shall be surrendered to the board upon discontinuance of internship for any reason including licensure as a pharmacist. No individual not properly licensed by the board as an intern shall take, use, or exhibit the title of intern, or any other term of similar like or import.

**History:** Effective October 1, 1999.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 28-32-02, 43-15-10, 43-15-18

**61-03-03.1-04. Supervision.** An intern shall be allowed to engage in the practice of pharmacy provided that such activities are under direct supervision of a pharmacist. The pharmacist shall physically review the prescription drug order and the dispensed pharmaceutical before the pharmaceutical is delivered to the patient or the patient's agent. The pharmacist is responsible for the practice of the intern.

**History:** Effective October 1, 1999.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 28-32-02, 43-15-10, 43-15-18

**61-03-03.1-05. Evidence of completion.** Applicants for licensure as pharmacists shall submit evidence that they have satisfactorily completed not less than one thousand five hundred hours of internship credit per board forms under educational instruction and supervision of a licensed pharmacist as an approved preceptor.

**History:** Effective October 1, 1999.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 28-32-02, 43-15-10, 43-15-18

### **61-03-03.1-06. Board and college responsibilities.**

1. The intern shall submit a yearly affidavit of internship completed, as certified by a licensed pharmacist preceptor.
2. The intern shall maintain a record of objectives and activities as part of the approved pharmacy experiential program and shall submit said record upon completion of the fourth professional year.

**History:** Effective October 1, 1999; amended effective January 1, 2005.

**General Authority:** NDCC 28-32-02, 43-15-10(12)(14)

**Law Implemented:** NDCC 28-32-02, 43-15-10, 43-15-18

**61-03-03.1-07. Change of address or practice site.** An intern shall notify the board immediately upon change of an experiential rotation and residence address.

**History:** Effective October 1, 1999.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 28-32-02, 43-15-10, 43-15-18

## CHAPTER 61-03-04 CONTINUING PHARMACEUTICAL EDUCATION

### Section

61-03-04-01 Definitions

61-03-04-02 Requirements for Continuing Pharmaceutical Education

61-03-04-03 Approved Continuing Education

61-03-04-04 Advisory Council on Continuing Pharmaceutical Education

### **61-03-04-01. Definitions.**

1. Continuing pharmaceutical education is a planned learning experience beyond a formal degree program designed to promote the continual development of professional knowledge, professional skills, and professional attitudes on the part of the practitioners and includes, but is not limited to, professional postgraduate education in any of the following subjects:
  - a. Properties and actions of drugs and drug dosage forms.
  - b. Etiology, characteristics, and therapeutics of the disease state.
  - c. Pharmacy practice.
  - d. Legal, psychological, and socioeconomic aspects of health care delivery.
2. One continuing education unit (c.e.u.) equals ten hours of instruction.

**History:** Effective April 1, 1986.

**General Authority:** NDCC 28-32-02, 43-15-10(12)(14), 43-15-25.1

**Law Implemented:** NDCC 28-32-03, 43-15-10(12)(14), 43-15-25.1

### **61-03-04-02. Requirements for continuing pharmaceutical education.**

1. Each pharmacist shall complete at least fifteen hours (1.5 c.e.u.) of approved continuing pharmaceutical education every year as a condition of renewal of a certificate of licensure as a pharmacist in the state of North Dakota.
2. There may be no carryover or extension of continuing education units with the exception that continuing education units obtained twelve months prior to the beginning of each annual reporting period which begins March first of each year and ends the last day of February, may be used in the current annual reporting period or the previous reporting period. However, they may not be counted as credit in both reporting periods. The failure to obtain the required fifteen hours of continuing education by the renewal date may result in a suspension for the minimum of thirty days or a maximum of the period ending the date the continuing education is completed.
3. Pharmacists shall maintain their own records on forms supplied by the board. The records shall be maintained for a two-year period.
4. The requirements of this section do not apply to a pharmacist applying for a first renewal of a certificate of licensure.
5. A pharmacist holding a certificate of licensure from the board may make application to the board for a waiver of compliance with the continuing pharmaceutical education requirements and may be granted an exemption by the board. No pharmacist holding such an exemption may practice pharmacy in North Dakota until reinstated by the board after completing fifteen hours of continuing pharmaceutical education (one and one-half c.e.u.) during the year before reinstatement.
6. Upon request of the board, proof of compliance must be furnished to the board.

**History:** Effective April 1, 1986; amended effective January 1, 2005; January 1, 2010.

**General Authority:** NDCC 28-32-02, 43-15-10(12)(14), 43-15-25.1

**Law Implemented:** NDCC 28-32-03, 43-15-10(12)(14), 43-15-25.1

### **61-03-04-03. Approved continuing education.**

1. Approved continuing pharmaceutical education means those continuing pharmaceutical education programs made available by an approved provider. Postgraduate courses offered by a school or college of pharmacy recognized by the board as an approved school shall constitute approved continuing pharmaceutical education. The board shall maintain a record of approved programs including the hours of credit assigned to each program which shall be available upon request.

2. Approved provider means any association, corporation, educational institution, organization, or person who has been recognized by the American council on pharmaceutical education in accordance with its policy and procedure, as having met its criteria indicative of the ability to provide quality continuing pharmaceutical education programs.

**History:** Effective April 1, 1986.

**General Authority:** NDCC 28-32-02, 43-15-10(12)(14), 43-15-25.1

**Law Implemented:** NDCC 28-32-03, 43-15-10(12)(14), 43-15-25.1

#### **61-03-04-04. Advisory council on continuing pharmaceutical education.**

1. There is hereby established an advisory council to the state board of pharmacy consisting of:
  - a. Two pharmacists appointed by the state board of pharmacy.
  - b. Two pharmacists appointed by the North Dakota state university college of pharmacy.
  - c. Two pharmacists appointed by the North Dakota state pharmaceutical association.
2. The advisory council on continuing pharmaceutical education shall advise the state board of pharmacy in the implementation, coordination, and accreditation of programs of continuing pharmaceutical education and members shall serve without compensation.
3. The advisory council on continuing pharmaceutical education shall meet at least annually, and at such other times as determined by the council. The advisory council shall annually elect a chairman and vice chairman from its membership, and the secretary of the state board of pharmacy shall act as secretary to the council.
4. Membership of each pharmacist on the advisory council on continuing pharmaceutical education shall be for a two-year term, with one of the two pharmacists appointed by the state board of pharmacy, North Dakota state university college of pharmacy, and the North Dakota state pharmaceutical association, to have a term of one year upon the initial appointment of pharmacists to the advisory council, and thereafter shall have a two-year term. The purpose of this requirement is to stagger the membership so that not all members will be replaced at the end of each two-year period.

**History:** Effective April 1, 1986.

**General Authority:** NDCC 28-32-02, 43-15-10(12)(14), 43-15-25.1

**Law Implemented:** NDCC 28-32-03, 43-15-10(12)(14), 43-15-25.1

### **ARTICLE 61-04 PROFESSIONAL PRACTICE**

#### **Chapter**

- 61-04-01 Return of Drugs and Devices Prohibited
- 61-04-02 Physician Exemption
- 61-04-03 Destruction of Controlled Substances
- 61-04-03.1 Identification Required for Controlled Substances
- 61-04-04 Unprofessional Conduct
- 61-04-05 Electronic Transmission of Prescriptions
- 61-04-05.1 Prescription Transfer Requirements
- 61-04-06 Prescription Label Requirements
- 61-04-07 Pharmacy Patient's Bill of Rights
- 61-04-08 Limited Prescriptive Practices
- 61-04-09 Warning Notice
- 61-04-10 CLIA Waived Laboratory Tests
- 61-04-11 Administration of Medications and Immunizations
- 61-04-12 Limited Prescriptive Authority for Naloxone

### **CHAPTER 61-04-01 RETURN OF DRUGS AND DEVICES PROHIBITED**

#### **Section**

- 61-04-01-01 Return of Drugs and Devices Prohibited

**61-04-01-01. Return of drugs and devices prohibited.** Pharmacists and pharmacies are prohibited from accepting from patients or their agents for reuse, reissue, or resale any drugs, prescribed medications, chemicals, poisons, or medical devices except:



1. In a hospital with a licensed pharmacy, drugs, devices, or other items may be returned to the pharmacy for disposition by a pharmacist in accordance with good professional practice.
2. In licensed nursing homes or basic care facilities where United States pharmacopeia storage requirements can be assured, pharmaceuticals (not controlled substances) dispensed in unit dose or in individually sealed doses which meet United States pharmacopeia packaging requirements may be returned to the pharmacy from which they were dispensed. The dispensing pharmacy or pharmacist is responsible to determine the suitability of the product for reuse. No product where lot number and integrity cannot be assured may be credited or reused. A redispensed pharmaceutical must be assigned an expiration date within the manufacturers original limits but not to exceed six months from the date of redispensing. No product may be redispensed more than one time.
3. This section shall not apply to the return of medical devices provided that proper sanitary procedures are used prior to the reuse, resale, or rereuse of the devices.

**History:** Amended effective July 1, 1996.

**General Authority:** NDCC 28-32-02, 43-15-10(12)(14)

**Law Implemented:** NDCC 28-32-03

## CHAPTER 61-04-02 PHYSICIAN EXEMPTION

### Section

#### 61-04-02-01 Physician Exemption

**61-04-02-01. Physician exemption.** The exemption contained in subsection 1 of North Dakota Century Code section 43-15-02 for a duly licensed practitioner of medicine supplying the practitioner's own patients with such remedies as the practitioner may desire shall exempt such practitioners who dispense remedies as an incident to the practice of their profession for a patient's immediate needs, which would be those drugs required for a seventy-two-hour time period, full course of antibiotic treatment, start pack of prepackaged medications, or up to a ten-day supply of initial therapy of a maintenance medication that should be started immediately, but shall not exempt such a practitioner who regularly engages in dispensing such remedies to the practitioner's patients for which such patients are charged either separately or together with charges for other professional services, from recordkeeping, dispensing, labeling, counseling as required by North Dakota Century Code section 43-15-31.2, patient profile system as required by North Dakota Century Code section 43-15-31.1, and all other requirements of the practice of pharmacy as set forth in this chapter or by federal and state laws as they pertain to the regulation of the practice of pharmacy. Documented charts shall meet the requirements of the patient profile system.

**History:** Effective August 1, 1983; amended effective October 1, 2014.

**General Authority:** NDCC 19-02.1-02(2), 19-02.1-14, 28-32-02, 43-15-10(12), 43-15-10(14)

**Law Implemented:** NDCC 19-02.1-02(2), 19-02.1-14, 28-32-03, 43-15-10(12), 43-15-10(14)

## CHAPTER 61-04-03 DESTRUCTION OF CONTROLLED SUBSTANCES

### Section

#### 61-04-03-01 Destruction of Controlled Substances

**61-04-03-01. Destruction of controlled substances.** Pharmacists and pharmacies are prohibited from destruction of controlled substances as defined in subsection 4 of North Dakota Century Code section 19-03.1-01. Destruction of controlled substances is permitted and shall be limited to the executive secretary of the board, or a compliance officer of the board, or any one member of the board. A board member may not destroy controlled substances within a pharmacy in which the member is employed, has an ownership interest, or is the pharmacist in charge.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02, 43-15-10(12), 43-15-10(14)

**Law Implemented:** NDCC 28-32-03, 43-15-10(12), 43-15-10(14)

## CHAPTER 61-04-03.1

### IDENTIFICATION REQUIRED FOR CONTROLLED SUBSTANCES

**61-04-03.1-01. Identification required for controlled substances.** Pharmacists, pharmacy interns, pharmacy technicians, and clerical personnel are required to obtain positive identification if they are unsure of the identity of the person picking up a prescription for any controlled substance, tramadol, or carisoprodol. Positive identification means a document issued by a governmental agency which:

1. Contains a description of the person or a photograph of the person, or both; and
2. Includes, but is not limited to, a passport, military identification card, or driver's license.

**History:** Effective July 1, 2011.

**General Authority:** 28-32-02, 43-15-10(12)(14)

**Law Implemented:** 28-32-03, 43-15-10(12)(14)

## CHAPTER 61-04-04

### UNPROFESSIONAL CONDUCT

#### Section

#### 61-04-04-01 Definition of Unprofessional Conduct

**61-04-04-01. Definition of unprofessional conduct.** The definition of "unprofessional conduct" for purposes of subdivision i of subsection 1 of North Dakota Century Code section 43-15-10 for disciplinary purposes includes, but is not limited to, the following:

1. The violating or attempting to violate, directly, indirectly, through actions of another, or assisting in or abetting the violation of, or conspiring to violate, any provision or term of North Dakota Century Code chapter 43-15, the Prescription Drug Marketing Act, the Robinson-Patman Act, or of the applicable federal and state laws and rules governing pharmacies or pharmacists.
2. Failure to establish and maintain effective controls against diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels as provided by state or federal laws or rules.
3. Making or filing a report or record which a pharmacist or pharmacy knows to be false, intentionally or negligently failing to file a report or record required by federal or state law, or rules, willfully impeding or obstructing such filing, or inducing another person to do so. Such reports or records include only those which the pharmacist or pharmacy is required to make or file in the capacity as a licensed pharmacist or pharmacy.
4. Being unable to practice pharmacy with reasonable skill and safety by reason of illness, use of drugs, narcotics, chemicals, or any other type of material, or as a result of any mental or physical condition. A pharmacist affected under this subsection shall at reasonable intervals be afforded an opportunity to demonstrate that the pharmacist can resume the competent practice of pharmacy with reasonable skill and safety to the pharmacist's customers.
5. Knowingly dispensed a prescription drug after the death of a patient.
6. Using a facsimile machine to circumvent documentation, authenticity, verification, or other standards of pharmacy practice.
7. Billing or charging for quantities greater than delivered, or for a brand when a generic is dispensed.
8. Submits fraudulent billing or reports to a third-party payor of prescription charges.
9. Refuses to provide information or answer questions when requested to do so by the patient, which affect the patient's use of medications prescribed and dispensed by the pharmacy.
10. Does not address or attempt to resolve and document a possible prescription error or situation of potential harm to the patient when apparent or should have been apparent to the pharmacist.
11. Does not attempt to affect the possible addiction or dependency of a patient to a drug dispensed by the pharmacist, if there is reason to believe that patient may be so dependent or addicted.
12. The assertion or inference in a public manner of material claims of professional superiority in the practice of pharmacy that cannot be substantiated.
13. The publication or circulation of false, misleading, or otherwise deceptive statements concerning the practice of pharmacy.
14. Refusing to compound and dispense prescriptions that may reasonably be expected to be compounded or dispensed in pharmacies by a pharmacist.

15. Participation in agreements or arrangements with any person, corporation, partnership, association, firm, or others involving rebates, kickbacks, fee-splitting, or special charges in exchange for professional pharmaceutical services, including, but not limited to, the giving, selling, donating, or otherwise furnishing or transferring, or the offer to give, sell, donate, or otherwise furnish or transfer money, goods, or services free or below cost to any licensed health care facility or the owner, operator, or administrator of a licensed health care facility as compensation or inducement for placement of business with that pharmacy or pharmacist. Monetary rebates or discounts which are returned to the actual purchaser of drugs as a cost-justified discount or to meet competition are permitted if the rebates or discounts conform with other existing state and federal rules and regulations.
16. Discriminating in any manner between patients or groups of patients for reasons of religion, race, creed, color, sex, age, or national origin.
17. Disclosing to others the nature of professional pharmaceutical services rendered to a patient without the patient's authorization or by order or direction of a court or as otherwise permitted by law. This does not prevent pharmacies from providing information copies of prescriptions to other pharmacies or to the person to whom the prescription was issued and does not prevent pharmacists from providing drug therapy information to physicians for their patients.
18. Improper advertising. Prescription drug price information may be provided to the public by a pharmacy, if all the following conditions are met: No representation or suggestion concerning the drug's safety, effectiveness, or indications for use, is made. No reference is made to controlled substances listed in schedules II-V of the latest revision of the Federal Controlled Substances Act, North Dakota Uniform Controlled Substances Act, and the rules of the state board of pharmacy.
19. Failure to report to the prescription drug monitoring program as required by North Dakota Century Code chapter 19-03.5.
20. Failure to comply with the reporting requirement of North Dakota Century Code section 43-15-42.3, including:
  - a. Actions that affect the licensee's or registrant's practice privileges in a facility.
  - b. Actions that result in the loss of the licensee's or registrant's employment or membership in a professional organization due to alleged incompetence, negligence, unethical or unprofessional conduct, or physical, mental, or chemical impairment.
  - c. Actions based on a professional liability claim against the licensee or registrant, such as an adverse judgment or settlement, a refusal to issue or renew coverage, or a cancellation of coverage.
  - d. Actions resulting in the loss of the licensee's or registrant's authorization to practice by any state or jurisdiction.
  - e. Conviction of the licensee or registrant of any misdemeanor or felony in this or any other state, territory, or jurisdiction.
21. Notwithstanding any other provision, a practitioner who diagnoses a sexually transmitted disease, such as chlamydia, gonorrhea, or any other sexually transmitted infection, in an individual patient may prescribe or dispense, and a pharmacist may dispense, prescription antibiotic drugs to that patient's sexual partner or partners, without there having been an examination of that patient's sexual partner or partners.

Interpretation of this definition of unprofessional conduct is not intended to hinder or impede the innovative practice of pharmacy, the ability of the pharmacist to compound, alter, or prepare medications, subsequent to a practitioner's order for the appropriate treatment of patients. Further, it is not intended to restrict the exercise of professional judgment of the pharmacist when practicing in the best interest of the pharmacist's patient.

**History:** Effective November 1, 1991; amended effective December 1, 2003; October 1, 2007; January 1, 2009.

**General Authority:** NDCC 28-32-02, 43-15-10(1)(i)(12)(14)

**Law Implemented:** NDCC 28-32-02

## CHAPTER 61-04-05

### ELECTRONIC TRANSMISSION OF PRESCRIPTIONS

#### Section

61-04-05-01 Facsimile Transmission of Prescriptions

61-04-05-02 Electronic Transmission of Prescriptions

61-04-05-03 Computer Transmission of Prescriptions

**61-04-05-01. Facsimile transmission of prescriptions.** In addition to the requirements in section 61-04-05-02, a prescription order may be transmitted from an authorized prescribing practitioner to a pharmacy under the following provisions:

1. Using facsimile equipment to transmit schedule II controlled substance prescriptions is not allowed except when the patient is a hospice patient or resides in a licensed long-term care facility, a facsimile may serve as the pharmacy's original prescription, if it has been signed by the practitioner before faxing and is in compliance with subsection 3.
2. Schedule III, IV, and V controlled substances prescriptions received by facsimile equipment may serve as the pharmacy's original prescription, if it has been signed by the practitioner before faxing and is in compliance with subsection 3.
3. A facsimile copy prescription must be reduced to writing either manually or by other process (computer, photocopying, etc.) which produces a nonfading document and proper notation on the file copy must indicate that the prescription order was initially received by facsimile equipment.
4. The receiving facsimile machine must be in the prescription department of the pharmacy to protect patient-pharmacist authorized prescribing practitioner confidentiality and security.

**History:** Effective October 1, 1993; amended effective October 1, 1999; January 1, 2005.

**General Authority:** NDCC 28-32-02, 43-15-10(9)(12)(14)

**Law Implemented:** NDCC 28-32-03, 43-15-10(9)(12)(14)

**61-04-05-02. Electronic transmission of prescriptions.** The terms "electronic", "electronic record", "electronic signature", and "security procedure" have the meaning ascribed to them in North Dakota Century Code chapter 9-16-01. A prescription order may be transmitted electronically from an authorized prescribing practitioner to a pharmacy under the following provisions:

1. Actual transmittal is done by or under the supervision of the authorized prescribing practitioner or the practitioner's authorized agent.
2. Practitioners or their authorized agents transmitting medication orders using electronic equipment are obligated to provide voice verification when requested by the pharmacist receiving the medication order. If requested voice verification is refused, the electronically transmitted prescription may not be filled.
3. Pharmacists are precluded from supplying or leasing facsimile equipment, or computer hardware or software, to prescribing practitioners, hospitals, nursing homes, or any medical provider or facility.
4. Using facsimile equipment or other electronic transmission to circumvent documentation, authenticity, verification, or other standards of pharmacy practice or drug diversion will be considered unprofessional conduct under chapter 61-04-04.
5. The board of pharmacy recognizes that the electronic transmission of prescriptions will depend on the type of pharmaceutical services offered, and therefore, variations of the requirements for electronic transmission of prescriptions may be granted by the state board of pharmacy.
6. A third-party intermediary may be used to facilitate transmission of the prescription order as long as the intent of the prescriber is not changed and procedures are in place to protect patient confidentiality.

**History:** Effective January 1, 2005.

**General Authority:** NDCC 28-32-02, 43-15-10(9)(12)(14)

**Law Implemented:** NDCC 28-32-03, 43-15-10(9)(12)(14)

**61-04-05-03. Computer transmission of prescriptions.** In addition to the requirements in section 61-04-05-02, a prescription order may be transmitted from an authorized prescribing practitioner to a pharmacy under the following provisions:

1. Schedule II, III, IV, and V controlled substances prescriptions received via computer require an electronic signature by the authorized prescriber, as defined in North Dakota Century Code section 9-16-01, for the prescription to serve as the original copy.
2. Transmission of schedule II controlled substance prescriptions via computer is allowed when the prescribing system and the pharmacy system are in compliance with drug enforcement agency requirements for e-prescribing.
3. The required legend must appear on the practitioner's prescription screen. The practitioner must take a specific overt action to include the "brand medically necessary" language with the electronic transmission as set forth in subsections 3 and 4 of North Dakota Century Code section 19-02.1-14.1. For example, the practitioner or the practitioner's agent must type out "brand medically necessary" letter by letter.

**History:** Effective January 1, 2005; amended effective July 1, 2011.

**General Authority:** NDCC 28-32-02, 43-15-10(9)(12)(14)

**Law Implemented:** NDCC 28-32-03, 43-15-10(9)(12)(14)

## **CHAPTER 61-04-05.1 PRESCRIPTION TRANSFER REQUIREMENTS**

### Section

61-04-05.1-01 Prescription Transfer Requirements

61-04-05.1-02 Prescription Transfer Requirements for Transferring Pharmacy

61-04-05.1-03 Prescription Transfer Requirements for Receiving Pharmacy

61-04-05.1-04 Additional Prescription Transfer Requirements for Controlled Drugs

**61-04-05.1-01. Prescription transfer requirements.** The transfer of original prescription information for the purpose of refill dispensing is permissible between pharmacies subject to the following requirements:

1. The transfer is communicated directly between licensed pharmacists, licensed pharmacy interns, or registered pharmacy technicians and the transferring person records the information on the hard copy or the electronic record.
2. The transfer is limited to the number of refills authorized on the original prescription.
3. Both the original and transferred prescription are kept for five years from the date of last refill.
4. Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode of prescription transferal.

**History:** Effective October 1, 1999.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 28-32-02, 43-15-10

**61-04-05.1-02. Prescription transfer requirements for transferring pharmacy.** The person transferring the prescription shall record on the original prescription or the electronic record:

1. The name and address of the pharmacy to which the prescription was transferred.
2. The name of the person receiving the prescription information and the name of the person transferring the prescription information.
3. The date of the transfer.
4. The number of refills transferred. If all refills are transferred the original prescription must be marked "VOID".

**History:** Effective October 1, 1999.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 28-32-02, 43-15-10

**61-04-05.1-03. Prescription transfer requirements for receiving pharmacy.** The person receiving the transfer of a prescription shall record on the hard copy or the electronic record:

1. The word "transfer" on the face of the transferred prescription.
2. The following information:
  - a. All information required to be on a prescription pursuant to section 61-04-06-02 or 61-04-06-03.
  - b. The name of the pharmacy and address and original prescription number from which the prescription information is transferred.
  - c. The original date of issuance and date of dispensing if different from the date of issuance.
  - d. The number of valid refills remaining and date of last refill.
  - e. The name of the person transferring the prescription information and the name of the person receiving the prescription information.
  - f. The date of the transfer.
3. Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode of prescription transferal.

**History:** Effective October 1, 1999.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 28-32-02, 43-15-10

**61-04-05.1-04. Additional prescription transfer requirements for controlled drugs.** The transfer of original prescription information for a controlled drug for the purpose of refill dispensing is permissible between pharmacies on a one-time basis subject to the following requirements:

1. The transferring person shall:
  - a. Write the word "VOID" on the face of the invalidated prescription.
  - b. Record on the reverse of the invalidated prescription the name, address, and drug enforcement administration registration number of the pharmacy to which it was transferred and person receiving the prescription information.
2. The receiving person shall:
  - a. Record the drug enforcement administration registration number of the pharmacy from which the prescription was transferred.
  - b. Verify with the transferring person that the original prescription was signed and then the transferred prescription does not require another signature.
3. A practitioner's signature is not required on the received prescription. A signature on the prescription at the transferring pharmacy will be deemed in compliance with North Dakota Century Code section 19-03.1-22.

**History:** Effective October 1, 1999.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 28-32-02, 43-15-10

## CHAPTER 61-04-06 PRESCRIPTION LABEL REQUIREMENTS

### Section

61-04-06-01 The Prescription Label

61-04-06-02 Requirements of a Prescription Order for Noncontrolled Drugs

61-04-06-03 Requirements of Prescription Order for Controlled Drugs

**61-04-06-01. The prescription label.** Controlled drugs and noncontrolled drugs dispensed pursuant to a prescription must bear a label, permanently affixed to the immediate container in which the drug is dispensed or delivered and which is received by the purchaser or patient, which must include the following:

1. The name and address of the dispenser or pharmacy;
2. The serial number of the prescription;
3. The current date of its filling or refilling;
4. The name of the prescriber;
5. The name of the patient;
6. The directions for use, including precautions, if any, as indicated on the prescription;
7. The initials or name of the dispensing pharmacist;

8. The telephone number of the pharmacy; and
9. The drug name and strength and quantity.

The prescription label for controlled drugs, in addition to the above, must comply with the label requirements of the Federal and State Uniform Controlled Substances Act, including the transfer warning auxiliary label.

**History:** Effective October 1, 1993.

**General Authority:** NDCC 28-32-02, 43-15-10(9)(12)(14)

**Law Implemented:** NDCC 28-32-03, 43-15-10(9)(12)(14)

**61-04-06-02. Requirements of a prescription order for noncontrolled drugs.** The patient hard copy prescription form for noncontrolled drugs must contain the following:

1. The name and address of the patient;
2. The date of issuance;
3. The name of the drug;
4. The quantity;
5. The strength;
6. Adequate directions for use;
7. The prescriber's name, either printed or stamped;
8. The prescriber's indication of refill authorization;
9. A reminder legend in at least six-point uppercase print stating, "In order to require that a brand name product be dispensed, the practitioner must hand write the words 'brand medically necessary'"; and
10. The signature of the prescriber, unless an oral or telephoned prescription.

**History:** Effective October 1, 1993; amended effective October 1, 2012.

**General Authority:** NDCC 28-32-02, 43-15-10(9)(12)(14)

**Law Implemented:** NDCC 43-15-10(9)(12)(14)

**61-04-06-03. Requirements of prescription order for controlled drugs.** The patient hard copy prescription form for controlled drugs must contain the following:

1. The name address of the patient;
2. The date of issuance;
3. The name of the drug;
4. The quantity;
5. The strength;
6. Adequate directions for use;
7. The prescriber's name, either printed or stamped;
8. The prescriber's indication of refill authorization;
9. A reminder legend in at least six-point uppercase print stating, "In order to require that a brand name product be dispensed, the practitioner must hand write the words 'brand medically necessary'";
10. The DEA number of the prescriber; and
11. The signature of the prescriber.

**History:** Effective October 1, 1993; amended effective October 1, 2012.

**General Authority:** NDCC 28-32-02, 43-15-10(9)(12)(14)

**Law Implemented:** NDCC 43-15-10(9)(12)(14)

## CHAPTER 61-04-07 PHARMACY PATIENT'S BILL OF RIGHTS

### Section

#### 61-04-07-01 Pharmacy Patient's Bill of Rights

**61-04-07-01. Pharmacy patient's bill of rights.** North Dakota pharmacies and pharmacists shall provide pharmaceutical care so that the patient has the following rights:

1. To professional care provided in a competent and timely manner in accordance with accepted standards of pharmacy practice.
2. To be treated with dignity, consistent with professional standards, regardless of manner of payment, race, sex, age, nationality, religion, disability, or other discriminatory factors.

3. To pharmaceutical care decisions made in the patient's best interest in cooperation with the patient's physician.
4. To have the pharmacist serve as one of the patient's advocates for appropriate drug therapy and to make reasonable efforts to recommend alternative choices in cooperation with the patient's physician.
5. To have the patient's pharmaceutical records maintained in an accurate and confidential manner and used routinely to maximize the patient's pharmaceutical care.
6. To receive health care information and to review the patient's records upon request.
7. To receive patient counseling, using the methods appropriate to the patient's physical, psychosocial, and intellectual status.
8. To have the patient's prescriptions dispensed and pharmacy services provided at a pharmacy of the patient's choice in an atmosphere that allows for confidential communication.
9. To have the patient's drug therapy monitored for safety and efficacy and to make reasonable efforts to detect and prevent drug allergies, adverse reactions, or contraindications.
10. To monitor the patient's compliance and proper drug use and to institute remedial interventions when necessary.
11. To have the pharmacy patient's bill of rights posted in a prominent place within the pharmacy readily visible to the patient.

**History:** Effective July 1, 1996.

**General Authority:** NDCC 28-32-02, 43-15-10(12)(14)(18)

**Law Implemented:** NDCC 28-32-03

## **CHAPTER 61-04-08**

### **LIMITED PRESCRIPTIVE PRACTICES**

#### Section

61-04-08-01 Purpose

61-04-08-02 Definitions

61-04-08-03 Eligibility and Approval

61-04-08-04 Procedures

61-04-08-05 Initiation of Drug Therapy

61-04-08-06 Modification of Drug Therapy

61-04-08-07 Form

**61-04-08-01. Purpose.** The purpose of these rules is to implement limited prescriptive practices provisions of the North Dakota Century Code.

**History:** Effective December 1, 1996.

**General Authority:** NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

**Law Implemented:** NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

**61-04-08-02. Definitions.** For purposes of this chapter:

1. "Collaborative agreement" means the written document signed by a practitioner and a pharmacist which describes the limited prescribing authority granted the pharmacist under North Dakota Century Code section 43-15-31.4.
2. "Immediate notification" means interactive two-way communication between the pharmacist and practitioner within twenty-four hours of the initiation or modification of drug therapy, unless specific reference is made in the collaborative agreement to situations in which a notification time limit of up to seventy-two hours is appropriate.
3. "Initiate drug therapy" means to begin administering for the first time a prescribed drug therapy for treating a patient with an existing diagnosis. A licensed practitioner shall make any diagnosis required.
4. "Medical record" means a written record of clinical care developed and maintained by a patient's practitioner which contains information and data about a patient's condition sufficient to justify the diagnosis and subsequent treatment. The record must contain further appropriate information as described in section 33-07-01.1-20.
5. "Modify drug therapy" means to change, within the same therapeutic class of drugs, a specific drug, the dosage, or route of delivery of a drug currently being administered for an existing diagnosis.



6. "Practitioner" means a licensed physician or advanced practice registered nurse.
7. "Supervision" means the active role taken by the practitioner to oversee the pharmacist throughout the provision of drug therapy to patients under the terms of a collaborative agreement.

**History:** Effective December 1, 1996; amended effective December 1, 2003; April 1, 2016.

**General Authority:** NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

**Law Implemented:** NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

#### **61-04-08-03. Eligibility and approval.**

1. A practitioner and a pharmacist who are licensed and practicing their respective professions in this state are eligible, provided the conditions of this section and any applicable statutes are met, to enter into the collaborative agreement allowing the pharmacist to provide prescription drug therapy to patients.
2. The practitioner and the pharmacist must have access to the patient's appropriate medical records. The care provided to the patient by the pharmacist must be recorded in the patient's medical records and communicated to the practitioner.
3. The collaborative agreement may be between a medical director and pharmacist-in-charge. The medical director and pharmacist-in-charge shall report to the respective board of any practitioner and pharmacist covered under the agreement.
4. Each individual collaborative agreement must be reviewed by the board of medicine or the board of nursing and the board of pharmacy, and will not become effective until the respective boards grant approval and notify the parties. Each agreement must be reviewed at least every four years or when modifications to the scope of the pharmacist's prospective practices are proposed by the parties, and must receive continued approval from both boards in order remain in effect. Removal or addition of either practitioners or pharmacists involved in the agreement shall be communicated to all respective boards. Unless deemed necessary, a change in personnel does not necessitate board approval of the collaborative agreement.
5. A collaborative agreement may be terminated by any of the involved boards for good cause, including adverse action taken against either licensee. Noncompliance with the terms of these rules or of a collaborative agreement may be considered evidence of unprofessional conduct by any of the involved boards.
6. Either party of a collaborative agreement may terminate the agreement at will by notifying either board of their desire to do so.
7. Neither party to a collaborative agreement may seek to gain personal financial benefit by participating in any incentive-based program that influences or encourages therapeutic or product changes.

**History:** Effective December 1, 1996; amended effective April 1, 2016.

**General Authority:** NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

**Law Implemented:** NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

**61-04-08-04. Procedures.** A practitioner who has signed an approved collaborative agreement with a pharmacist shall remain responsible for the care of the patient following initial diagnosis, and for the supervision of the pharmacist as prescriptive authority is exercised. The practitioner shall remain available to receive immediate notification from the pharmacist regarding prescriptive drug therapy being provided. The parties may modify as necessary, within the practice guidelines described in the collaborative agreement, their relationship in the joint provision of care to each patient as the requirements of the patient or drug therapy change.

**History:** Effective December 1, 1996; amended effective April 1, 2016.

**General Authority:** NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

**Law Implemented:** NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

**61-04-08-05. Initiation of drug therapy.** To initiate drug therapy, a pharmacist must hold a valid North Dakota pharmacist license and have a collaborative agreement with the treating practitioner. The pharmacist must provide immediate notification to the practitioner when the pharmacist initiates drug therapy.

**History:** Effective December 1, 1996; amended effective April 1, 2016.

**General Authority:** NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

**Law Implemented:** NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

**61-04-08-06. Modification of drug therapy.**

1. To modify drug therapy, a pharmacist must hold a valid North Dakota pharmacist license and have a collaborative agreement with the treating practitioner. A pharmacist may modify drug therapy as warranted to assure an appropriate course of treatment for the patient. The pharmacist must provide immediate notification to the practitioner when the pharmacist modifies drug therapy.
2. The practitioner and pharmacist entering into a collaborative agreement must have indicated on the form the scope and authority to be exercised by the pharmacist and the type or class of drugs or drug therapy to be utilized or prohibited under the agreement. Authority to prescribe schedule II drugs may not be delegated to a pharmacist. The parties may also indicate the type of medical diagnoses to be included or excluded within the collaborative relationship.
3. The current medical record of each patient receiving drug therapy must be readily accessible to the pharmacist and practitioner. The pharmacist, unless the practitioner directs otherwise, shall provide timely documentation and indications for all drug therapies initiated or modified by the pharmacist as part of the medical record.
4. Contingency treatment should be addressed for treating allergic or acute adverse drug reactions.

**History:** Effective December 1, 1996; amended effective April 1, 2016.

**General Authority:** NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

**Law Implemented:** NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

**61-04-08-07. Form.**

1. The collaborative agreement form utilized under this section is attached as an appendix to these rules as approved by the board of medicine, board of nursing, and board of pharmacy. Upon request, a board shall supply a copy of the rules and form to any interested party.
2. A copy of each collaborative agreement and subsequent amendments approved by the boards shall remain on file with the boards. Each party shall retain the original or a copy of the agreement and amendments, and either party shall provide a copy to a facility within which an agreement is operative.
3. Either board may disseminate a current listing of the individual parties who are practicing under an approved collaborative agreement.
4. More details may be provided. Further stipulations or details shall be supplied on a separate page.

**History:** Effective December 1, 1996; amended effective April 1, 2016.

**General Authority:** NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

**Law Implemented:** NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

## APPENDIX

## COLLABORATIVE AGREEMENT FORM

The pharmacists and practitioners listed below are parties to this collaborative agreement, through which the pharmacist receives limited prescriptive authority under the supervision of the practitioner in accordance with North Dakota Century Code section 43-15-31.4 and administrative rules.

_____ Facility	_____ Facility
_____ Address	_____ Address
_____ Telephone	_____ Telephone
_____ Pharmacist Name    License Number	_____ Practitioner Name    License Number
_____ Pharmacist Name    License Number	_____ Practitioner Name    License Number
_____ Pharmacist Name    License Number	_____ Practitioner Name    License Number
	_____ Practitioner Name    License Number

[Please review the administrative rules governing collaborative agreements which accompany this form before proceeding.]

1. Describe the scope and authority to be exercised by the pharmacist. (If requesting authority to initiate drug therapy, pharmacist must include credential verification.)
2. Indicate any restrictions placed on the use of certain types or classes of drugs or drug therapies under this agreement. (Note: Schedule II drugs are excluded by these rules.)
3. If appropriate, indicate any diagnoses which are specifically included or excluded under this agreement.
4. Attach any protocols or guidelines to be used in decisionmaking or other activities contemplated under this agreement. This must include a protocol for treating acute allergic or other adverse reactions related to drug therapy.
5. Describe approved situations, if any, in which the notification time limit may be extended beyond twenty-four hours (not to exceed seventy-two hours).

Attach additional sheets if necessary.

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Pharmacist Signature      Date

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Practitioner Signature      Date

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Pharmacist Signature      Date

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Practitioner Signature      Date

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Pharmacist Signature      Date

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Practitioner Signature      Date

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Practitioner Signature      Date

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State Board of      Approval Date  
Pharmacy

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State Board of Medicine      Approval Date

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State Board of Nursing      Approval Date

## CHAPTER 61-04-09 WARNING NOTICE

### Section

61-04-09-01 Purpose

61-04-09-02 Recipient

61-04-09-03 Issuance

61-04-09-04 Filing

61-04-09-05 Failure to Respond

61-04-09-06 Board Review of Two Notices

**61-04-09-01. Purpose.** A warning notice to the pharmacist, pharmacy permittee, licensee, or registrant protects public health by allowing them to expeditiously correct violations of laws and rules and report these corrections to the board of pharmacy in writing.

**History:** Effective October 1, 1999.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 28-32-02, 43-15-10

**61-04-09-02. Recipient.** A warning notice may be issued to any permittee, licensee, or registrant found to be violating the provisions of this title, North Dakota Century Code chapter 43-15 or 43-19, or any federal, state, or local laws and rules.

**History:** Effective October 1, 1999.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 28-32-02, 43-15-10

**61-04-09-03. Issuance.** An agent of the North Dakota state board of pharmacy may issue a warning notice at the time a violation is found.

**History:** Effective October 1, 1999.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 28-32-02, 43-15-10

**61-04-09-04. Filing.** The warning notice may become an integral part of a file and be maintained in the file sixty months and discarded if no further action is pending.

**History:** Effective October 1, 1999.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 28-32-02, 43-15-10

**61-04-09-05. Failure to respond.** Permittees, licensees, or registrants who fail to satisfactorily respond to a warning notice may be referred to the board for review or complaint and hearing by the executive director of the board.

**History:** Effective October 1, 1999.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 28-32-02, 43-15-10

**61-04-09-06. Board review of two notices.** Any permittee, licensee, or registrant receiving two or more warning notices within a twenty-four month period may be referred to the board for review or complaint and hearing.

**History:** Effective October 1, 1999.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 28-32-02, 43-15-10

## CHAPTER 61-04-10 CLIA WAIVED LABORATORY TESTS

### Section

61-04-10-01 Definitions

61-04-10-02 Education Requirements for Pharmacists to Perform CLIA Waived Laboratory Tests

61-04-10-03 Minimum Quality Standards Required 61-04-10-04 Proper CLIA Registration

61-04-10-04 Proper CLIA Registration

61-04-10-05 Notification of the Board of Pharmacy

61-04-10-06 Exempt Tests and Methods

**61-04-10-01. Definitions.** For purposes of this chapter:

1. "CLIA" means the federal Clinical Laboratory Improvement Act of 1988, as amended.
2. "OSHA" means the federal occupational safety and health administration.
3. "Portfolio review" means a review by the board of a pharmacist's records of training logs, control testing logs, and records of patient tests performed to determine that a pharmacist is continuously and consistently providing a service in a quality and competent manner.

**History:** Effective December 1, 1999; amended effective April 1, 2016.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 43-15-25.3

**61-04-10-02. Education requirements for pharmacists to perform CLIA waived laboratory tests.** A pharmacist must meet the following requirements in order to perform CLIA waived laboratory tests authorized by North Dakota Century Code section 43-15-25.3 or added to the list as allowed by section 61-04-10-06:

1. Successfully complete training and education that incorporates, at a minimum:
  - a. Infection control;
  - b. OSHA requirements;
  - c. Proper technique to collect laboratory specimens;
  - d. Recognized screening and monitoring values;
  - e. Quality control; and
  - f. The manufacturers' instructions for the waived tests being performed.
2. Obtain and recertify the CLIA waived certificate every two years.

**History:** Effective December 1, 1999; amended effective April 1, 2016.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 43-15-25.3

**61-04-10-03. Minimum quality standards required.** Pharmacists performing CLIA waived laboratory tests must meet the following standards:

1. Develop and maintain a policy and procedure manual that includes the following areas:
  - a. Quality control;
  - b. Infection control;
  - c. Hazardous waste disposal;
  - d. Recordkeeping; and
  - e. Test result reporting.

**History:** Effective December 1, 1999; amended effective April 1, 2016.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 43-15-25.3

**61-04-10-04. Proper CLIA registration.** The pharmacist-in-charge of a licensed pharmacy performing tests or any pharmacist operating in a facility not licensed by the board is responsible for ensuring that the pharmacy performing the CLIA waived test has a proper CLIA certificate.

**History:** Effective December 1, 1999; amended effective April 1, 2016.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 43-15-25.3

**61-04-10-05. Notification of the board of pharmacy.** The pharmacist-in-charge of a licensed pharmacy that has obtained a CLIA certificate or any pharmacist operating in a facility not licensed by the board of pharmacy must notify the board prior to the initial performance of any CLIA waived tests.

**History:** Effective December 1, 1999; amended effective April 1, 2016.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 43-15-25.3

**61-04-10-06. Exempt tests and methods.** An individual licensed by the board, performing the following food and drug administration-waived tests and using the following methods, is exempt from the provisions of North Dakota Century Code chapter 43-48:

1. Total cholesterol, HDL cholesterol, LDL cholesterol, and triglycerides test by any accepted method.
2. Any of the following tests by nonautomated or automated urinalysis by dipstick:
  - a. Bilirubin.
  - b. Blood.
  - c. Glucose.
  - d. Ketone.
  - e. Leukocyte.
  - f. Nitrate.
  - g. Potential of hydrogen (pH).
  - h. Protein.
  - i. Specific gravity.
  - j. Urobilinogen.
3. Fecal occult blood by any accepted method.
4. Ovulation test by visual color comparison.
5. Qualitative urine pregnancy test by visual color comparison.
6. Erythrocyte sedimentation rate by any accepted nonautomated method.
7. Whole blood glucose by any accepted single analyte method.
8. Spun microhematocrit by any accepted method.
9. Hemoglobin by single analyte instrument or manual copper sulfate method.
10. Any of the following tests by immunoassay using a rapid test device that detects antibodies or antigens:
  - a. Helicobacter pylori.
  - b. Influenza.
  - c. Mononucleosis.
  - d. Streptococcus group A.
  - e. Hepatitis C virus.
  - f. Respiratory syncytial virus.
11. Prothrombin time international normalized ratio by mechanical endpoint.
12. Antibodies to human immunodeficiency virus types 1 and 2.
13. Nicotine or cotinine test by urine.
14. Thyroid stimulating hormone test by blood.
15. Bone mass and bone mineral density test by any accepted method.
16. Drug screening tests by urine.

**History:** Effective April 1, 2016.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 43-15-25.3

## CHAPTER 61-04-11 ADMINISTRATION OF MEDICATIONS AND IMMUNIZATIONS

### Section

61-04-11-01 Definitions

61-04-11-02 Qualifications Established to Obtain Certificate of Authority

61-04-11-03 Procedures to Obtain Certificate of Authority

61-04-11-04 Requirements of Physician or Nurse Practitioner Order for a Pharmacist to Administer Injections

61-04-11-05 Requirements of Written Protocol

61-04-11-06 Requirements of Records and Notifications

61-04-11-07 Location of Administration by Injection

61-04-11-08 Policy and Procedural Manual

**61-04-11-01. Definitions.** For purposes of this chapter:

1. "Authorized pharmacist" means a pharmacist who has successfully completed a board-approved course of study pertaining to the injectable administration of drugs and maintains continuing competency according to rules adopted by the board.
2. "Certificate of authority" means documentation provided by the board to an authorized pharmacist, which must be displayed in the pharmacy at which the pharmacist is practicing.
3. "Written protocol" means a standing medical order between a physician or nurse practitioner and an authorized pharmacist which contains information required by board rules.

**History:** Effective May 1, 2002.

**General Authority:** NDCC 43-15-10

**Law Implemented:** NDCC 43-15-10, 43-15-31.5

**61-04-11-02. Qualifications established to obtain certificate of authority.** A pharmacist must possess the following qualifications in order to obtain a certificate of authority from the board:

1. Obtain and maintain a license to practice pharmacy issued by the North Dakota state board of pharmacy;
2. Successfully complete a board-approved twenty-hour course of study and examination pertaining to the administration of medications by injection, which includes the current guidelines and recommendations of the centers for disease control and prevention. The course of study must be administered by an approved provider and consist of study material and hands-on training in techniques for administering injections. The course must require testing and completion with a passing score. The provider of the course of study shall provide successful participants with a certificate of completion. A copy of said certificate must be mailed to the state board of pharmacy offices and placed in the pharmacist's permanent file. The course of study must include, at a minimum:
  - a. Basic immunology, including the human immune response;
  - b. The mechanism of immunity, adverse effects, dose, and administration schedule of available vaccines;
  - c. Vaccine-preventable diseases;
  - d. Current immunization guidelines and recommendations of the centers for disease control and prevention;
  - e. Vaccine storage and management;
  - f. Management of adverse events due to the administration of medications by injection, including identification, appropriate response, documentation, and reporting;
  - g. Patient education on the need for immunizations;
  - h. Informed consent;
  - i. Physiology and techniques for subcutaneous, intradermal, and intramuscular injection; and
  - j. Recordkeeping requirements established by law and rules or established standards of care;
3. Obtain and maintain current certification in cardiopulmonary resuscitation or basic cardiac life support;
4. Complete an application process adopted by the board and provide required documentation; and



5. Maintain continuing competency to retain the certificate of authority. A minimum of six hours of the thirty-hour requirement for continuing education, every two years, must be dedicated to this area of practice.

**History:** Effective May 1, 2002.

**General Authority:** NDCC 43-15-10

**Law Implemented:** NDCC 43-15-10, 43-15-31.5

**61-04-11-03. Procedures to obtain certificate of authority.** An authorized pharmacist shall provide the board with a copy of a certificate of completion from a board-approved course, a copy of current certification in cardiopulmonary resuscitation or basic cardiac life support, and other information required on a form supplied by the board. If requirements are met, the board shall issue a certificate of authority that shall be valid for two years. In order to renew the certificate, the pharmacist shall submit evidence of six hours of continuing education dedicated to this area of practice.

**History:** Effective May 1, 2002.

**General Authority:** NDCC 43-15-10

**Law Implemented:** NDCC 43-15-10, 43-15-31.5

**61-04-11-04. Requirements of physician or nurse practitioner order for a pharmacist to administer injections.** The order must be written, received electronically or if received orally be reduced to writing, and must contain at a minimum the:

1. Identity of the physician or nurse practitioner issuing the order;
2. Identity of the patient to receive the injection;
3. Identity of the medication or vaccine, and dose, to be administered; and
4. Date of the original order and the dates or schedule, if any, of each subsequent administration.

**History:** Effective May 1, 2002; amended effective January 1, 2005.

**General Authority:** NDCC 43-15-10

**Law Implemented:** NDCC 43-15-10, 43-15-31.5

**61-04-11-05. Requirements of written protocol.** A physician or nurse practitioner may prepare a written protocol governing the administration of medications by injection with an authorized pharmacist for a specific period of time or purpose. The written protocol may be valid for a time period not to exceed two years, subject to earlier withdrawal by the physician or nurse practitioner. The protocol must contain the:

1. Identity of the participating physician or nurse practitioner and the pharmacist;
2. Identity of the immunization or vaccination which may be administered;
3. Identity of the patient or groups of patients to receive the authorized immunization or vaccination;
4. Identity of the authorized routes and sites of administration allowed;
5. Identity of the course of action the pharmacist shall follow in the case of reactions following administration;
6. Identity of the location at which the pharmacist may administer the authorized immunization or vaccination; and
7. Recordkeeping requirements and procedures for notification of administration.

**History:** Effective May 1, 2002.

**General Authority:** NDCC 43-15-10

**Law Implemented:** NDCC 43-15-10, 43-15-31.5

**61-04-11-06. Requirements of records and notifications.** A pharmacist administering by injection shall meet the following recordkeeping and notification requirements:

1. Notification of administration must be made to the ordering physician or nurse practitioner and other authorities as required by law and rule.
  - a. When administration has occurred pursuant to an order, the pharmacist shall notify the ordering physician or nurse practitioner within forty-eight hours of the identity of the patient, identity of the medication or vaccine administered, route of administration site of the administration, dose administered, and date of administration and the disposition of any adverse events or reactions experienced by the patient.

- b. When administration has occurred pursuant to a written protocol, the pharmacist shall notify the participating physician or nurse practitioner within fourteen days of the identity of the patient, identity of the medication or vaccine administered, site of the administration, dose administered, and date of administration and the disposition of any adverse events or reactions experienced by the patient.
  - c. In the case of immunizations and vaccinations, the pharmacist shall also provide notification to the physician or nurse practitioner of the manufacturer and lot number of the product administered.
2. Every record, including notification, which is required to be made under this section, must be kept by the administering pharmacist and by the pharmacy when in legal possession of the drugs administered for at least two years from the date of administration. Records of administration must contain all information required in subsection 1, plus the name of the ordering physician or nurse practitioner. Records of administration by order must be by patient name and, in the case of administration by written protocol, records may be maintained in roster form.

**History:** Effective May 1, 2002.

**General Authority:** NDCC 43-15-10

**Law Implemented:** NDCC 43-15-10, 43-15-31.5

**61-04-11-07. Location of administration by injection.** Pharmacists may administer medications by injection within a licensed North Dakota pharmacy or at a location within North Dakota specifically identified in a written protocol. The location in the pharmacy must:

1. Ensure privacy;
2. Be maintained to promote an aseptic environment;
3. Have adequate telecommunications devices to summon aid and communicate emergency situations; and
4. Have adequate equipment and supplies to respond to adverse events and emergency situations.

**History:** Effective May 1, 2002.

**General Authority:** NDCC 43-15-10

**Law Implemented:** NDCC 43-15-10, 43-15-31.5

**61-04-11-08. Policy and procedural manual.** The pharmacy shall maintain a policy and procedural manual, with a section related to the administration of medications by injection, in compliance with section 61-02-01-18.

**History:** Effective May 1, 2002; amended effective October 1, 2014.

**General Authority:** NDCC 43-15-10

**Law Implemented:** NDCC 43-15-10, 43-15-31.5

## CHAPTER 61-04-12 LIMITED PRESCRIPTIVE AUTHORITY FOR NALOXONE

Section

61-04-12-01 Definitions

61-04-12-02 Pharmacists Furnishing Naloxone

**61-04-12-01. Definitions.** For purposes of this chapter:

1. "Opioid-related drug overdose" means a condition including extreme physical illness, decreased level of consciousness, respiratory depression, coma, or death resulting from the consumption or use of an opioid or another substance with which an opioid was combined. This would include an overdose that requires medical assistance or a coroner, clinical suspicion for drug overdose (respiratory depression, unconsciousness, altered mental status), and either a urine toxicology screen positive for opiates or negative urine toxicology screen without other conditions to explain the clinical condition.
2. "Patient" means both an individual who is at risk of opioid overdose and a person who is not at risk of opioid overdose but who may be in a position to assist another individual during an overdose who has received patient information.
3. "Patient information" means the information provided to the patient on drug overdose prevention and recognition, opioid antidote dosage and administration, the importance of calling 911, care for the overdose victim after administration of the overdose antidote, and other issues as necessary.

**History:** Effective April 1, 2016.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 23-01-42, 43-15-10(23)

**61-04-12-02. Pharmacists furnishing naloxone.**

1. Protocol.
  - a. Pharmacists are authorized to furnish naloxone drug therapy solely in accordance with the written protocol for naloxone drug therapy approved by the board.
  - b. Any pharmacist exercising prescriptive authority for naloxone drug therapy shall maintain a current copy of the written protocol for naloxone drug therapy approved by the board.
2. Procedure. When a patient requests naloxone, or when a pharmacist in his or her professional judgment decides to advise of the availability and appropriateness of naloxone, the pharmacist shall complete the following steps:
  - a. Screen for the following conditions:
    - (1) Whether the potential recipient currently uses or has a history of using illicit or prescription opioids (if yes, skip to subdivision b and continue with procedure);
    - (2) Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids (if yes, continue with procedure); and
    - (3) Whether the person to whom the naloxone would be administered has a known hypersensitivity to naloxone (if yes, do not furnish).
  - b. Provide training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.
  - c. When naloxone is furnished:
    - (1) The pharmacist shall provide the patient with appropriate patient information and counseling on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. A pharmacist furnishing naloxone drug therapy may not permit the patient to whom the drug is furnished to waive the patient information required by the board.
    - (2) The pharmacist shall provide the patient with any resources and referrals to appropriate resources if the patient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.
    - (3) The pharmacist shall answer all questions the recipient may have regarding naloxone.
3. Authorized drugs.
  - a. Prescriptive authority is limited to naloxone and includes any device approved for the administration of naloxone.
  - b. Those administering naloxone should choose the route of administration based on the formulation available, how well they can administer it, the setting, and local context.
4. Education and training. Prior to furnishing naloxone, pharmacists who participate in this protocol shall successfully complete a minimum of one hour of an approved continuing education program specific to the use of naloxone, or an equivalent curriculum-based training program completed in a board-recognized school of pharmacy.
5. Records. The prescribing pharmacist must generate a written or electronic prescription for any naloxone dispensed and the pharmacist shall record themselves as the prescriber or the protocol practitioner if appropriate. Documentation shall be made in a medication record for the patient. The prescription shall be kept on file and maintained for five years as required in North Dakota Century Code section 43-15-31.
6. Notification. If the patient is the potential individual to whom the naloxone will be administered, the pharmacist shall notify the patient's primary care provider of any drugs and devices furnished, or enter the appropriate information in a record system shared with the primary care provider. If the patient does not have a primary care provider, the pharmacist shall provide a written record of the drugs and devices furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

**History:** Effective April 1, 2016.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 23-01-42, 43-15-10(23)

## **ARTICLE 61-05 RADIOPHARMACEUTICAL SERVICES**

Chapter

61-05-01 Radiopharmaceutical Services

### **CHAPTER 61-05-01 RADIOPHARMACEUTICAL SERVICES**

Section

61-05-01-01 Purpose and Scope

61-05-01-02 Definitions

61-05-01-03 General Requirements for Nuclear Pharmacies Providing Radiopharmaceutical Services

61-05-01-04 General Requirements for Nuclear Pharmacists to Manage a Nuclear Pharmacy Providing Radiopharmaceutical Services

61-05-01-05 Library

61-05-01-06 Minimum Equipment Requirements

**61-05-01-01. Purpose and scope.** It is unlawful to receive, possess, or transfer radioactive drugs, except in accordance with North Dakota Century Code chapter 43-15, this article, and the North Dakota radiological health rules in article 33-10. It is also unlawful for any person to provide radiopharmaceutical services unless that person is a pharmacist meeting the qualifications of section 61-05-01-04, or a person acting under the direct supervision of a pharmacist meeting those qualifications and acting in accordance with North Dakota Century Code chapter 43-15, state board of pharmacy regulations, and the North Dakota radiological health rules in article 33-10, with the exception of a medical practitioner, who is listed as an authorized user on a radioactive materials license, for administration to the practitioner's patients. No person may receive, acquire, possess, use, transfer, or dispose of any radioactive material except in accordance with the conditions of a radioactive material license on which the person is an authorized user, as required by the state department of health pursuant to article 33-10. The requirements of this chapter are in addition to, and not in substitution for, other applicable provisions of regulations of the state board of pharmacy and the state department of health.

**History:** Effective August 1, 1983; amended effective October 1, 2012.

**General Authority:** NDCC 28-32-02, 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13), 43-15-10(14), 43-15-36

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13), 43-15-10(14), 43-15-36

#### **61-05-01-02. Definitions.**

1. "Authentication of product history" includes identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.
2. "Internal test assessment" includes conducting those tests of a quality assurance necessary to ensure the integrity of the test.
3. "Radiopharmaceutical quality assurance" includes the performance of appropriate chemical, biological, and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history, and the keeping of proper records.
4. "Radiopharmaceutical service" 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.

**History:** Effective August 1, 1983.

**General Authority:** NDCC 28-32-02, 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13), 43-15-10(14), 43-15-36

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13), 43-15-10(14), 43-15-36

**61-05-01-03. General requirements for nuclear pharmacies providing radiopharmaceutical services.**

1. A nuclear pharmacy providing radiopharmaceutical services shall only be managed by a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct supervision of the nuclear pharmacist. The nuclear pharmacist is responsible for all operations of the licensed area and shall be physically present at all times that the pharmacy is open for business. In emergency situations, in the nuclear pharmacist's absence, the nuclear pharmacist may designate one or more other qualified licensed professionals, who are authorized users, listed by name, on a radioactive materials license, to have access to the licensed area. These individuals may obtain single doses of radiopharmaceuticals, only if the single dose is already prepared by a qualified nuclear pharmacist, for the immediate emergency and must document such withdrawals in the control system.
2. Nuclear pharmacies providing radiopharmaceuticals shall have adequate space, commensurate with the scope of services required and provided, meeting minimal space requirements established for all pharmacies in the state. The area shall be separate from the pharmacy areas for nonradioactive drugs and shall be secured from unauthorized personnel. All nuclear pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area, occupying at least twenty-five square feet [2.32 square meters] of space, separate from and exclusive of the hot laboratory, compounding, dispensing, quality assurance, and office area. A nuclear pharmacy handling radioactive drugs exclusively may be exempted from the general space requirements for pharmacies by obtaining a waiver from the state board of pharmacy. Detailed floor plans shall be submitted to the state board of pharmacy before approval of the license.
3. Nuclear pharmacies providing radiopharmaceutical services shall only dispense radiopharmaceuticals which comply with acceptable standards of radiopharmaceutical quality assurance.
4. Nuclear pharmacies providing radiopharmaceutical services shall maintain records of acquisition and disposition of all radioactive drugs and byproduct material for the duration of the license.
5. Nuclear pharmacies providing radiopharmaceutical services shall comply with all applicable laws and regulations of federal and state agencies, including those laws and regulations governing nonradioactive drugs.
6. Radioactive drugs are to be dispensed only upon a request from a licensee authorized to possess, use, and administer radiopharmaceuticals. A pharmacist providing radiopharmaceutical services may transfer to authorized persons radioactive materials not intended for drug use, in accordance with North Dakota rules and regulations pertaining to radiation control.
7. A radiopharmaceutical may be provided only to a facility licensed under article 33-10, with an authorized user for the radioactive drug requested. A nuclear pharmacy must have on file a copy of the current radioactive materials license for the licensed facility requesting any radioactive drug before the radioactive drug is permitted to be dispensed to that facility. The radioactive drug must be delivered to the authorized address in the license for receipt, logging in, testing for contamination, and determining the current activity and then the dose is available to be administered to a patient.
8. In addition to any labeling requirements of the state board of pharmacy for nonradioactive drugs, the immediate outer container of a radioactive drug to be dispensed shall also be labeled with:
  - a. The standard radiation symbol;
  - b. The words "Caution—Radioactive Material";
  - c. The radionuclide;
  - d. The chemical form;
  - e. The amount of radioactive material contained, in millicuries or microcuries;
  - f. If a liquid, the volume in milliliters; and
  - g. The requested calibration time for the amount of radioactivity contained.

9. The immediate container shall be labeled with:
  - a. The standard radiation symbol;
  - b. The words "Caution—Radioactive Material";
  - c. The name, address, and telephone number of the pharmacy; and
  - d. The prescription number.
10. The amount of radioactivity shall be determined by dose calibrator or other appropriate radiometric methods for each individual dose immediately prior to dispensing.
11. Nuclear pharmacies may redistribute national food and drug administration approved radioactive drugs if the pharmacy does not process the radioactive drugs in any manner nor violate the product packaging.

**History:** Effective August 1, 1983; amended effective October 1, 2012.

**General Authority:** NDCC 28-32-02, 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13), 43-15-10(14), 43-15-36

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13), 43-15-10(14), 43-15-36

**61-05-01-04. General requirements for nuclear pharmacists to manage a nuclear pharmacy providing radiopharmaceutical services.** A qualified nuclear pharmacist shall:

1. Meet minimal standards of training for medical uses of radioactive material.
2. Hold a current, active license to practice pharmacy in this state.
3. Have completed a minimum of seven hundred contact hours in a structured educational program consisting of didactic instruction in nuclear pharmacy and clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy providing nuclear pharmacy services, or in a structured clinical nuclear pharmacy training program with emphasis in the following areas:
  - a. Radiation physics and instrumentation.
  - b. Radiation protection.
  - c. Mathematics pertaining to the use and measurement of radioactivity.
  - d. Chemistry of byproduct material for medical use.
  - e. Radiation biology.
  - f. Shipping, receiving, and performing related radiation surveys.
  - g. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha-emitting or beta-emitting radionuclides.
  - h. Calculating, assaying, and safely preparing dosages for patients or human research subjects.
  - i. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures.
4. Obtain written attestation, signed by an authorized nuclear pharmacist stating that the pharmacist has completed the requirements of this section and has achieved a level of competence sufficient to function independently as an authorized nuclear pharmacist and submit that to the state board of pharmacy.
5. Submit evidence to the state board of pharmacy that the pharmacist is certified by a specialty board whose certification has been recognized under 10 CFR 35.55(a).

**History:** Effective August 1, 1983; amended effective October 1, 2012.

**General Authority:** NDCC 28-32-02, 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13), 43-15-10(14), 43-15-36

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13), 43-15-10(14), 43-15-36

**61-05-01-05. Library.** Each nuclear pharmacy providing radiopharmaceutical services shall have current editions or revisions of:

1. United States Pharmacopoeia National Formulary, with supplements.
2. Current issues of the Journal of Nuclear Medicine or online access.
3. State laws and regulations relating to pharmacy.
4. State and federal regulations governing the use of applicable radioactive materials, including North Dakota radiological health rules, article 33-10.
5. Nuclear Medicine: The Requisites - by Thrall and Ziessman.

6. Principles and Practice of Nuclear Medicine - by Early and Sodee.
7. Nuclear Pharmacy - by Chilton and Witcofski.
8. Radiopharmaceuticals in Nuclear Pharmacy and Nuclear Medicine - by Kowalski and Phelan.

The state board of pharmacy recognizes that the library needed will depend on the type of radiopharmaceutical services offered. Variations in the required library may be granted by the state board of pharmacy.

**History:** Effective August 1, 1983; amended effective October 1, 2012.

**General Authority:** NDCC 28-32-02, 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13), 43-15-10(14), 43-15-36

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13), 43-15-10(14), 43-15-36

**61-05-01-06. Minimum equipment requirements.** Each pharmacy providing radiopharmaceutical services shall have the following equipment:

1. Area radiation monitor which is stationary and away from other activity.
2. Dose calibrator and well counter.
3. Portable survey meter, capable of measuring up to two thousand mR/hr for determining contamination and for other physic procedures.
4. Sufficient quantity of lead bricks, lead plates, leaded glass of high density, and leaded or tungsten syringe shields.
5. Refrigerator with freezer with temperature-monitoring capabilities.
6. Class A prescription balance or balance of greater sensitivity.
7. Single-channel or multichannel scintillation counter.
8. Sink with hot and cold running water.
9. Wipe test counter capable of detecting 0.005 microcuries of the radionuclides in question.
10. Chromatographic equipment.
11. Annually calibrated fume hood, if handling volatile radioactive materials.
12. Chemical exhaust hood, if handling large quantities of chemicals.
13. Electronic balance or class A prescription balance.
14. Lighted microscope or hemocytometer, or both.
15. ISO class 5 laminar flow-dispensing hood.
16. Forceps or tongs for remote handling of material.
17. Hotplate or heat block, or both.
18. Class II biosafety cabinet for handling blood samples for labeling.
19. Glassware.
20. Other equipment necessary for radiopharmaceutical services provided as required by the state board of pharmacy.

The state board of pharmacy recognizes that the equipment needed will depend on the type of radiopharmaceutical services offered. Variations for required equipment may be granted by the state board of pharmacy.

**History:** Effective August 1, 1983; amended effective October 1, 2012.

**General Authority:** NDCC 28-32-02, 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13), 43-15-10(14), 43-15-36

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(13), 43-15-10(14), 43-15-36

## **ARTICLE 61-06**

### **HOME HEALTH CARE PHARMACY SERVICES**

Chapter

61-06-01 Home Health Care Pharmacy Services

#### **CHAPTER 61-06-01**

### **HOME HEALTH CARE PHARMACY SERVICES**

Section

61-06-01-01 Definitions

61-06-01-02 Registration

61-06-01-03 Personnel

- 61-06-01-04 Physical Requirements
- 61-06-01-05 Drug Distribution and Control
- 61-06-01-06 Cytotoxic Agents
- 61-06-01-07 Patient Care Guidelines
- 61-06-01-08 Quality Control

**61-06-01-01. Definitions.** For the purpose of this chapter, the following definitions apply:

1. **Pharmacy providing home health care pharmacy services.** A pharmacy providing home health care pharmacy services is a licensed pharmacy that routinely prepares and dispenses compounded, sterile parenteral products to outpatients.
2. **Outpatient.** An outpatient is defined as a patient in the home environment or an institutionalized patient that is receiving compounded sterile parenteral products from a pharmacy outside the institution.
3. **Compounded, sterile parenteral products.** Compounded, sterile parenteral products are defined as those parenteral drug products that require manipulation by the pharmacist and which must be sterile, stable, and effective when dispensed for patient use.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

**61-06-01-02. Registration.** All pharmacies providing home health care pharmacy services shall have a current pharmacy permit as provided by North Dakota law and rules of the board. They shall comply with all pharmacy laws and rules as well as the following special rules. The requirements of this chapter are in addition to, and not in substitution for, other applicable laws of North Dakota and rules of the board.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

**61-06-01-03. Personnel.**

1. **Pharmacist-in-charge.** In addition to the pharmacist-in-charge requirements of section 61-02-01-10, that section of the pharmacy providing home health care pharmacy services must be managed by a pharmacist licensed to practice pharmacy in the state and who is knowledgeable in the specialized functions of preparing and dispensing compounded, sterile parenteral products, including the principles of aseptic technique and quality assurance. This knowledge is usually obtained through residency training programs, continuing education programs, or experience in an intravenous admixture facility. The pharmacist-in-charge is responsible for the purchasing, storage, compounding, repackaging, dispensing, and distribution of all drugs and pharmaceuticals and is also responsible for the development and continuing review of all policies and procedures, training manuals, and the quality assurance programs. The pharmacist-in-charge may be assisted by additional pharmacists adequately trained in this area of practice.
2. **Supportive personnel.** The pharmacist managing the section of the pharmacy providing home health care pharmacy services may be assisted by supportive personnel. These personnel must have specialized training in this field, and shall work under the immediate supervision of a licensed pharmacist. The training provided to these personnel must be described in writing in a training manual. The duties and responsibilities of these personnel must be consistent with their training and experience.
3. **Secretarial support.** Secretarial support must be provided as required to assist with recordkeeping and other administrative duties.
4. **Staffing.** A pharmacist must be accessible at all times to respond to patients' and other health professionals' questions and needs.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

**61-06-01-04. Physical requirements.** The physical requirements are as follows:

1. **Space.** The pharmacy providing home health care pharmacy services shall have a designated area for preparing compounded, sterile parenteral products. This area must be physically separate from other



areas and should be designed to avoid unnecessary traffic and airflow disturbances. It must be used only for the preparation of these specialty products. It must be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

2. **Equipment.**

- a. Laminar airflow hood.
- b. Infusion pumps, if appropriate.
- c. Sink with hot and cold running water which is convenient to the compounding area for the purpose of hand scrubs prior to compounding.
- d. Facility for light/dark field examination.
- e. Appropriate disposal containers for used needles, syringes, etc., and if applicable, cytotoxic waste from the preparation of chemotherapy agents.
- f. A class II vertical flow biological safety cabinet, if chemotherapy agents are routinely prepared.
- g. Refrigerator/freezer.

3. **Supplies.**

- a. Disposable needles, syringes, and other supplies needed for aseptic admixture.
- b. Disinfectant cleaning solutions.
- c. Handwashing agent with bactericidal action.
- d. Disposable, lint-free paper towels.
- e. Appropriate filters and filtration equipment.
- f. Disposable masks and sterile, disposable gloves.
- g. Gowns, if chemotherapy agents are routinely prepared.
- h. An oncology drug spill kit, if chemotherapy agents are routinely prepared.

4. **References.** In addition to references required in a retail pharmacy, current edition of an established reference on intravenous stability and incompatibility, such as, Handbook on Injectable Drugs, or King's Guide to Parenteral Admixtures.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(14)

**61-06-01-05. Drug distribution and control.**

1. **General.** A drug distribution system is the entirety of that mechanism by which a physician's prescription is executed, from the time the drug is ordered and received in the pharmacy, to the time the prescribed drug is dispensed to the patient.
2. **Purchasing.** All drugs and pharmaceutical products purchased and dispensed by a pharmacy providing home health care pharmacy services must meet national standards of quality (USP-NF standards) and must be clearly and accurately labeled by the manufacturer or distributor as to contents.
3. **Procedure manual.** A policy and procedure manual must be prepared in accordance with section 61-02-01-18 home health care pharmacy services.
4. **Prescription.** The pharmacist or pharmacy intern acting under the immediate supervision of a pharmacist must receive a written or verbal prescription from a physician before dispensing any compounded, sterile parenteral product. Prescriptions must be filed as required by law or rules of the board.
5. **Profile.** A pharmacy generated profile must be maintained for each patient as required by North Dakota Century Code section 43-15-31.1, and must also include:
  - a. Age.
  - b. Weight.
  - c. Sex.
  - d. Patient directions.
  - e. Other drugs patient is receiving.
  - f. Drug sensitivities and allergies to drugs and foods.
  - g. Primary diagnosis.
  - h. Documentation of patient training and continued competency.
  - i. Documentation of patient visits.

6. **Labeling.** Each compounded, sterile parenteral product dispensed to outpatients must be labeled with a permanent label with the following information:
  - a. Name, address, and telephone number of the pharmacy providing home health care pharmacy services.
  - b. Date and identifying prescription number.
  - c. Patient's full name.
  - d. Name of each drug, strength, and amount.
  - e. Directions for use to the patient, including infusion rate.
  - f. Physician's full name.
  - g. Required precautionary information.
  - h. Date and time of compounding.
  - i. Expiration date and time.
  - j. Identity of pharmacist compounding and dispensing.
7. **Records and reports.** The pharmacist managing the section of the pharmacy providing home health care pharmacy services shall maintain access to and submit, as appropriate, such records and reports as are required to ensure patient's health, safety, and welfare. Such records must be readily available, maintained for five years, and subject to inspections by the board of pharmacy or its agents. These must include, as a minimum, the following:
  - a. Policy and procedures manual.
  - b. Training manuals.
  - c. Policies and procedures for cytotoxic waste, if applicable.
  - d. Such other records and reports as may be required by law and rules of the board of pharmacy.
8. **Delivery service.** The pharmacist managing the section of the pharmacy providing home health care pharmacy services is responsible for the environment control of all products shipped. Therefore, any compounded, sterile parenteral product that is frozen, or requires refrigeration, must be shipped or delivered to a patient in appropriate coolers and stored appropriately in the patient's home.

**History:** Effective April 1, 1988; amended effective October 1, 2014.

**General Authority:** NDCC 28-32-02

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14), 43-15-31, 43-15-31.1

**61-06-01-06. Cytotoxic agents.** The following additional requirements are necessary for those pharmacies providing home health care pharmacy services that routinely prepare chemotherapy agents to ensure the protection of the personnel involved:

1. All chemotherapy agents should be compounded in a vertical flow, class II, biological safety cabinet. If possible, other products should not be compounded in this cabinet.
2. Protective apparel must be worn by personnel compounding chemotherapy drugs. This includes disposable masks, gloves, and gowns with tight cuffs.
3. Proper aseptic and safety techniques must be used by personnel compounding chemotherapy agents.
4. Appropriate disposal procedures for cytotoxic waste must be developed that comply with applicable state and federal regulations.
5. Written procedures for handling both major and minor spills of cytotoxic agents must be developed.
6. Prepared doses of chemotherapy must be dispensed and shipped in a manner to minimize the risk of accidental rupture of the primary container.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

**61-06-01-07. Patient care guidelines.**

1. **Primary provider.** There must be a designated physician primarily responsible for the patient's medical care. There must be a clear understanding between the physician, the patient, and the pharmacist of the responsibilities of each in the areas of the delivery of care, the monitoring of the patient, and the reimbursement for services. This must be documented in the patient's profile.
2. **Patient training.** The patient, the patient's physician, or the patient's pharmacist shall demonstrate or document the patient's training and competency in managing this type of therapy in the home environment prior to any drugs, supplies, or equipment being dispensed. A pharmacist must be involved

in the patient training process in any area that relates to drug compounding, labeling, storage, stability, or incompatibility. The pharmacist shall reassess and document on the profile the patient's competency in the necessary areas at least every six months.

3. **Pharmacist-patient relationship.** It is imperative that a pharmacist-patient relationship be established and maintained throughout the patient's course of therapy. The patient should be visited by the pharmacist at least monthly; telephone contact will not suffice. This must be documented in the patient's profile.
4. **Patient monitoring.** The pharmacist should have access to clinical and laboratory data concerning each patient and should monitor each patient's response to the patient's drug therapy. Any unexpected or untoward response should be reported to the prescribing physician.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

**61-06-01-08. Quality control.** There must a documented, ongoing quality control program that monitors personnel performance, equipment, and facilities. The end product must be examined on a sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications.

1. **Hood certification.** All laminar flow hoods must be certified by federal standard 209B for operational efficiency at least every twelve months. Appropriate records must be maintained.
2. **Prefilters.** Prefilters for the clean air source must be replaced on a regular basis and these activities documented.
3. **Bulk compounding.** If bulk compounding of parenteral solutions is performed utilizing nonsterile chemicals, extensive end product testing must be documented prior to the release of the product from quarantine. This process must include testing for sterility and pyrogens.
4. **Expiration dates.** If the product is assigned a lengthy expiration date (anything exceeding ten days), there must be in-house data or data in the literature to assure the sterility and stability of the product at the time it is used by the patient.
5. **Quality control audits.** There must be documentation of quality assurance audits at regular, planned intervals.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

## ARTICLE 61-07 HOSPITAL PHARMACY

### Chapter

#### 61-07-01 Hospital Pharmacy

## CHAPTER 61-07-01 HOSPITAL PHARMACY

### Section

- 61-07-01-01 Definitions
- 61-07-01-02 Applicability
- 61-07-01-03 Registration
- 61-07-01-04 Personnel
- 61-07-01-05 Absence of Pharmacist
- 61-07-01-06 Physical Requirements
- 61-07-01-07 Drug Distribution and Control
- 61-07-01-08 Nondistributive Roles of the Pharmacist
- 61-07-01-09 Administration of Drugs
- 61-07-01-10 Drugs From Outside Sources
- 61-07-01-11 Quality Assurance
- 61-07-01-12 Investigational Drugs
- 61-07-01-13 Inspection
- 61-07-01-14 Pharmacist First Dose Review

**61-07-01-01. Definitions.** For purposes of this chapter, the following definitions apply:

1. The terms "hospital" and "medical center" are synonymous.
2. "Hospital pharmacy" is defined as those portions of a hospital where drugs, medications, devices, and other materials used in the diagnosis and treatment of injury, illness, and disease (hereinafter referred to as "drugs") are manufactured, produced, sold, or distributed.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

**61-07-01-02. Applicability.** This chapter is applicable to all hospital pharmacies as defined by section 61-07-01-01.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

**61-07-01-03. Registration.** All hospital pharmacies shall register annually with the board of pharmacy; certificates of registration may be issued only to those hospital pharmacies which satisfy the provisions of all rules of the board and laws of North Dakota.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

**61-07-01-04. Personnel.**

1. **Director.** Each hospital pharmacy must be directed by a pharmacist-in-charge, hereinafter referred to as the director of pharmacy, who is licensed to engage in the practice of pharmacy in this state, and who is knowledgeable in and thoroughly familiar with the specialized functions of hospital pharmacies. The director of pharmacy is responsible for all activities of the hospital pharmacy, and for meeting the requirements of the North Dakota pharmacy practice act and this chapter. Contractual providers of pharmacy services shall meet the same requirements as director of pharmacy services.
2. **Supportive personnel.** The director of a hospital pharmacy must be assisted by a sufficient number of additional pharmacists and ancillary personnel as may be required to operate such pharmacy competently, safely, and adequately to meet the needs of the patients of the hospital.
  - a. Pharmacy technicians may be employed provided they have been approved by the director. The director shall develop and implement written policies and procedures to specify the duties to be performed by such technical personnel. These policies and procedures shall, at a minimum, specify that ancillary technical personnel are properly or adequately supervised by a registered pharmacist and that ancillary technical personnel are not assigned duties which may be performed only by pharmacists.
  - b. Secretarial support should be provided as required to assist with recordkeeping, report submission, and other administrative duties.
3. **Supervision.** All of the activities and operations of each hospital pharmacy must be personally and directly supervised by its director or pharmacist's designee. All functions and activities of ancillary personnel must be personally and directly supervised by a sufficient number of registered pharmacists to ensure that all such functions and activities are performed competently, safely, and without risk of harm to patients.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

**61-07-01-05. Absence of pharmacist.**

1. **General.** During such times as a hospital pharmacy may be unattended by a pharmacist, arrangements must be made in advance by the director for the provision of drugs to the medical staff and other authorized personnel of the hospital, by use of night cabinets or floor stock, or both, and in emergency circumstances, by access to the pharmacy. A pharmacist must be available for consultation during all absences; this protocol can be accomplished by telephone.

2. **Night cabinets.** If night cabinets are used, the following should prevail: absence of a pharmacist, must be by locked cabinets or other enclosures constructed and located outside of the pharmacy area, to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons by force or otherwise. The director shall, in conjunction with the appropriate committee of the hospital, develop inventory listings of those drugs to be included in such cabinets and shall ensure that:
  - a. Such drugs are available therein, properly labeled.
  - b. Only prepackaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements.
  - c. Whenever access to such cabinets shall have been gained, written physician's orders and proofs of use, if applicable, are provided.
  - d. Written policies and procedures are established to implement the requirements of this subsection.
3. **Access to pharmacy.** Whenever any drug is not available from floor supplies or night cabinets, and such drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drug may be obtained from the pharmacy in accordance with the requirements of this section. One supervisory registered professional nurse and only one in any given eight-hour shift is responsible for removing drugs therefrom. The responsible nurse, in times of emergency, may delegate this duty to another nurse. The responsible nurse must be designated by position, in writing, by the appropriate committee of the hospital and, prior to being permitted to obtain access to the pharmacy, shall receive thorough education and training in the proper methods of access, removal of drugs, and records and procedures required. Such education and training must be given by the director of pharmacy, who shall require, at a minimum, the following records and procedures:
  - a. Removal of any drug from the pharmacy by an authorized nurse must be recorded on a suitable form showing patient name, room number, name of drug, strength, amount, date, time, and signature of nurse.
  - b. Such form must be left with the container from which the drug was removed, both placed conspicuously so that it will be found by a pharmacist and checked properly and promptly; or, in the case of a unit dose, place an additional dose of the drug, or the box, on the form.
4. **Emergency kits.** Emergency drugs, as approved by the medical staff, must be in adequate and proper supply in the pharmacy and in designated hospital areas. The pharmacist is responsible both for the contents of emergency medication carts, kits, and for the inspection procedure to be used.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

#### **61-07-01-06. Physical requirements.**

1. **Area.** A hospital pharmacy shall have within the hospital it services, sufficient floor space allocated to it to ensure that drugs are prepared in sanitary, well-lighted, and enclosed places, and which meet the other requirements of this section.
2. **Equipment and materials.** Each hospital pharmacy shall have sufficient equipment and physical facilities for proper compounding, dispensing, and storage of drugs, including parenteral preparations, and, as a minimum, access to the references for the following subjects:
  - a. Drug interactions.
  - b. Drug compatibility.
  - c. Poison and antidote information.
  - d. Chemistry:
    - (1) Organic;
    - (2) Pharmaceutical; and
    - (3) Biological.
  - e. Toxicology.
  - f. Pharmacology.
  - g. Bacteriology.
  - h. Sterilization and disinfection.
  - i. Pharmacy technology.

- j. Patient counseling.
- k. Rational therapy.
- l. Pathology.
- m. Current United States Pharmacopeia and National Formulary dispensing information.
- n. Current state and federal regulations applicable to controlled substances.

The technical equipment required by section 61-02-01-03 may be either at the hospital pharmacy or the community pharmacy servicing the hospital pharmacy.

- 3. **Storage.** All drugs must be stored in designated areas within the hospital pharmacy which are sufficient to ensure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security.
- 4. **Alcohol and flammables.** Alcohol and flammables must be stored in areas that shall meet, at a minimum, basic local building code requirements for the storage of volatiles and such other laws, ordinances, regulations as may apply.
- 5. **Unattended areas.** In the absence of authorized personnel, and whenever any area of a hospital pharmacy is not under the personal and direct supervision of authorized personnel, such area must be locked.
- 6. **Security.** All areas occupied by a hospital pharmacy must be capable of being locked by key or combination, so as to prevent access by unauthorized personnel. The director shall designate, in writing, by title and specific area, those persons who shall have access to particular areas within the pharmacy.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(14)

#### **61-07-01-07. Drug distribution and control.**

- 1. **General.** The director of pharmacy services shall establish written procedures for the safe and efficient distribution of pharmaceutical products. An annual updated copy of such procedures must be on hand for inspections.
- 2. **Responsibility.** The director is responsible for the safe and efficient distribution of, control of, and accountability for drugs. The other professional staff of the hospital shall cooperate with the director in meeting this responsibility and in ordering, administering, and accounting for pharmaceutical materials so as to achieve this purpose. Accordingly, the director is responsible for, at a minimum, the following:
  - a. Preparation and sterilization of parenteral medications manufactured within the hospital.
  - b. Admixture of parenteral products, including education and training of nursing personnel concerning incompatibility and provision of proper incompatibility information when the admixture of parenteral products is not accomplished within the hospital pharmacy.
  - c. Manufacture of drugs, if applicable.
  - d. Establishment of specifications for procurement of all materials, including drugs, chemicals, and biologicals, subject to approval of the appropriate committee of the hospital.
  - e. Participation in development of a formulary for the hospital.
  - f. Filling and labeling all containers from which drugs are to be administered.
  - g. Maintaining and making available a sufficient inventory of antidotes and other emergency drugs, both in the pharmacy and inpatient care areas, as well as current antidote information, telephone numbers of regional poison control centers, and other emergency assistance organizations, and such other materials and information as may be deemed necessary by the appropriate committee of the hospital, if any.
  - h. Records of all transactions of the hospital pharmacy as may be required by applicable law, state and federal, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials.
  - i. Participation in drug usage evaluation activities.
  - j. Full cooperation with teaching or research programs, or both, in the hospital, if any.
  - k. Implementation of the policies and decisions of the appropriate committees of the hospital.
  - l. Effective and efficient messenger and delivery service to connect the pharmacy with appropriate parts of the hospital on a regular basis throughout the normal workday of the hospital.

- m. Meeting all compliance and other requirements of the North Dakota board of pharmacy rules and laws and this chapter.

**3. Labeling.**

- a. For use inside the hospital. All drugs dispensed by a hospital pharmacy, not on an individual prescription, intended for use within the hospital, must be dispensed in appropriate containers and adequately labeled so as to identify, at a minimum, brand name or generic name, strength, quantity, source, and expiration date.
- b. For use outside the pharmacy. All drugs dispensed by a hospital pharmacy to patients about to be discharged or to whom it is certain will carry the item dispensed outside of the hospital, in compliance with pharmacy practice act and rules, must be labeled with the following information:
  - (1) Name, address, and telephone number of the hospital pharmacy.
  - (2) Date and identifying serial number.
  - (3) Full name of patient.
  - (4) Name of drug strength, and number of units.
  - (5) Directions for use to the patients.
  - (6) Name of physician prescribing.
  - (7) Required precautionary information regarding controlled substances.
  - (8) Such other and further accessory cautionary information as may be required or desirable for proper use and safety to the patient.
- c. Drugs added to parenteral admixtures. Whenever any drugs are added to parenteral admixtures, whether within or outside the direct and personal supervision of a pharmacist, such admixtures must be labeled with a distinctive supplementary label indicating the name and the amount of the drug added, date and time of addition and expiration, and name of person so adding.

**4. Discontinued drugs.** The director shall develop and implement policies and procedures to ensure that discontinued and outdated drugs and containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition or that the director or the director's designee make proper disposition or dispose of such drugs at the storage site.

**5. Physician's orders.** Drugs may be dispensed from the hospital pharmacy only upon written or verbal orders, direct copies or facsimiles thereof, of authorized physicians. Verbal orders for drugs are accepted only by personnel so designated in accordance with applicable law and regulations governing such acts and in accordance with the approved medical staff rules and regulations.

- a. Authorization. The appropriate committee of the hospital shall designate, from time to time as appropriate, those physicians who are authorized to issue orders to the pharmacy.
- b. Abbreviations. Orders employing abbreviations and chemical symbols may be utilized and filled only if such abbreviations and symbols appear on a published list of accepted abbreviations developed by the appropriate committee of the hospital.
- c. Requirements - Orders for drugs for use by inpatients. Orders for drugs for use by inpatients shall contain, at a minimum: patient name and room number, drug name, strength, directions for use, date, and physician's signature or that of the physician's authorized representative.
- d. Requirements - Orders for drugs for use by outpatients. Orders for drugs for use by outpatients become prescriptions and must meet all requirements of the law.
- e. Pharmacist review. The pharmacist shall review the prescriber's order, or a direct copy thereof, before the initial dose of medication is dispensed (with the exception of emergency orders when time does not permit). In cases when the medication order is written when the pharmacy is "closed" or the pharmacist is otherwise unavailable, the medication order should be reviewed by the pharmacist as soon thereafter as possible, preferably within twenty-four hours.
- f. Signature. A means of identifying the signatures of all practitioners authorized to use the pharmaceutical services, as well as a listing of their drug enforcement administration numbers, must be maintained.

**6. Controlled drug accountability.** The hospital shall establish effective procedures and maintain adequate records regarding use and accountability of controlled substances and such other drugs as the appropriate hospital committee may designate which may specify at least the following:

- a. Name of drug.
- b. Dose.

- c. Physician.
  - d. Patient.
  - e. Date and time of administration.
  - f. Person administering the drug.
7. **Recall.** The director shall develop and implement a recall procedure that can be readily activated to assure the medical staff of the hospital that all drugs included on the recall, whether within or outside the hospital, are returned to the pharmacy for proper disposition.
  8. **Suspected adverse drug reactions.** Any and all suspected adverse drug reactions must be reported orally immediately to the ordering physician and in writing to the pharmacy, and to the appropriate committee of the hospital. Appropriate entry on the patient's record must also be made. The director may, at the director's discretion, make further reports of such suspected reactions to the hospital reporting program of the United States food and drug administration, to the manufacturer, and to the United States pharmacopeia.
  9. **Records and reports.** The director shall maintain and submit, as appropriate, such records and reports as are required to ensure patient health, safety, and welfare, and, at a minimum, the following:
    - a. Physician's orders, direct copies, or facsimiles thereof.
    - b. Controlled drug accountability report.
    - c. Reports of suspected adverse drug reactions.
    - d. Inventories of night cabinets and emergency kits.
    - e. Inventories of the pharmacy.
    - f. Biennial controlled substances inventories.
    - g. Alcohol and flammables reports.
    - h. Such other and further records and reports as may be required by law and this chapter.
  10. **Distribution systems.**
    - a. Floor or ward stock system. In this system, all but the most unusual drug items are stocked on the nursing stations. Drug products which require special control (e.g., antineoplastic agents) are often omitted from floor stock, and are sent to the nursing unit upon receipt of a prescription order for the individual patient. All containers used for floor stock must meet specific labeling requirements as addressed in these rules.
    - b. Individual prescription order system. In this system, all medications are dispensed by the pharmacist on individual prescription orders.
    - c. Combination of floor stock and the individual prescription order system. In this system, most drugs are dispensed on an individual prescription basis. The remaining drugs are obtained via limited floor stock.
    - d. Unit dose. In this system, medications are contained in single unit packages; they are dispensed in as ready-to-administer form as possible, for most medications. All doses will be labeled properly to include name, strength, expiration date, or lot number or control number, or both.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

**61-07-01-08. Nondistributive roles of the pharmacist.** These functions include, but are not limited to, chart review; audits; clinical tasks; committee participation; drug information; inservice training of the pharmacists, the pharmacy staff, and other health professionals; poison control; nursing unit inspections; preparation of medication histories; monitoring of drug therapy; patient education; detection and reporting of adverse drug reactions; drug therapy selection; participation in drug usage evaluation; and other quality assurance programs.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

#### **61-07-01-09. Administration of drugs.**

1. **General.** Drugs may be administered at a hospital only upon the orders of those members of the medical staff who have been granted clinical privileges or who are authorized members of the house staff and, by authorized licensed hospital personnel in accordance with policies and procedures



specified by the appropriate committee of the facility, under applicable law and rules, and by usual and customary standards of good medical practice.

2. **Self-administration.** Self-administration of drugs by patients may be permitted only when specifically authorized by the treating or ordering physician; provided, however, the patient has been educated and trained in the proper manner of self-administration and there is no risk of harm to the patient or others. The label should contain patient's name, room number, date directions, and name and strength of medication, at a minimum.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

#### **61-07-01-10. Drugs from outside sources.**

1. Outside pharmacies. Whenever drugs or pharmaceutical services are obtained from outside of a hospital, arrangements must be made to ensure that such outside pharmacist provides services with sufficient professionalism, quality, and availability to adequately protect the safety of the patients and to properly serve the needs of the hospital. Such arrangements must be made in writing and must, at a minimum, specify that:
  - a. The outside pharmacist shall act in the capacity of the director (subsection 1 of section 61-07-01-04) and, therefore, is subject to this chapter.
  - b. Such arrangement is contingent upon approval of the board of pharmacy.
  - c. The pharmacist must be available for consultation during all absences, or provide a protocol to contact another pharmacist.
  - d. Adequate storage facilities for drugs will be provided.
  - e. All drugs supplied must be labeled so as to ensure that recalls can be effected and that proper control and supervision of such drugs may be exercised.
2. Brought by patients. Whenever patients bring drugs into a hospital, such drugs may not be administered unless they can be precisely identified; administration must be pursuant to a physician's order only. The director of pharmacy will specify the policy and procedure for handling these medications.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

**61-07-01-11. Quality assurance.** The director of pharmacy services is responsible for developing procedures for an ongoing quality assurance program of pharmaceutical services that includes a mechanism for reviewing and evaluating drug-related patient care, as well as an appropriate response to findings. This written plan should clearly establish responsibility and the need for documentation of an effective program. The director of pharmacy services is responsible for developing procedures for quality assurance in centralized intravenous admixture services. Such procedures must encompass selection, education, and training of personnel, in process controls, end-product testing, and sampling guidelines. Cautionary measures for the safe admixture of parenteral products must be developed.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

**61-07-01-12. Investigational drugs.** Investigational drugs must be properly labeled and may be administered only under the personal and direct supervision of the principal physician-investigator or physician-investigator's authorized clinician with prior approval of the appropriate committees of the hospital. Nurses may administer such drugs only after they have been educated and trained concerning relevant pharmacologic information about such drugs by the clinician or the pharmacist. A central unit must be maintained wherein essential information regarding such drugs may be obtained. Patients' or representatives' informed consent must be obtained prior to investigational drug therapy. Investigational drugs must be stored under the same regulations as Schedule II controlled substances.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

### 61-07-01-13. Inspection.

1. **Monthly.** The director of pharmacy shall inspect, no less than once a month, personally or by qualified designee, all matters within the director's jurisdiction and responsibility and make appropriate written records and notations of such inspections. Such inspections shall verify, at a minimum, that:
  - a. Drugs are dispensed only by pharmacists.
  - b. Ancillary pharmacy personnel are properly directed and supervised.
  - c. Disinfectants and drugs for external use are stored separately and apart from drugs for internal use or injection.
  - d. Drugs requiring special storage conditions to ensure their stability are properly stored.
  - e. Outdated drugs or otherwise unusable drugs have been identified and their distribution and administration prevented. An area must be designated for authorized storage of such drugs prior to their proper disposition.
  - f. Distribution and administration of controlled substances are properly and adequately documented and reported by both pharmacy and medical personnel.
  - g. Emergency drugs designated pursuant to subsection 4 of section 61-07-01-05 are adequate and in proper supply both within the pharmacy and at outside storage locations.
  - h. All necessary and required security and storage standards are met.
  - i. Metric-apothecaries' weight and measure conversion tables and charts are reasonably available to all medical personnel.
  - j. All policies and procedures of the director and of appropriate committees of the hospital relevant to pharmacy are followed.
  - k. The telephone number of the regional poison control information center should be posted by all telephones in the nursing stations where drugs are stored.
2. **Annual.** The board of pharmacy shall inspect, no less than once a year, by one of its members or by its qualified designee, all aspects of the management and operation of all hospital pharmacies in the state, to verify compliance with the law, this chapter, and such other standards as may be appropriate to ensure that the health, safety, and welfare of patients of the hospital serviced by the pharmacy are protected. Written reports of an inspection must be filed with the board and the director. Any discrepancies or deficiencies noted must be corrected within a reasonable time. Written notice of such corrections must be filed with the board. Board recommendations may be questioned by written notice to the executive secretary of the board of pharmacy. Consideration must be given by the board's inspector or designee to giving thirty days' notice of an inspection to the director of the pharmacy to be visited. Consideration must also be given to any recent survey by the joint commission on accreditation of health care organizations.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

### 61-07-01-14. Pharmacist first dose review.

1. A hospital pharmacy must have a pharmacist review all medication order prior to the first dose being administered to the patient. Policies and procedures must be put into place to ensure compliance.
2. Either a pharmacist onsite or the use of hospital telepharmacy services will be sufficient to comply with the requirement.
3. This provision does not apply to the following situations:
  - a. When the physician controls the ordering, dispensing, and administration of the drug, such as in the operating room, endoscopy suite, or emergency room.
  - b. When time does not permit the pharmacist's review, such as with "stat" orders or when the clinical status of the patient would be significantly compromised by the delay resulting from the pharmacist's review of the order.
4. Each hospital pharmacy must be in compliance with this rule by June 30, 2013.

**History:** Effective October 1, 2012.

**General Authority:** NDCC 28-32-02, 43-15-10(9), 43-15-10(14)

**Law Implemented:** NDCC 43-15-10(9), 43-15-10(14)

## ARTICLE 61-08

## OUT-OF-STATE PHARMACIES

### Chapter

#### 61-08-01 Requirements for Out-of-State Pharmacies

### CHAPTER 61-08-01

## REQUIREMENTS FOR OUT-OF-STATE PHARMACIES

### Section

#### 61-08-01-01 Permit

#### 61-08-01-02 Permit Application - Renewal

#### 61-08-01-03 Fees

#### 61-08-01-04 Pharmacy Permit - Home Jurisdiction

#### 61-08-01-05 Applicable Law and Rules

#### 61-08-01-06 Compliance

#### 61-08-01-07 Reporting

#### 61-08-01-08 Administrative Inspection

#### 61-08-01-09 Records

#### 61-08-01-10 Counseling Services

#### 61-08-01-11 Patient Profile Record System and Prescription Drug Information Required

#### 61-08-01-12 Jurisdiction

#### 61-08-01-13 Agent

**61-08-01-01. Permit.** Any pharmacy operating outside the state which ships, mails, or delivers in any manner a dispensed prescription drug or legend drug into North Dakota shall obtain and hold a pharmacy permit issued by the North Dakota state board of pharmacy and that part of the pharmacy operation dispensing the prescription for a North Dakota resident shall abide by state law and rules of the board.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**Law Implemented:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**61-08-01-02. Permit application - Renewal.** Pharmacy permit application forms must be available from the board and submitted for approval. Pharmacy permits must be renewed annually by July first.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**Law Implemented:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**61-08-01-03. Fees.** The out-of-state pharmacy annual permit fee must be set by the board not to exceed three hundred dollars.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**Law Implemented:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**61-08-01-04. Pharmacy permit - Home jurisdiction.** An out-of-state pharmacy doing business in North Dakota by dispensing and delivering prescription drugs to North Dakota consumers shall maintain a document that it has a pharmacy permit in good standing in its respective home jurisdiction.

**History:** Effective April 1, 1988; amended effective January 1, 2005.

**General Authority:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**Law Implemented:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**61-08-01-05. Applicable law and rules.** North Dakota pharmacy laws and rules shall be applicable to control interjurisdictional prescription commerce and to govern the practice of pharmacy for that portion of the pharmacy practice or operation.

**History:** Effective April 1, 1988; amended effective January 1, 2005.

**General Authority:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**Law Implemented:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**61-08-01-06. Compliance.** The pharmacist in charge and pharmacy owner, or partners, or corporate officer and owners where applicable, appearing on the permit or the permittee will be responsible for complete

compliance with the North Dakota laws or rules insofar as the standards of practice for the pharmacy operation pertaining to the provisions of receiving, dispensing, and delivering prescription drugs to North Dakota.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**Law Implemented:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**61-08-01-07. Reporting.** The pharmacist in charge appearing on the permit shall submit an affidavit with the initial permit application and renewal applications annually which affirm that the pharmacist understands North Dakota pharmacy laws and rules and that the pharmacy is in complete compliance with applicable standards of care when dispensing prescription orders for delivery to North Dakota consumers. The out-of-state pharmacy shall also disclose the pharmacist in charge and location, names, and titles of all principal corporate officers and all pharmacists who are dispensing prescription drugs to residents of this state. This disclosure must be on an annual basis.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**Law Implemented:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**61-08-01-08. Administrative inspection.** North Dakota pharmacy inspectors may conduct onsite periodic routine inspections during reasonable business hours of out-of-state pharmacies registered to do business in North Dakota. Alternatively, the North Dakota board of pharmacy may contract with the respective out-of-state regulatory authorities to conduct and perfect periodic routine inspections.

1. To obtain a license as a nonresident pharmacy, an applicant shall:
  - a. Have submitted an application form prescribed by the board as required under section 61-08-01-02; and
  - b. Have paid the fees specified by the board for the issuance of the license as specified in article 61-11.
2. The pharmacy owner, if an individual, and principals and owners who directly or indirectly own greater than ten percent interest in the company, if the company is not publically held, shall have undergone a state and federal fingerprint-based criminal background check as specified by the board.
3. The facility shall be inspected in a manner and frequency prescribed by the board:
  - a. For nonresident pharmacies that prepare and ship sterile or nonsterile compounded products, or sterile and nonsterile compounded products into this state, the facility must be inspected at least once every twelve months by:
    - (1) The board or its duly authorized agent; or
    - (2) A duly authorized agent of a third party approved by the board which is the national association of boards of pharmacy verified pharmacy program.
  - b. For nonresident pharmacies that do not ship sterile and nonsterile compounded products into this state, the facility must be inspected at least once every two years by:
    - (1) The resident state board of pharmacy, if the resident board's inspection is substantially equivalent to the inspection in this state;
    - (2) The board or its duly authorized agent; or
    - (3) A duly authorized agent of a third party approved by the board, which is the national association of boards of pharmacy verified pharmacy program.
  - c. Nonresident pharmacies that dispense more than twenty-five percent of the pharmacy's total prescription volume as a result of original prescriptions or refills solicited through the internet, must be accredited by:
    - (1) The national association of boards of pharmacy verified internet pharmacy practice sites program; or
    - (2) The national association of boards of pharmacy veterinary verified internet pharmacy practice sites program.
  - d. Costs for inspections conducted by the board or an approved third party will be paid by the applicant.

4. At the time of renewal, the nonresident pharmacy shall:
  - a. Submit an application form prescribed by the board;
  - b. Provide proof of a recent inspection as outlined in subsection 3; and
  - c. Submit the national association of boards of pharmacy e-profile identification (NABP e-Profile ID) of the pharmacy and pharmacist-in-charge.
5. The board may waive the requirement for a separate criminal background check in subsection 2. If the nonresident pharmacy is a current participant in a pharmacy verification program that provides complete and accurate owner criminal background screening and licensure, disciplinary, and inspection information to the state board of pharmacy, this requirement may also be waived.
6. Any new applicant or renewal application received after July 1, 2015, shall hold the required accreditation from the national association of boards of pharmacy.

**History:** Effective April 1, 1988; amended effective January 1, 2005; October 1, 2014.

**General Authority:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**Law Implemented:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**61-08-01-09. Records.** Prescription records documenting prescriptions dispensed and distributed to North Dakota consumers must be readily retrievable and available for board review. North Dakota prescription orders, when initially dispensed, must be separated or readily retrievable or stamped in the lower left-hand corner of the order form face with a one-inch [25.40-millimeters] green letter "ND" or separate prescription files.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**Law Implemented:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**61-08-01-10. Counseling services.** Out-of-state pharmacies shall provide accessible telephone counseling service for patients' drug inquiries with a licensed pharmacist during regular working hours. Available telephone counseling service must be provided that is consistent with the standard of due care. The pharmacies' telephone number will be prominently identified and affixed on the prescription container label.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**Law Implemented:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**61-08-01-11. Patient profile record system and prescription drug information required.** An out-of-state pharmacy shall comply with the patient profile record system requirements of North Dakota Century Code section 43-15-31.1 and the prescription drug information requirements of North Dakota Century Code section 43-15-31.2 for that part of the pharmacy operation dispensing a prescription for a North Dakota resident.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**Law Implemented:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**61-08-01-12. Jurisdiction.** Out-of-state pharmacies soliciting, receiving, and dispensing prescription orders delivered to North Dakota ultimate residents constitutes doing business in the state.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**Law Implemented:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**61-08-01-13. Agent.** The out-of-state pharmacies doing business in North Dakota by dispensing and delivering prescription orders to North Dakota consumers shall designate a resident agent and a registered office in North Dakota for the service of process.

**History:** Effective April 1, 1988.

**General Authority:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

**Law Implemented:** NDCC 28-32-02, 43-15-10(7)(8)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36, 43-15-38

## ARTICLE 61-09

### PRESCRIPTION DRUG INVENTORY OF AMBULANCE SERVICES

## Chapter

61-09-01 Prescription Drug Inventory of Ambulance Services

61-09-02 Prescription Drug Inventory of Nursing Supply Kits

**CHAPTER 61-09-01****PRESCRIPTION DRUG INVENTORY OF AMBULANCE SERVICES**

## Section

61-09-01-01 Prescription Drug Safeguard and Control Policy

61-09-01-02 Requirement of Pharmacy Supplier of Ambulance Service Drugs

**61-09-01-01. Prescription drug safeguard and control policy.** Each ambulance service shall adopt a written prescription drug safeguard policy which, as a condition precedent to obtaining prescription drugs for ambulance service purposes, at a minimum, must include the following requirements:

1. All prescription drugs must be obtained from a North Dakota licensed pharmacy, wholesaler, or authorized prescriber, at the request of the ambulance service's medical director or designee. The prescription drugs must be the property of the pharmacy or medical director and not the property of the ambulance service.
2. The initial inventory of prescription drugs must be obtained by an ambulance service only upon the written authorization of the ambulance service's medical director who must be a "practitioner" as defined by subsection 17 of North Dakota Century Code section 43-15-01.
3. The pharmacist-in-charge of the licensed pharmacy, a licensed pharmacist, or the medical director must be responsible for the security and accountability of the prescription drug inventory obtained by an ambulance service.
4. Dispensing or administration of all prescription drugs must be pursuant to a standing order, oral instructions, or prescription of a practitioner.
5. All medications administered must be promptly documented on a patient care report, reviewed by the ambulance service's medical director on a monthly basis either directly or indirectly through a quality assurance process approved by the medical director.
6. Replenishment of prescription drugs must be requested by a responsible individual. If obtained from a pharmacy, the request must be documented on an administration record justifying the order.
7. If obtained by, or on behalf of, the medical director, drugs must be obtained from a North Dakota licensed pharmacy, a wholesaler, or an authorized prescriber.
8. Expired, damaged, or unused prescription drugs must be returned to the licensed pharmacy where obtained or disposed of by the medical director or the medical director's designee, according to a written protocol established for this purpose.
9. Lost, stolen, or misused prescription drugs must be reported to the ambulance service's medical director or the pharmacy where they were obtained.
10. The licensed ambulance service must have a process, approved by the ambulance service's medical director, or pharmacist-in-charge where the drugs were obtained that accounts for all schedule II, III, and IV controlled substances, at least daily. The daily accounting of schedule II controlled substances must balance and be documented on a daily log.
11. Controlled substances must be sealed in a double lock secure system. A record separate from the other prescription drugs is to be kept for schedule II controlled substances. A system approved by the ambulance service's medical director to account for the use and waste of schedule II, III, and IV controlled substances must be used. The system must include:
  - a. Patient's name and address (if available);
  - b. Medication and strength or amount given and amount wasted (if any);
  - c. Date;
  - d. Physician's name; and
  - e. The signature of the individual administering the controlled substance.
12. Any unused portion of a prescription drug must be disposed of in a manner that it cannot be collected or recovered. The disposal of all controlled substances must be witnessed and cosigned by another person legally qualified to administer controlled substances.

**History:** Effective July 1, 1990; amended effective October 1, 2012.

**General Authority:** NDCC 28-32-02, 43-15-10(12), 43-15-10(14)

**Law Implemented:** NDCC 28-32-03, 43-15-10 (12), 43-15-10 (14)

**61-09-01-02. Requirement of pharmacy supplier of ambulance service drugs.** The pharmacist-in-charge of the licensed pharmacy or the pharmacist supplying prescription drugs to an ambulance service, prior to supplying said drugs, shall review the written prescription drug safeguard policy of the ambulance service to determine that all of section 61-09-01-01 requirements are contained therein and that the ambulance service is complying with those requirements. No prescription drugs may be supplied to an ambulance service if the requirements of section 61-09-01-01 are not contained in the written prescription drug safeguard policy or if the ambulance service is not in compliance with these requirements.

**History:** Effective July 1, 1990; amended effective October 1, 2012.

**General Authority:** NDCC 28-32-02, 43-15-10(12), 43-15-10(14)

**Law Implemented:** NDCC 28-32-03, 43-15-10(12), 43-15-10(14)

## **CHAPTER 61-09-02**

### **PRESCRIPTION DRUG INVENTORY OF NURSING SUPPLY KITS**

#### Section

61-09-02-01 Prescription Safeguard and Control Policy

61-09-02-02 Requirements of Suppliers of Nursing Supply Kits

**61-09-02-01. Prescription safeguard and control policy.** Each home health care agency, hospital, health system, or pharmacy serving at-home patients shall adopt a written prescription drug safeguard policy and procedures which, as a condition precedent to obtaining prescription drugs for nursing supply kits, at a minimum, must include the following requirements:

1. All prescription drugs must be obtained from a licensed pharmacy or licensed pharmacist, which may include a hospital pharmacy. The prescription drugs must be the property of the pharmacy or pharmacist and not the property of the nurse, nursing agency, or home health care agency.
2. The pharmacy from which the drugs are obtained shall maintain ownership and be responsible for the medications and supplies in the nursing supply kit.
  - a. Each supply kit must be sealed with a tamperproof seal to ascertain entry.
  - b. Each kit must be delivered to and under the control of a registered nurse. Each kit must have a number which must be designated to a registered nurse.
  - c. Each kit must be labeled on the outside of the container with a list of drugs and supplies.
3. All drugs must be stored at proper temperature and conditions as required.
4. All drugs and supplies must be replaced within seventy-two hours of use and a tamperproof seal must be applied to the kit.
5. The nursing supply kit may contain a specified list of drugs which meet the needs of the nursing personnel for emergency care and maintenance of their patients' at-home therapy. This list should be specific and included in the safeguard policy and procedures. These safeguard policy and procedures should be maintained as part of the nursing agency's and pharmacy's policy and procedures.
6. Drugs and supplies in the kits must be checked by pharmacy staff for outdates at least quarterly. Tamperproof seals must be inspected, documented, and records maintained in the pharmacy.
7. The pharmacy must be furnished with a copy of each prescriber's prescription order or reference to approved protocols to be used as a prescription before prescription drug replacement.
8. Any unused portion of a prescription drug must be returned for disposal or destruction to the pharmacy supplying prescription drugs to the nurse or nursing agency. The return of the unused prescription drug should be documented in writing at the pharmacy by the nurse, cosigned by a licensed pharmacist, and witnessed by one other person.

**History:** Effective October 1, 1999.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 28-32-02, 43-15-10

**61-09-02-02. Requirements of suppliers of nursing supply kits.** The pharmacist-in-charge of the licensed pharmacy or the pharmacist supplying prescription drugs to a nurse or nursing agency, prior to supplying said drugs, shall review the written prescription drug safeguard policy and procedures of the nurse or nursing agency to determine that all of section 61-09-02-01 requirements are contained therein and that the nurse or nursing agency is complying with those requirements. No prescription drug may be supplied to a nurse or nursing agency if the requirements of section 61-09-02-01 are not contained in the written prescription drug safeguard policy and procedures or if the nurse or nursing agency is not in compliance with these requirements.

**History:** Effective October 1, 1999.

**General Authority:** NDCC 28-32-02, 43-15-10

**Law Implemented:** NDCC 28-32-02, 43-15-10

## ARTICLE 61-10 WHOLESALE DRUG DISTRIBUTORS

Chapter

61-10-01 Wholesale Drug Distributors

### CHAPTER 61-10-01 WHOLESALE DRUG DISTRIBUTORS

Section

61-10-01-01 Scope

61-10-01-02 Purpose

61-10-01-03 Definitions

61-10-01-04 Wholesale Drug Distributor Licensing Requirement

61-10-01-05 Minimum Required Information for Licensure

61-10-01-06 Minimum Qualifications

61-10-01-07 Personnel

61-10-01-08 Violations and Penalties

61-10-01-09 Minimum Requirements for the Storage and Handling of Prescription Drugs and for the Establishment and Maintenance of Prescription Drug Distribution Records

**61-10-01-01. Scope.** This article applies to any person, partnership, corporation, or business firm engaging in the wholesale distribution of any prescription drugs in the state of North Dakota.

**History:** Effective June 1, 1992.

**General Authority:** NDCC 43-15.1-07

**Law Implemented:** NDCC 43-15.1

**61-10-01-02. Purpose.** The purpose of this article is to implement the Prescription Drug Marketing Act of 1987 by providing minimum standards, terms, and conditions for the licensing by the North Dakota state board of pharmacy of persons who engage in wholesale distribution in the state of North Dakota of any prescription drugs.

**History:** Effective June 1, 1992.

**General Authority:** NDCC 43-15.1-07

**Law Implemented:** NDCC 43-15.1; 21 USC 353(e)

**61-10-01-03. Definitions. As used in this article:**

1. "Article" or "this article" means all of the terms and provisions contained in article 61-10, including sections 61-10-01-01 through 61-10-01-09, inclusive, and any amendments or additions to said article or any of said sections.
2. "Board of pharmacy" means the North Dakota state board of pharmacy.
3. "Blood" means whole blood collected from a single donor processed either for transfusion or further manufacturing.
4. "Blood component" means that part of blood separated by physical or mechanical means.
5. "Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.



6. "Manufacturer" is defined as provided in subsection 2 of North Dakota Century Code section 43-15.1-01.
7. "Prescription drug" is defined as provided in subsection 4 of North Dakota Century Code section 43-15.1-01.
8. "Wholesale drug distribution" is defined as provided in subsection 5 of North Dakota Century Code section 43-15.1-01, provided that:
  - a. Concerning the exclusion from the definition of "wholesale drug distribution" for "intracompany sale" set forth in subdivision a of subsection 5 of North Dakota Century Code section 43-15.1-01, such "sale" includes any transaction or transfer between any division, subsidiary, parent, and/or affiliated or related company under common ownership and control of a corporate entity.
  - b. For purposes of subdivision a of this subsection and subdivision d of subsection 5 of North Dakota Century Code section 43-15.1-01, "common control" means the power to direct or cause the direction of the management and policies of a person or organization, whether by ownership by stock, voting rights, by contract, or otherwise.
  - c. For purposes of subdivision e of subsection 5 of North Dakota Century Code section 43-15.1-01, "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, except that the gross dollar value of such transfers may not exceed five percent of the total prescription drug sales revenue of either the transferor or transferee retail pharmacy during any twelve-consecutive-month period.
  - d. "Wholesale drug distribution" does not include the sale, purchase, or trade of blood and blood components intended for transfusion.
9. "Wholesale drug distributor" is defined as provided in subsection 6 of North Dakota Century Code section 43-15.1-01.

**History:** Effective June 1, 1992.

**General Authority:** NDCC 43-15.1-07

**Law Implemented:** NDCC 43-15.1

**61-10-01-04. Wholesale drug distributor licensing requirement.** Every wholesale drug distributor whether located in this state or any other state or foreign territory who engages in wholesale drug distribution of any prescription drugs in the state of North Dakota must be licensed by the board of pharmacy in accordance with this article and North Dakota Century Code chapter 43-15.1 before engaging in wholesale distribution of any prescription drugs in the state of North Dakota.

**History:** Effective June 1, 1992.

**General Authority:** NDCC 43-15.1-07

**Law Implemented:** NDCC 43-15.1-04, 43-15.1-05

**61-10-01-05. Minimum required information for licensure.**

1. Each wholesale drug distributor shall provide to the board of pharmacy the following minimum information as part of the application for the license described in this article or North Dakota Century Code chapter 43-15.1 and as part of any application for renewal of such license:
  - a. The name, full business address, and telephone number of the licensee;
  - b. All trade or business names used by the licensee;
  - c. Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs;
  - d. The type of ownership or operation, i.e., partnership, corporation, or sole proprietorship; and
  - e. The names of the owner or operator, or both, of the licensee, including:
    - (1) If a person, the name of the person;
    - (2) If a partnership, the name of each partner, and the name of the partnership;
    - (3) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and
    - (4) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

2. The board of pharmacy may provide for a single license for a business entity operating more than one facility within the state, or for a parent entity with divisions, subsidiaries, and/or affiliate companies within the state when operations are conducted at more than one location and there exists joint ownership and control among all the entities.
3. Changes in any information in subsection 1 must be submitted to the board of pharmacy by the licensee within thirty days of any change.

**History:** Effective June 1, 1992.

**General Authority:** NDCC 43-15.1-07

**Law Implemented:** NDCC 43-15.1-04, 43-15.1-05, 43-15.1-06

**61-10-01-06. Minimum qualifications.**

1. The board of pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications for licensure of persons who engage in wholesale distribution of prescription drugs within the state of North Dakota:
  - a. Any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
  - b. Any felony convictions of the applicant under federal, state, or local laws;
  - c. The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;
  - d. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;
  - e. Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;
  - f. Compliance with licensing requirements under previously granted licenses, if any;
  - g. Compliance with requirements to maintain or make available to the board of pharmacy or to federal, state, or local law enforcement officials, or both, those records required under this section;
  - h. Any other factors or qualifications the board of pharmacy considers relevant to and consistent with the public health and safety; and
  - i. Other factors or requirements contained in subsection 5 of North Dakota Century Code section 43-15.1-04.
2. The board of pharmacy has the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest. Public interest considerations must be based on factors and qualifications that are directly related to the protection of the public health and safety.

**History:** Effective June 1, 1992.

**General Authority:** NDCC 43-15.1-07

**Law Implemented:** NDCC 43-15.1-04, 43-15.1-05

**61-10-01-07. Personnel.** As a condition for receiving and retaining a wholesale drug distributor license, the licensee shall require each person employed in any prescription drug wholesale distribution activity to have education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety, and security will at all times be maintained as required by law.

**History:** Effective June 1, 1992.

**General Authority:** NDCC 43-15.1-07

**Law Implemented:** NDCC 43-15.1-04, 43-15.1-05

**61-10-01-08. Violations and penalties.**

1. The board of pharmacy has the authority to restrict or suspend any licenses granted under this article or pursuant to North Dakota Century Code chapter 43-15.1 upon conviction of any violation of federal, state, or local drug laws or regulations which constitutes a clear and present danger to the public health and safety in the state of North Dakota. Before any license may be restricted or suspended, a wholesale distributor has a right to prior notice and a hearing pursuant to North Dakota Century Code chapter 28-32.

2. The board of pharmacy may restrict or suspend any license granted under this article and North Dakota Century Code chapter 43-15.1 for willful and serious violations of this article which constitute a clear and present danger to the public health and safety in the state of North Dakota in the manner provided in subsection 1.

**History:** Effective June 1, 1992.

**General Authority:** NDCC 43-15.1-07

**Law Implemented:** NDCC 43-15.1-08

**61-10-01-09. Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.** The following constitutes minimum requirements for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their officers, agents, representatives, and employees:

1. **Facilities.** All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:
  - a. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
  - b. Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
  - c. Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;
  - d. Be maintained in a clean and orderly condition; and
  - e. Be free from infestation by insects, rodents, birds, or vermin of any kind.
2. **Security.**
  - a. All facilities used for wholesale drug distribution must be secure from unauthorized entry.
    - (1) Access from outside the premises must be kept to a minimum and be well-controlled.
    - (2) The outside perimeter of the premises must be well-lighted.
    - (3) Entry into areas where prescription drugs are held must be limited to authorized personnel.
  - b. All facilities must be equipped with an alarm system to detect entry after hours.
  - c. All facilities must be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system must provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
3. **Storage.** All prescription drugs must be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary.
  - a. If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.
  - b. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs, or combination thereof, must be utilized to document proper storage of prescription drugs.
  - c. The recordkeeping requirements in subsection 6 must be followed for all stored drugs.
4. **Examination of materials.**
  - a. Upon receipt, each outside shipping container must be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
  - b. Each outgoing shipment must be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.
  - c. The recordkeeping requirements in subsection 6 must be followed for all incoming and outgoing prescription drugs.

## 5. **Returned, damaged, and outdated prescription drugs.**

- a. Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.
- b. Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used must be identified as such, and must be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.
- c. If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug must be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.
- d. The recordkeeping requirements in subsection 6 must be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

## 6. **Recordkeeping.**

- a. Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records must include the following information:
  - (1) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;
  - (2) The identity and quantity of the drugs received and distributed or disposed of; and
  - (3) The dates of receipt and distribution or other disposition of the drugs.
- b. Inventories and records must be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two years following disposition of the drugs.
- c. Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable must be made available for inspection within three business days of a request by an authorized official of a federal, state, or local law enforcement agency.

## 7. **Written policies and procedures.** Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which must be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors must include in their written policies and procedures the following:

- a. A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.
- b. A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure must be adequate to deal with recalls and withdrawals due to:
  - (1) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the board of pharmacy;
  - (2) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or
  - (3) Any action undertaken to promote public health and safety by replacement of existing merchandise with an improved product or new package design.
- c. A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

- d. A procedure to ensure that any outdated prescription drugs must be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure must provide for written documentation of the disposition of outdated prescription drugs. This documentation must be maintained for two years after disposition of the outdated drugs.
8. **Responsible persons.** Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.
9. **Compliance with federal, state, and local law.** Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.
  - a. Wholesale drug distributors shall permit the board of pharmacy's authorized personnel and authorized federal, state, and local law enforcement officials, to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. Such officials are required to show appropriate identification prior to being permitted access to wholesale drug distributors' premises and delivery vehicles.
  - b. Wholesale drug distributors that deal in controlled substances shall register with the North Dakota controlled substances board and with the drug enforcement administration, and shall comply with all applicable state, local, and drug enforcement administration regulations.
10. **Salvaging and reprocessing.** Wholesale drug distributors are subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including all applicable provisions of this article.

**History:** Effective June 1, 1992.

**General Authority:** NDCC 43-15.1-07

**Law Implemented:** NDCC 43-15.1-04, 43-15.1-05

## ARTICLE 61-11 FEES

Chapter  
61-11-01 Fees

### CHAPTER 61-11-01 FEES

Section  
61-11-01-01 Fees

#### **61-11-01-01. Fees. The following fees must be paid to the board of pharmacy:**

- |  |          |
|--|----------|
| 1. North Dakota examination  | \$100.00 |
| 2. Original or duplicate certificate   | 25.00    |
| 3. Reciprocal licensure  | 150.00   |
| 4. a. Internship licensure - North Dakota State University professional student<br>(\$90 is paid to the NDSU College of Pharmacy for student programs) | 100.00   |
| b. Internship licensure - Pre-pharmacy students  | 10.00    |
| 5. Manufacturer-distributor-warehouse-reverse distributor-wholesale drug license   |          |
| Chain drug warehouse   | 200.00   |
| Chain pharmacy warehouse   | 200.00   |
| Hospital offsite warehouse   | 200.00   |
| Jobber or broker   | 400.00   |
| Manufacturer   | 400.00   |
| Own label distributor  | 400.00   |
| Pharmacy distributor   | 200.00   |
| Private label distributor  | 400.00   |
| Repackager   | 400.00   |
| Reverse distributor  | 200.00   |
| Third-party logistic provider  | 400.00   |
| Veterinary-only distributor  | 200.00   |

Virtual manufacturer	400.00
Virtual wholesaler or distributor	400.00
Wholesaler or distributor	400.00
Penalty for late renewal	50.00
6. Pharmacy or drug store permit	175.00
Permitting in additional classes	0.00
Penalty for late renewal	50.00
7. Annual renewal for pharmacist in state (active)	100.00
Penalty for late renewal	25.00
8. Annual renewal for pharmacist in state (inactive status)	75.00
Penalty for late renewal	25.00
9. Annual renewal for pharmacist out of state	35.00
Penalty for late renewal	25.00
10. Annual registration for pharmacy technician	35.00
(\$17.50 is forwarded to the Northland Association of Pharmacy Technicians (NAPT))	
Penalty for late renewal	10.00
11. Pharmacy technician-in-training (per year)	10.00
(two years allowed to complete a program)	
12. License verifications (self-addressed return envelope)	25.00

**History:** Effective January 1, 2006; amended effective October 1, 2010; July 1, 2011; October 1, 2014.

**General Authority:** NDCC 43-15-10

**Law Implemented:** NDCC 43-15-10, 43-15-18, 43-15-20, 43-15-25, 43-15-27, 43-15-34, 43-15-38, 43-15.1-04, 43-15.1-05, 43-15.3-01, 43-15.3-12

## ARTICLE 61-12 PRESCRIPTION DRUG MONITORING PROGRAM

### Chapter

#### 61-12-01 Prescription Drug Monitoring Program

## CHAPTER 61-12-01 PRESCRIPTION DRUG MONITORING PROGRAM

### Section

#### 61-12-01-01 Definitions

#### 61-12-01-02 Dispenser Reporting

#### 61-12-01-03 Operation of Program

#### 61-12-01-04 Required Use of Certain Dispensing Situations

**61-12-01-01. Definitions.** For purposes of this chapter:

1. "Board" means the North Dakota board of pharmacy.
2. "Central repository" means a place where electronic data related to the prescribing and dispensing of controlled substances is collected.
3. "Controlled substance" means a drug, substance, or immediate precursor in schedules I through V as set out in North Dakota Century Code chapter 19-03.1 and any other drugs required by law to be monitored by the program.
4. "De-identified information" means health information that is not individually identifiable information because an expert has made that determination under title 45, Code of Federal Regulations, section 164.514, or direct identifiers and specified demographic information have been removed in accordance with the requirements of that section.
5. "Department" means the North Dakota department of human services.
6. "Dispense" means to deliver a controlled substance to an ultimate user by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for delivery.

7. "Dispenser" means an individual who delivers a controlled substance to the ultimate user, but does not include:
  - a. A licensed hospital pharmacy that provides a controlled substance for the purpose of inpatient hospital care; or
  - b. A licensed health care practitioner or other authorized individual in those instances when the practitioner administers a controlled substance to a patient. For purposes of this section, administer means the direct application of a controlled substance to the body of a patient and does not include the prescribing of a controlled substance for administration by the patient or someone other than the health care practitioner.
8. "Individually identifiable health information" has the meaning set forth in title 45, Code of Federal Regulations, section 160.103.
9. "Patient" means an individual or the owner of an animal who is the ultimate user of a controlled substance for whom a prescription is issued and for whom a controlled substance is dispensed.
10. "Prescriber" 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.
11. "Program" means the North Dakota prescription drug monitoring program implemented under North Dakota Century Code chapter 19-03.5.

**History:** Effective December 1, 2006.

**General Authority:** NDCC 19-03.5

**Law Implemented:** NDCC 19-03.5

#### **61-12-01-02. Dispenser reporting.**

1. Each dispenser licensed by a regulatory agency in the state of North Dakota who dispenses a controlled substance to a patient shall submit to the central repository by electronic means information regarding each prescription dispensed for a controlled substance. The information submitted for each prescription shall include all of the data elements in the American society for automation in pharmacy rules-based standard implementation guide for prescription monitoring programs issued September 2011, version 4, release 2.
2. Each dispenser shall submit the information required by this chapter to the central repository at least once every day unless the board waives this requirement for good cause shown by the dispenser.
3. An extension of the time in which a dispenser must report the information required by this chapter may be granted to a dispenser that is unable to submit prescription information by electronic means if:
  - a. The dispenser suffers a mechanical or electronic failure or cannot report within the required time for other reasons beyond the dispenser's control; or
  - b. The central repository is unable to receive electronic submissions.

**History:** Effective December 1, 2006; amended effective October 1, 2014.

**General Authority:** NDCC 19-03.5

**Law Implemented:** NDCC 19-03.5

#### **61-12-01-03. Operation of program.**

1. The board may charge a fee to an individual who requests the individual's own information from the central repository.
2. The board may charge a fee to a person who requests statistical, aggregate, or other de-identified information.

**History:** Effective December 1, 2006.

**General Authority:** NDCC 19-03.5

**Law Implemented:** NDCC 19-03.5

#### **61-12-01-04. Required use for certain dispensing situations.**

1. Prior to dispensing a prescription, each dispenser licensed by a regulatory agency in the state of North Dakota who dispenses a controlled substance to a patient, for the treatment of pain or anxiety shall, at a minimum, request and review a prescription drug monitoring report covering at least a one-year time period or another state's report, or both reports, when applicable and available, if the dispenser becomes aware of a person currently:
  - a. Receiving reported drugs from multiple prescribers;

- b. Receiving reported drugs for more than twelve consecutive weeks;
  - c. Abusing or misusing reported drugs (i.e., over-utilization; early refills; appears overly sedated or intoxicated upon presenting a prescription for a reported drug; or an unfamiliar patient requesting a reported drug by specific name, street name, color, or identifying marks);
  - d. Requesting the dispensing of a reported drug from a prescription issued by a prescriber with whom the dispenser is unfamiliar (i.e., the prescriber is located out-of-state or the prescriber is outside the usual pharmacy geographic prescriber care area); or
  - e. Presenting a prescription for reported drugs when the patient resides outside the usual pharmacy geographic patient population.
2. After obtaining an initial prescription drug monitoring report on a patient, a dispenser shall use professional judgment based on prevailing standards of practice in deciding the frequency of requesting and reviewing further prescription drug monitoring reports or other state's reports, or both reports, for that patient.
  3. In the rare event a report is not immediately available, the dispenser shall use professional judgment in determining whether it is appropriate and in the patient's best interest to dispense the prescription prior to receiving and reviewing a report.
  4. For the purpose of compliance with subsection 1, a report could be obtained through a prescription drug monitoring program integration with software or also a board-approved aggregate tool, for which the NARxCHECK will be an approved tool. The national association of boards of pharmacy foundation's NARxCHECK service is a risk assessment tool for health care providers and pharmacists that accesses patient prescription information from prescription drug monitoring databases, analyzes the data, and provides a risk-based score that includes prescription drug monitoring program data and graphical analysis to assist in prescribing and dispensing decisions.

**History:** Effective October 1, 2014.

**General Authority:** NDCC 19-03.5, 19-03.5-09, 43-15-10(12)

**Law Implemented:** NDCC 19-03.5

## ARTICLE 61-13 CONTROLLED SUBSTANCES

### Chapter

#### 61-13-01 Controlled Substances Schedules

### CHAPTER 61-13-01 CONTROLLED SUBSTANCES SCHEDULES

#### Section

##### 61-13-01-01 Purpose and Scope

##### 61-13-01-02 Definitions

##### 61-13-01-03 Scheduling

**61-13-01-01. Purpose and scope.** The purpose of this chapter is to schedule substances which have an actual or relative potential for abuse and which bear risk to the public health by unknown individuals using them by inhaling the smoke or vapors or by ingesting or injecting the substances.

**History:** Effective February 26, 2010.

**General Authority:** NDCC 19-03.1-02, 19-03.1-05

**Law Implemented:** NDCC 19-03.1-02

**61-13-01-02. Definitions.** The definitions under this rule have the meaning as set forth in North Dakota Century Code chapters 19-03.1 and 43-15.

**History:** Effective February 26, 2010.

**General Authority:** NDCC 19-03.1-02, 19-03.1-05

**Law Implemented:** NDCC 19-03.1-02

#### **61-13-01-03. Scheduling.**

1. The following substances are hereby placed in schedule I of the Controlled Substances Act, North Dakota Century Code section 19-03.1-05, schedule I, subsection 5, hallucinogenic substances:



- a. CP 47,497 and homologues 2-[(1R,3S)-hydroxycyclohexyl]-5-(2-methyloctan-2-yl)phenol).
- b. HU-210[(6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10, 10a-tetrahydrobenzo[c] chromen-1-ol)].
- c. HU-211 (dexanabinol, (6aS,10aS)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl) (-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol).
- d. JWH-018 1-Pentyl-3(1-naphthoyl)indole.
- e. JWH-073 1-Butyl-3-(1-naphthoyl)indole.
- f. Cannabinoids, synthetic: it includes the chemicals and chemical groups listed below, including their homologues, salts, isomers, and salts of isomers. The term "isomer" includes the optical, position, and geometric isomers.
  - (1) Naphthoylindoles. Any compound containing a 3-(1-naphthoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, or (tetrahydropyran-4-yl)methyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent.
  - (2) Naphthylmethylindoles. Any compound containing a 1H-indol-3-yl-(1-naphthyl) methane structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, or (tetrahydropyran-4-yl)methyl group whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent.
  - (3) Naphthoylpyrroles. Any compound containing a 3-(1-naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, or (tetrahydropyran-4-yl)methyl group whether or not further substituted in the pyrrole ring to any extent, whether or not substituted in the naphthyl ring to any extent. Examples include: (5-(2-fluorophenyl)-1-pentylpyrrol-3-yl)-naphthalen-1-ylmethanone - Other names: JWH-307
  - (4) Naphthylmethylindenes. Any compound containing a naphthylideneindene structure with substitution at the 3-position of the indene ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, or (tetrahydropyran-4-yl)methyl group whether or not further substituted in the indene ring to any extent, whether or not substituted in the naphthyl ring to any extent. Examples include: E-1-[1-(1Naphthalenylmethylene)-1H-inden-3-yl]pentane - Other names: JWH-176.
  - (5) Phenylacetylindoles. Any compound containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, or (tetrahydropyran-4-yl)methyl group whether or not further substituted in the indole ring to any extent, whether or not substituted in the phenyl ring to any extent.
  - (6) Cyclohexylphenols. Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, or (tetrahydropyran-4-yl)methyl group whether or not substituted in the cyclohexyl ring to any extent.
  - (7) Benzoylindoles. Any compound containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, or (tetrahydropyran-4-yl)methyl group whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent.

- (8) Tetramethylcyclopropanoylindoles. Any compound containing a 3-tetramethylcyclopropanoylindole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, or (tetrahydropyran-4-yl)methyl group whether or not further substituted in the indole ring to any extent and whether or not substituted in the tetramethylcyclopropanoyl ring to any extent.
- (1-Pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone - Other names: UR-144.
  - (1-(5-fluoropentyl)indol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone - Other names: XLR-11.
  - (1-(2-morpholin-4-ylethyl)-1H-indol-3-yl)-(2,2,3,3-tetra methylcyclopropyl)methanone  
Other names: A-796,260.
- (9) Others specifically named:
- 1-[(N-methylpiperidin-2-yl)methyl]-3-(adamant-1- oyl) indole - Other names: AM-1248.
  - N-Adamantyl-1-pentyl-1H-indole-3-carboxamide Other names: JWH-018 adamantyl carboxamide.
  - N-Adamantyl-1-fluoropentylindole-3-carboxamide Other names: STS-135.
  - N-Adamantyl-1-pentyl-1H-Indazole-3-carboxamide Other names: AKB 48.
  - 1-Pentyl-3-(1-adamantoyl)indole - Other names: AB-001 and JWH-018 adamantyl analog.
  - Naphthalen-1-yl-(4-pentyloxynaphthalen-1yl)methanone - Other names: CB-13.
- g. Substituted phenethylamines. This includes any compound, unless specifically excepted, specifically named in this schedule, or listed under a different schedule, structurally derived from phenylethan-2-amine by substitution on the phenyl ring in any of the following ways, that is to say - by substitution with a fused methylenedioxy ring, fused furan ring, or a fused tetrahydrofuran ring; by substitution with two alkoxy groups; by substitution with one alkoxy and either one fused furan, tetrahydrofuran, or tetrahydropyran ring system; by substitution with two fused ring systems from any combination of the furan, tetrahydrofuran, or tetrahydropyran ring systems.
- Whether or not the compound is further modified in any of the following ways, that is to say:
    - By substitution of phenyl ring by any halo, hydroxyl, alkyl, trifluoromethyl, alkoxy, or alkylthio groups, or
    - By substitution at the 2-position by any alkyl groups, or
    - By substitution at the 2-amino nitrogen atom with alkyl, dialkyl, benzyl, hydroxybenzyl, or methoxybenzyl groups.
  - Examples include:
    - 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (also known as 2C-Cor2,5-Dimethoxy-4-chlorophenethylamine).
    - 2-(2,5-Dimethoxy-4-methylphenyl) ethanamine (also known as 2C-D or 2,5-Dimethoxy-4-methylphenethylamine).
    - 2-(2,5-Dimethoxy-4-ethylphenyl) ethanamine (also known as 2C-E or 2,5-Dimethoxy-4-ethylphenethylamine).
    - 2-(2,5-Dimethoxyphenyl) ethanamine (also known as 2C-H or 2,5-Dimethoxyphenethylamine).
    - 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (also known as 2C-I or 2,5-Dimethoxy-4-iodophenethylamine).
    - (2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (also known as 2C-N or 2,5-Dimethoxy-4-nitrophenethylamine).
    - 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (also known as 2C-P or 2,5-Dimethoxy-4-propylphenethylamine).
    - 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (also known as 2C-T-2 or 2,5-Dimethoxy-4-ethylthiophenethylamine).
    - 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl] ethanamine (alsoknown as 2C-T-4 2,5-Dimethoxy-4-isopropylthiophenethylamine). or
    - 2-(4-bromo-2,5-dimethoxyphenyl)ethanamine (also known as 2C-B 2,5-Dimethoxy-4-bromophenethylamine). or

- (k) 2-(2,5-dimethoxy-4-(methylthio)phenyl)ethanamine (also known as 2C-T or 4-methylthio-2,5-dimethoxyphenethylamine).
  - (l) 1-(2,5-dimethoxy-4-iodophenyl)-propan-2-amine (also known as DOI or 2,5-Dimethoxy-4-iodoamphetamine).
  - (m) 1-(4-Bromo-2,5-dimethoxyphenyl)-2-aminopropane (also known as DOB or 2,5-Dimethoxy-4-bromoamphetamine).
  - (n) 1-(4-chloro-2,5-dimethoxy-phenyl)propan-2-amine (also known as DOC or 2,5-Dimethoxy-4-chloroamphetamine).
  - (o) 2-(4-bromo-2,5-dimethoxyphenyl)-N-[(2-methoxyphenyl) methyl]ethanamine (also known as 2C-B-NBOMe; 25B-NBOMe or 2,5-Dimethoxy-4-bromo -N-(2-methoxybenzyl)phenethylamine).
  - (p) 2-(4-iodo-2,5-dimethoxyphenyl)-N-[(2-methoxyphenyl) methyl] ethanamine (also known as 2C-I-NBOMe; 25I-NBOMe or 2,5-Dimethoxy-4-iodo-N-(2-methoxybenzyl)phenethylamine).
  - (q) N-(2-Methoxybenzyl)-2-(3,4,5-trimethoxyphenyl)ethanamine (also known as Mescaline-NBOMe or 3,4,5-trimethoxy-N-(2-methoxybenzyl)phenethylamine).
  - (r) 2-(4-chloro-2,5-dimethoxyphenyl)-N-[(2-methoxyphenyl) methyl]ethanamine (also known as 2C-C-NBOMe; 25C-NBOMe or 2,5-Dimethoxy-4-chloro-N-(2-methoxybenzyl)phenethylamine).
  - (s) 2-(7-Bromo-5-methoxy-2,3-dihydro-1-benzofuran-4-yl) ethanamine (also known as 2CB-5-hemiFLY).
  - (t) 2-(8-bromo-2,3,6,7-tetrahydrofuro [2,3-f][1]benzofuran-4-yl) ethanamine (also known as 2C-B-FLY).
  - (u) 2-(10-Bromo-2,3,4,7,8,9-hexahydropyrano[2,3-g]chromen- 5-yl)ethanamine (also known as 2C-B-butterFLY).
  - (v) N-(2-Methoxybenzyl)-1-(8-bromo-2,3,6,7-tetrahydrobenzo[1,2- b:4,5-b']difuran-4-yl)-2-aminoethane (also known as 2C-B-FLY-NBOMe).
  - (w) 1-(4-Bromofuro[2,3-f][1]benzofuran-8-yl)propan-2-amine (also known as bromo-benzodifuranyl-isopropylamine or bromo-dragonFLY).
  - (x) N-(2-Hydroxybenzyl)-4-iodo-2,5-dimethoxyphenethylamine (also known as 2C-I-NBOH or 25I-NBOH).
  - (y) 5-(2-Aminopropyl)benzofuran (also know as 5-APB).
  - (z) 6-(2-Aminopropyl)benzofuran (also known as 6-APB).
  - (aa) 5-(2-Aminopropyl)-2,3-dihydrobenzofuran (also known as 5-APDB).
  - (bb) 6-(2-Aminopropyl)-2,3-dihydrobenzofuran (also known as 6-APDB).
  - (cc) 2,5-dimethoxy-amphetamine (also known as 2, 5-dimethoxy-a-methylphenethylamine; 2, 5-DMA).
  - (dd) 2,5-dimethoxy-4-ethylamphetamine (also known as DOET).
  - (ee) 2,5-dimethoxy-4-(n)-propylthiophenethylamine (also known as 2C-T-7).
  - (ff) 5-methoxy-3,4-methylenedioxy-amphetamine.
  - (gg) 4-methyl-2,5-dimethoxy-amphetamine (also known as 4-methyl-2,5-dimethoxy-a-methylphenethylamine; DOM and STP).
  - (hh) 3,4-methylenedioxy amphetamine (also known as MDA).
  - (ii) 3,4-methylenedioxymethamphetamine (also known as MDMA).
  - (jj) 3,4-methylenedioxy-N-ethylamphetamine (also known as N-ethyl-alpha-methyl-3,4(methylenedioxy) phenethylamine, MDE, MDEA).
  - (kk) 3,4,5-trimethoxy amphetamine.
  - (ll) Mescaline (also known as 3,4,5-trimethoxyphenethylamine).
- h. Substituted tryptamines
- (1) 5-methoxy-N,N-diallyltryptamine (also known 5-MeO-DALT).
  - (2) 4-acetoxy-N,N-dimethyltryptamine (also known 4-AcO-DMT or O-Acetylpsilocin).
  - (3) 4-hydroxy-N-methyl-N-ethyltryptamine (also known 4-HO-MET).
  - (4) 4-hydroxy-N,N-diisopropyltryptamine (also known 4-HO-DIPT).
  - (5) 5-methoxy-N-methyl-isopropyltryptamine (also known 5-MeO-MIPT).
  - (6) 5-Methoxy-N,N-Dimethyltryptamine (also known 5-MeO-DMT).

- (7) Bufotenine(also known as 3-(Beta-Dimethyl-aminoethyl)-5-hydroxyindole; 3-(2dimethylaminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N, N- dimethyltryptamine; mappine).
- (8) 5-methoxy-N,N-diisopropyltryptamine (also known as 5-MeO-DIPT).
- (9) Diethyltryptamine (also known as N,N-Diethyltryptamine; DET).
- (10) Dimethyltryptamine (also known as DMT).
- (11) Psilocyn.
  - i. 1-[3-(trifluoromethylphenyl)]piperazine (also known as TFMPP).
  - j. 1-[4-(trifluoromethylphenyl)]piperazine.
  - k. 6,7-dihydro-5H-indeno-(5,6-d)-1,3-dioxol-6-amine (also known as 5,6-Methylenedioxy-2-aminoindane or MDAI).
  - l. 2-(Ethylamino)-2-(3-methoxyphenyl)cyclohexanone (also known as Methoxetamine or MXE).
2. The following substances are hereby placed in schedule I of the Controlled Substances Act, North Dakota Century Code section 19-03.1-05, schedule I, subsection 7, stimulant substances:
  - a. Mephedrone (2-methylamino-1-*p*-tolylpropan-1-one) also known as 4-methylmethcathinone (4-MMC), 4-methylephedrone.
  - b. 3,4-Methylenedioxypropylpyrovalerone (MDPV).
  - c. Substituted cathinones. Any compound, material, mixture, preparation, or other product, unless listed in another schedule or an approved FDA drug (e.g., bupropion, pyrovalerone), structurally derived from 2-aminopropan-1-one by substitution at the 1-position with either phenyl, naphthyl, or thiophene ring systems, whether or not the compound is further modified in any of the following ways:
    - (1) By substitution in the ring system to any extent with alkyl, alkylenedioxy, alkoxy, haloalkyl, hydroxyl, or halide substituents, whether or not further substituted in the ring system by one or more other univalent substituents;
    - (2) By substitution at the 3-position with an acyclic alkyl substituent;
    - (3) By substitution at the 2-amino nitrogen atom with alkyl, dialkyl, benzyl, or methoxybenzyl groups; or
    - (4) By inclusion of the 2-amino nitrogen atom in a cyclic structure. Some trade or other names:
      - (a) 3,4-Methylenedioxy- $\alpha$ -pyrrolidinopropiophenone (also known as MDPPP).
      - (b) 3,4-Methylenedioxy-N-ethylcathinone (also known as Ethylone, MDEC, or bk-MDEA).
      - (c) 3,4-Methylenedioxy-N-methylcathinone (also known as Methylone or bk-MDMA).
      - (d) 3,4-Methylenedioxypropylpyrovalerone (also known as MDPV).
      - (e) 3,4-Dimethylmethcathinone (also known as 3,4-DMMC).
      - (f) 2-(methylamino)-1-phenylpentan-1-one (also known as Pentadrone).
      - (g) 2-Fluoromethcathinone.
      - (h) 3-Fluoromethcathinone.
      - (i) 4-Methylethcathinone (also known as 4-MEC).
      - (j) 4-Fluoromethcathinone (also known as Flephedrone).
      - (k) 4-Methoxy- $\alpha$ -pyrrolidinopropiophenone (also known as MOPPP).
      - (l) 4-Methoxymethcathinone (also known as Methedrone; bk-PMMA).
      - (m) 4'-Methyl- $\alpha$ -pyrrolidinobutiophenone (also known as MPBP).
      - (n)  $\alpha$ -methylamino-butyrophenone (also known as Buphedrone or MABP).
      - (o)  $\alpha$ -pyrrolidinobutiophenone (also known as  $\alpha$ -PBP).
      - (p)  $\alpha$ -pyrrolidinopropiophenone (also known as  $\alpha$ -PPP).
      - (q)  $\alpha$ -pyrrolidinopentiophenone (also known as  $\alpha$ -pyrrolidinovalerophenone or  $\alpha$ -PVP).
      - (r) Beta-keto-N-methylbenzodioxolylbutanamine (also known as Butylone or bk-MBDB).
      - (s) Ethcathinone (also known as N-Ethylcathinone).
      - (t) 4-Methylmethcathinone (also known as Mephedrone or 4-MMC).
      - (u) Methcathinone.
      - (v) N,N-dimethylcathinone (also known as metamfepramone).
      - (w) Naphthylpyrovalerone (also known as naphyrone). 10
      - (x) Fluoroamphetamine.

(y) Fluoromethamphetamine.

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**General Authority:** NDCC 19-03.1-02, 19-03.1-05

**Law Implemented:** NDCC 19-03.1-02

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## CHAPTER 43-15 PHARMACISTS.

### 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) Upon an order by a physician, a physician assistant, or nurse 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:
      - (a) Immunization and vaccination by injection of an individual who is at least eleven years of age; and
      - (b) Influenza vaccination by injection or by live, attenuated influenza vaccine of an individual who is at least five years of age; and
    - (3) Provision of drugs by subcutaneous, intradermal, and intramuscular injection to an individual who is at least eighteen years of age upon the order of a physician, a physician assistant, 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.
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 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.
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;
  - d. 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. "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. "Wholesaler" means a person with facilities located in this state who buys for resale and distribution to persons other than consumers.

#### **43-15-02. Exemptions.**

The provisions of this chapter shall not apply to the following:

1. A duly licensed practitioner of medicine supplying the practitioner's own patients with such remedies as the practitioner may desire.
2. The exclusive wholesale business of any dealer.
3. The keeping for sale and sale by general dealers of proprietary medicines in original packages and such simple household remedies as from time to time may be approved for such sale by the board.
4. Registered or copyrighted proprietary medicines.
5. The manufacture of proprietary remedies or the sale of the same in original packages by other than pharmacists.
6. A veterinary dispensing technician operating within a veterinary retail facility.

#### **43-15-03. Board of pharmacy - Appointment.**

The state board of pharmacy consists of seven members appointed by the governor. Five members of the board must be licensed pharmacists, one member must be a registered pharmacy technician, and one member must represent the public and may not be affiliated with any group or profession that provides or regulates any type of health care.

#### **43-15-04. State board of pharmacy - Term of office - Vacancies.**

The members of the board must be appointed for terms of five years each, with the terms of office so arranged that one term only expires on the eighth day of May of each year. Each member of the board shall qualify by taking the oath required of civil officers and shall hold office until a successor is appointed and qualified. The governor shall fill any vacancy by appointment for the unexpired term.

#### **43-15-05. Compensation of board - Disposition of fees.**

Each member of the board shall receive a per diem of 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.

#### **43-15-06. Organization of board.**

1. At the first regular meeting of the board after the appointment and qualification of a new member for a full term, the board shall elect a president, a secretary, and a treasurer. The president must be chosen from the membership of the board, but any suitable person, whether a member of the board or not, may be chosen for the other offices. In case of the death, removal, resignation, absence, or refusal or inability to act of the president of the board, the senior member present shall act as president. In case of the death, removal, resignation, absence, or refusal or inability to act of the secretary or treasurer, the board may choose another person to act temporarily or for the remainder of the year. The president of the board of pharmacy shall preside at all meetings of the board and is responsible for the performance of all of the duties and functions of the board required or permitted by this chapter. Each additional officer elected by the board shall perform those duties normally associated with the officer's position and such other duties assigned from time to time by the board.
2. The board shall employ a pharmacist to serve as a full-time employee of the board in the position of executive director. The executive director is responsible for the performance of the administrative functions of the board and such other duties as the board may direct. The executive director may also serve as secretary and treasurer of the board.
3. The executive director is authorized to sign on behalf of the board notices, complaints, statement of charges, stipulations, settlement agreements, findings of fact, conclusions of law, orders and decisions of the board without additional signatures of the president of the board or board members.

**43-15-07. Officers of board - Bond - Duties - Compensation.**

The secretary and treasurer of the board each must be bonded for the faithful discharge of their duties in the penal sum of not less than two thousand dollars. The president, secretary, and treasurer of the board shall perform such duties as the board may prescribe. Officers of the board may be allowed, in addition to their compensation as members of the board, such compensation as four-fifths of the members of the board agree upon.

**43-15-08. Oaths - President may administer.**

The president of the board may administer oaths to applicants for registration and to any witness in hearings, investigations, or proceedings pending before the board.

**43-15-09. Meetings - When held - Notice - Quorum.**

The board shall hold at least two and not more than four meetings in each calendar year for the examination of applicants for licensure. The board may hold such other meetings as may be necessary for the performance of its duties. A special meeting must be held at such time and place as a majority of the members agree upon, or may be called by the secretary, at the request of the president or any two members, by giving such notice to the members as the board may prescribe by its rules and regulations. A majority of the board constitutes a quorum for the transaction of business.

**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 pharmacy intern or pharmacy technician; or refuse to issue or renew, or suspend, revoke, restrict, or cancel, the license, permit, or registration of any pharmacy, pharmacist, or pharmacy intern or pharmacy technician, if any of the following grounds apply and the pharmacy, pharmacist, or 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.
21. To require information regarding an applicant's or licensee's fitness, qualifications, and previous professional record and performance from recognized data sources, including the national association of boards of pharmacy data bank, other data repositories, licensing and disciplinary authorities of other jurisdictions, professional education and training institutions, liability insurers, health care institutions, and law enforcement agencies be reported to the board. The board may require an applicant for licensure or a licensee who is the subject of a disciplinary investigation to submit to a statewide and nationwide criminal history record check. The nationwide criminal history record check must be conducted in the manner provided by section 12-60-24. All costs associated with obtaining a background check are the responsibility of the licensee or applicant.
22. To adopt, amend, and repeal rules as may be deemed necessary by the board to register veterinary dispensing technicians pursuant to qualifications established by the board, to charge a veterinary dispensing technician an annual registration fee not to exceed fifty dollars, to provide for suspension or revocation of a veterinary dispensing technician's registration, to provide for suspension or revocation of a veterinary retail facility's license, to regulate and control veterinary retail facilities, and to regulate and control veterinary dispensing technicians.
23. To establish limited prescriptive authority for individuals to distribute opioid antagonist kits, also known as "Naloxone rescue kits". If the board establishes limited prescriptive authority under this subsection, the board shall adopt rules to establish standards that may include training, certification, and continuing education requirements.

**43-15-11. Fees deposited with state treasurer - Separate fund - Vouchers.**

[Repealed by S.L. 1971, ch. 510, § 15.]

#### **43-15-12. State board of pharmacy - Report.**

The board may submit a biennial report to the governor and the secretary of state in accordance with section 54-06-04.

#### **43-15-13. State board of pharmacy - When members may teach pharmacy.**

[Repealed by S.L. 1995, ch. 407, § 1.]

##### **43-15-13.1. North Dakota pharmaceutical association - How governed.**

[Repealed by S.L. 2009, ch. 365, § 5.]

##### **43-15-13.2. Membership of North Dakota pharmaceutical association.**

[Repealed by S.L. 2009, ch. 365, § 5.]

##### **43-15-13.3. Rights of members of pharmaceutical association.**

[Repealed by S.L. 2009, ch. 365, § 5.]

##### **43-15-13.4. Moneys payable from board of pharmacy to North Dakota pharmaceutical association.**

[Repealed by S.L. 2009, ch. 365, § 5.]

##### **43-15-13.5. Method of expenditure of association's funds - Annual report of receipts and disbursements.**

[Repealed by S.L. 2009, ch. 365, § 5.]

##### **43-15-13.6. No liability upon state created by provisions of chapter.**

[Repealed by S.L. 2009, ch. 365, § 5.]

#### **43-15-14. Unlawful practice of pharmacy.**

1. Applicability. No person may engage in the practice of pharmacy unless licensed to practice pharmacy under this chapter, except that a registered pharmacy technician may perform specific tasks delegated by and under the immediate personal supervision and control of a licensed pharmacist, as permitted under rules adopted by the board. Physicians or other practitioners as defined in this chapter who are licensed under the laws of this state may dispense and administer prescription drugs to their patients in the practice of their respective professions if specifically authorized to do so by state law.
2. Penalties. Any person who is found by the board to have unlawfully engaged in the practice of pharmacy is subject to a fine to be imposed by the board not to exceed one thousand dollars for each offense. Each violation of this chapter or the rules adopted under this chapter pertaining to unlawfully engaging in the practice of pharmacy also constitutes a class B misdemeanor.
3. A pharmacy or licensed pharmacist that utilizes the services of a registered pharmacy technician as permitted by the board, may not be considered as aiding and abetting an unauthorized person to practice pharmacy; provided, however, that the pharmacy or licensed pharmacist must retain responsibility for any act performed by a registered pharmacy technician in the course of the registered pharmacy technician's employment.

#### **43-15-15. Qualifications of licensed pharmacist.**

Every applicant for license as a pharmacist in this state shall have the following qualifications:

1. Be at least eighteen years of age.
2. Be of good moral character.
3. Be a graduate of a school or college of pharmacy recognized by the board as an approved school. Any applicant who is a graduate of a school or college of pharmacy located outside the United States, whose school or college of pharmacy has not been recognized by the board as an approved school but who is otherwise qualified to apply for licensure to practice pharmacy in this state, may be deemed to have satisfied the requirements of subsection 3 by verification to the board of applicant's academic record and applicant's graduation and by meeting such other requirements as the board may establish from time to time. The board may require such applicant to successfully pass an examination or examinations given or approved by the board to establish proficiency in English and equivalency of education of such applicant with qualified graduates of a school or college recognized by the board as a prerequisite of taking the licensure examination provided for in section 43-15-19.

**43-15-16. Exception to qualificational requirements.**

Any person qualified to take the examination for licensure as a pharmacist in this state under the law in effect prior to July 1, 1927, who failed to apply for the examination, upon due proof to the board that the person was so qualified and that the person is a bona fide resident of this state, may take the examination. Upon passing the examination in a manner satisfactory to the majority of the board, such person shall be given a license as a licensed pharmacist.

**43-15-17. Qualifications for assistant registered pharmacist.**

[Repealed by S.L. 1979, ch. 467, § 16.]

**43-15-18. License of pharmacy intern.**

To register in this state a pharmacy intern must have completed one year of college, be registered in a prepharmacy program, and must be employed by a licensed pharmacist. At the date of entering into internship, an intern shall file with the executive director of the board the following certificates accompanied by a fee set by the board:

1. An application stating the applicant has entered into an internship giving the intern's name, residence, and educational qualifications.
2. A statement from the intern's employer stating that the applicant will be employed by the pharmacist, as a pharmacy intern, that to the employer's knowledge the applicant possesses the required education and qualifications.

The executive director of the board shall file the application and license the applicant as a pharmacy intern.

**43-15-18.1. Conviction not bar to license - Exceptions.**

Conviction of an offense does not disqualify a person from licensure under this chapter unless the board determines that the offense has a direct bearing upon a person's ability to serve the public as a pharmacist or that, following conviction of any offense, the person is not sufficiently rehabilitated under section 12.1-33-02.1.

**43-15-19. Examination for license.**

Except as otherwise provided in this chapter, every applicant for licensure as a pharmacist, before receiving a license from the board, shall pass such an examination as to the applicant's education and professional qualifications as the board shall prescribe.

**43-15-20. Fees for examination.**

Each applicant for licensure as a pharmacist in this state shall pay to the secretary of the board before examination a fee to be set by the board not to exceed three hundred dollars. If the applicant fails to pass a satisfactory examination, the applicant may be reexamined at any regular meeting of the board, upon the payment of a further fee to be set by the board not to exceed three hundred dollars.

**43-15-21. License - Issuance.**

The board shall cause to be issued to each pharmacist in this state whom it finds entitled thereto, a license showing:

1. The date of issue.
2. The fact that the person to whom it was issued is a licensed pharmacist.
3. The residence of the person to whom the license was issued.

The license must be signed by a majority of the members of the board.

**43-15-22. Licensing without examination.**

The board, without examination, may register and issue a license as a pharmacist to any person of good moral character who presents to the board satisfactory evidence that before coming to this state the applicant legally had been licensed as a pharmacist in another state or foreign country, in which the requirements for such license with respect to qualifications are equivalent to the requirements of this state, but the board need not recognize or accept such license, certificate, or registration as evidence of the applicant's qualifications unless it is satisfied that the applicant is in fact qualified to be a pharmacist in this state. The board may deny recognition or acceptance of the license, certificate, or registration of any state or foreign country which does not accord similar recognition to licentiates of this state. A fee to be set by the board not to exceed three hundred dollars must be paid prior to licensing without examination as provided for herein.

**43-15-23. Temporary certificate - How obtained.**

The secretary of the board, or any member thereof, on request by the secretary in writing, may examine an applicant orally or in writing and issue a temporary certificate to practice pharmacy in this state. The certificate must authorize such practice and must be valid until the next meeting of the board. Only one temporary certificate may be issued to the same applicant, and no temporary certificate may be issued to any person whose application has been acted on by the board. The applicant for a temporary certificate shall pay to the person making the examination the same fee as is provided by this chapter for an examination by the board, and such fees when paid must be for the benefit of the said board and must be delivered to the secretary by the person making the examination.

**43-15-24. Register.**

The secretary of the board shall keep a record or register in which, in addition to such other matters as the board may require, the secretary shall register each certificate issued under the provisions of this chapter, the facts appearing in the certificate, and all cancellations or renewals of the certificate or changes therein.

**43-15-25. Term of license - Renewal - Fee - Where displayed.**

The license issued by the board to a pharmacist under this chapter, and the registration thereof, entitles the holder to act in the capacity therein stated for one year unless duly canceled, suspended, or revoked. Every licensee who desires to retain a license, on or before the first day of March in each year, shall pay to the secretary of the board a renewal fee in an amount to be fixed by the board not to exceed one hundred dollars. Upon payment of the fee, the board shall issue a renewal license. The license and renewal must be displayed in a conspicuous place in the pharmacy and drugstore where the holder is employed. After a licensee has held licenses duly issued over a period of fifty consecutive years, the secretary of the board may issue the licensee a lifetime license that entitles the licensee to act in the capacity of pharmacist thereafter without further payment unless the license is canceled, revoked, or suspended.

**43-15-25.1. Continuing pharmaceutical education.**

1. Each pharmacist shall complete at least fifteen hours of approved continuing pharmaceutical education every year as a condition of renewal of a certificate of licensure as a pharmacist in this state.
2. An annual renewal of a license may not be issued to a pharmacist until the pharmacist has satisfactorily completed an accredited program of continuing professional education, all of which may be home self-study, during the previous year to help assure the pharmacist's continued competence to engage in the practice of pharmacy. The board from time to time shall determine the amount of continuing education to be required, not to exceed fifteen hours in each annual period. Upon request of the board, proof of compliance shall be furnished to the board.
3. The board shall adopt rules necessary to carry out the stated objectives and purposes and to enforce the provisions of this section, which shall include the methods of determining accredited programs, methods of determining compliancy, any fees, and such other rules consistent with this section as the board shall determine. This section and all rules adopted hereunder shall be uniformly applied by the board.



**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 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.

**43-15-25.3. Approved laboratory tests.**

Approved laboratory tests are the following waived screening tests: glucose monitoring devices (FDA cleared/home use) 9221, cholesterol 1020, HDL cholesterol 2550, triglyceride 6118, and glycosylated hemoglobin (Hgb A1C) 2204. Additional tests may be added to this list as jointly determined by the board and the North Dakota board of medicine.

**43-15-26. Failure to renew license - Renewal fee - Cancellation of license - Reinstatement.**

If a licensed pharmacist in this state fails to pay the fee for a renewal of a license within the time required, the secretary of the board shall mail the pharmacist a notice, addressed to the pharmacist's last-known place of residence, notifying the pharmacist of failure to obtain a renewal license. The delinquent licenseholder, within sixty days after the notice is mailed, may procure a renewal license upon the payment of a renewal fee to be set by the board not to exceed one hundred dollars. If the licenseholder fails to have a license renewed within sixty days after the notice is mailed, the original or renewal license, as the case may be, becomes void and the registry thereof must be canceled. The board, on application of the delinquent licenseholder and upon the payment of all unpaid fees, may authorize the issuance of a new license without examination, if it is satisfied that the applicant is a proper individual to receive the same.

**43-15-27. Change place of business - Record - Fee.**

Every licensed pharmacist, within thirty days after changing a place of business as designated on the books of the board, shall notify the secretary of the board of the new place of business and shall accompany the notice with a fee to be set by the board not to exceed twenty-five dollars. Upon receipt of the fee and the notice of change of place of business, the secretary shall make the necessary change in the register and issue a receipt for the fee to the person sending it.

**43-15-28. Certificate of registration canceled - Notice of hearing.**

[Repealed by S.L. 1989, ch. 522, § 2.]

**43-15-28.1. Temporary suspension - Appeal.**

1. If the board has verified evidence that probable cause or grounds for discipline requires the suspension of a pharmacy permit or license of a pharmacist and if harm to the public is so imminent and critical that substantial harm could or would likely result if the permit or license is not suspended prior to a hearing, the board may order a temporary suspension ex parte.
2. An ex parte temporary suspension remains in effect for not more than sixty days, unless otherwise terminated by the board.
3. The board shall set the date of a full hearing on the cause and grounds for discipline regarding the permit or license for not later than sixty days from the issuance of the ex parte temporary suspension order. Within three days after the issuance of the ex parte suspension order, the board shall serve the pharmacy or pharmacist with a copy of the order along with a copy of the complaint and notice of the date set for the full hearing.
4. The pharmacy or pharmacist may appeal the ex parte temporary suspension order prior to the full hearing. For purposes of appeal, the district court shall decide whether probable cause or grounds for discipline reasonably requires the temporary suspension to adequately protect the public interest. The court shall give priority to the appeal for prompt disposition.

**43-15-29. False registration - Penalty.**

Any person who procures or attempts to procure license as a pharmacist, for that person or any other person under this chapter, by making or causing to be made any false representations, or who falsely or fraudulently represents that the person is licensed, is guilty of a class A misdemeanor, and in addition to the penalty imposed by the court, shall, if a licensed pharmacist, have the license canceled by the board.

**43-15-30. Licensed pharmacist member of North Dakota pharmaceutical association.**

[Repealed by S.L. 2009, ch. 365, § 5.]

**43-15-31. Prescriptions to be filed and preserved.**

Every licensed pharmacist in the state shall file, or cause to be filed, any prescription, or a copy thereof, which has been compounded or dispensed in the pharmacist's pharmacy or drugstore. The prescription or a copy of the prescription must be preserved for at least five years after it has been filled. The pharmacist may furnish a copy of any prescription to the party presenting it on the request of such party only.

**43-15-31.1. Patient profile record system.**

A patient profile record system must be maintained in all pharmacies for persons for whom prescriptions are dispensed. The patient profile record system must be devised so as to enable the immediate retrieval of information necessary to enable the dispensing pharmacist to identify previously dispensed medication at the time a prescription is presented for dispensing. One profile card may be maintained for all members of a family living at the same address and possessing the same family name.

The following information must be recorded:

1. The family name and the first name of the person for whom the medication is intended, which is the patient.
2. The address of the patient.
3. An indication of the patient's age group, e.g., infant, child, adult.
4. The original date the medication is dispensed pursuant to the receipt of a physician's prescription.
5. The number or designation identifying the prescription.
6. The prescriber's name.
7. The name, strength, and quantity of the drug dispensed.
8. The initials of the dispensing pharmacist, and the date of dispensing medication as a renewal (refill) if said initials and such date are not recorded on the back of the original prescription.

The pharmacist shall attempt to ascertain and shall record any allergies and idiosyncrasies of the patient and any chronic conditions which may relate to drug utilization as communicated to the pharmacy by the patient.

Upon receipt of a prescription, a pharmacist must examine the patient's profile record before dispensing the medication to determine the possibility of a harmful drug interaction or reaction. Upon recognizing a potential harmful reaction or interaction, the pharmacist shall take appropriate action to avoid or minimize the problem which shall, if necessary, include consultation with the physician.

A patient profile record must be maintained for a period of not less than five years from the date of the last entry in the profile record.

**43-15-31.2. Prescription drug information required.**

With each prescription dispensed, the licensed pharmacist or the licensed intern pharmacist, in addition to labeling the prescription in accordance with law, must explain to the patient or the patient's agent the directions for use and a warning of the potential harmful effect of combining any form of alcoholic beverage with the medication and any additional information, in writing if necessary, to assure the proper utilization of the medication or device prescribed. For those prescriptions delivered outside the confines of the pharmacy, the explanation must be by telephone or in writing, provided that this does not apply to those prescriptions for patients in hospitals or institutions where the medication is to be administered by a nurse or other individual licensed to administer medications, or to those prescriptions for patients who are to be discharged from a hospital or institution.

**43-15-31.3. Oral transmission of prescriptions.**

An oral transmission of a prescription drug may be accepted and dispensed by a pharmacist or licensed pharmacist intern if received from a practitioner, or a nurse licensed under chapter 43-12.1 who is authorized by the practitioner to orally transmit the prescription, or a registered dental hygienist or a registered dental assistant who is authorized by the supervising dentist to orally transmit the prescription. The practitioner shall document the order for oral transmission in the patient's records. Only a licensed pharmacist or a licensed pharmacist intern or a registered pharmacy technician may receive an orally transmitted new or refill prescription.

**43-15-31.4. Limited prescriptive practices.**

1. A pharmacist has limited prescriptive practices to initiate or modify drug therapy following diagnosis by a licensed physician or an advanced practice registered nurse, under the supervision of the licensed physician or advanced practice registered nurse, in accordance with this section. The licensed physician or the advanced practice registered nurse and the pharmacist must have access to the patient's appropriate medical records. The care provided to the patient by the pharmacist must be recorded in the patient's medical records and communicated to the licensed physician or the advanced practice registered nurse.
2. The licensed physician or the advanced practice registered nurse and the pharmacist shall prepare a collaborative agreement concerning the scope of the pharmacist's prescriptive practices and shall update the agreement at least every four years or when they modify the scope of the pharmacist's prescriptive practices. The collaborative agreement, or an amendment to the agreement, is effective when approved by the North Dakota board of medicine or board of nursing and the board of pharmacy.
3. The collaborative agreement may be between a medical director and pharmacist-in-charge. The medical director and pharmacist-in-charge shall report to the respective board of any physician, advanced practice registered nurse, and pharmacist covered under the agreement.
4. If there is a change in personnel under the collaborative agreement, a pharmacist, physician, and advanced practice registered nurse under the collaborative agreement shall send immediate notice of the change to the respective licensing board of that individual. Unless necessary, a change in personnel does not necessitate board approval of the collaborative agreement.
5. The collaborative agreement must include a provision that requires the pharmacist to immediately notify the licensed physician or advanced practice registered nurse when the pharmacist initiates or modifies a drug therapy.
6. Any rules to implement this section must be jointly adopted by the board of medicine or the board of nursing and the board of pharmacy.

**43-15-31.5. Injection of drugs - Rules.**

Any pharmacist who administers drugs by injection must have a certificate of authority from the board. The authority to administer a drug by injection may not be delegated. The board shall adopt rules to establish educational and operational requirements for a pharmacist to obtain and maintain a certificate of authority to administer drugs by injection. Rules adopted by the board under this section must include:

1. Educational requirements of a minimum of twenty hours, which include, at a minimum:
  - a. Basic immunology, including the human immune response;
  - b. The mechanism of immunity, adverse effects, dose, and administration schedule of available vaccines and approved medication and immunization;
  - c. Current immunization guidelines and recommendations of the centers for disease control and prevention;
  - d. Management of adverse events, including identification, appropriate response, documentation, and reporting;
  - e. How to educate patients on the need for immunizations;
  - f. Physiology and techniques for subcutaneous, intradermal, and intramuscular injection; and
  - g. Recordkeeping requirements established by law, rule, and regulation or established standards of care.
2. A requirement that an authorized pharmacist must obtain and maintain current certification in cardiopulmonary resuscitation or basic cardiac life support.
3. Requirements to maintain continuing competency with completion of a minimum of six hours of education dedicated to this area of practice every two years.
4. Requirements for content of physician orders and protocols.
5. Requirements relating to the reporting of the administration by injection to a patient's primary health care provider and to the state department of health.
6. Requirements relating to environments in which injections may be administered.

**43-15-32. Who may engage in drug business.**

Every store, dispensary, pharmacy, laboratory, or office, selling, dispensing, or compounding drugs, medicines, or chemicals, or compounding or dispensing prescriptions of medical practitioners in the state, and every business carried on under a name which contains the words "drugs", "drugstore", or "pharmacy", or which is described or referred to in such terms by advertisements, circulars, posters, signs, or otherwise, must be in charge of a registered pharmacist.

**43-15-33. License to sell emergency medicines.**

[Repealed by S.L. 1999, ch. 379, § 8.]

**43-15-34. Operation of pharmacy - Permit required - Application - Fee.**

No person, copartnership, association, corporation, or limited liability company shall open, establish, operate, or maintain any pharmacy within this state without first obtaining a permit so to do from the board. Application for the permit shall be made upon a form to be prescribed and furnished by the board and shall be accompanied by a fee to be set by the board not to exceed three hundred dollars. A like fee shall be paid upon each annual renewal thereof. Separate applications shall be made and separate permits required for each pharmacy opened, established, operated, or maintained by the same owner and for the change of location, name, or ownership of an existing pharmacy.

**43-15-34.1. Out-of-state pharmacies.**

Any pharmacy operating outside the state which ships, mails, or delivers in any manner a dispensed prescription drug or legend drug into North Dakota shall obtain and hold a pharmacy permit issued by the North Dakota state board of pharmacy and that part of the pharmacy operation dispensing the prescription for a North Dakota resident shall abide by state law and rules of the board.

**43-15-35. Requirements for permit to operate pharmacy - Exceptions.**

1. The board shall issue a permit to operate a pharmacy, or a renewal permit, upon satisfactory proof of all of the following:
  - a. The pharmacy will be conducted in full compliance with existing laws and with the rules and regulations established by the board.
  - b. The equipment and facilities of the pharmacy are such that prescriptions can be filled accurately and properly, and United States pharmacopeia and national formulary preparations properly compounded and so that it may be operated and maintained in a manner that will not endanger public health and safety.
  - c. The pharmacy is equipped with proper pharmaceutical and sanitary appliances and kept in a clean, sanitary, and orderly manner.
  - d. The management of the pharmacy is under the personal charge of a pharmacist duly licensed under the laws of this state.
  - e. The applicant for such permit is qualified to conduct the pharmacy, and is a licensed pharmacist in good standing or is a partnership, each active member of which is a licensed pharmacist in good standing; a corporation or an association, the majority stock in which is owned by licensed pharmacists in good standing; or a limited liability company, the majority membership interests in which is owned by licensed pharmacists in good standing, actively and regularly employed in and responsible for the management, supervision, and operation of such pharmacy.
  - f. Suitable reference sources either in book or electronic data form, are available in the pharmacy or online, which might include the United States pharmacopeia and national formulary, the United States pharmacopeia dispensing information, facts and comparisons, micro medex, the American society of health-system pharmacists formulary, or other suitable references pertinent to the practice carried on in the licensed pharmacy.
2. The provisions of subdivision e of subsection 1 do not apply to:
  - a. The holder of a permit on July 1, 1963, if otherwise qualified to conduct the pharmacy, provided that any such permitholder that discontinues operations under such permit or fails to renew such permit upon expiration is not exempt from the provisions of subdivision e of subsection 1 as to the discontinued or lapsed permit.
  - b. A hospital pharmacy furnishing service only to patients in that hospital.

- c. The applicant for a permit to operate a pharmacy which is a hospital, if the pharmacy for which the hospital seeks a permit to operate is a retail pharmacy that is the sole provider of pharmacy services in the community and is a retail pharmacy that was in existence before the hospital took over operations. A hospital operating a pharmacy under this subdivision may operate the pharmacy at any location in the community.
- d. The applicant for a permit to operate a pharmacy which is the owner of a postgraduate medical residency training program if the pharmacy is collocated with and is run in direct conjunction with the postgraduate medical residency training program. For purposes of this subdivision, the postgraduate medical residency training program must be accredited by the accreditation council on graduate medical education or other national accrediting organization.

**43-15-36. Board shall make rules and regulations governing permits - Prescribe equipment necessary.**

The rules and regulations relating to the granting, revocation, and renewal of a permit must be adopted and become effective only upon the affirmative vote of a majority of the members of the board. The board shall prescribe the minimum of technical equipment which a pharmacy at all times must possess.

**43-15-37. Term of permit - Renewal - Fee - Application.**

[Repealed by omission from this code.]

**43-15-38. Failure to renew permit - When new permit granted.**

If an application for renewal of a permit issued for the operation or maintenance of a pharmacy in this state is not made before the first day of June of the fiscal year for which the permit was issued, the existing permit, or renewal permit, lapses and becomes null and void upon the thirtieth day of that month. A new or further renewal of a permit may be granted only:

- 1. Upon evidence satisfactory to the board of good and sufficient reason or excuse for failure to file an application within the time prescribed.
- 2. Upon payment of the regular renewal fee and an additional fee to be set by the board not to exceed two hundred dollars.

**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.

**43-15-39. Permit and renewal permit posted - Not transferable.**

The permit to operate and maintain a pharmacy in this state, and the renewal thereof, must be posted and exposed in a conspicuous place in the pharmacy. Such permit or renewal permit is not transferable.

**43-15-40. Board may revoke permits and renewal permits.**

The board, after due notice and opportunity to be heard, may revoke any permit to establish and maintain a pharmacy, or a renewal thereof, if it is disclosed upon an examination or inspection that the pharmacy is not being operated or conducted according to the rules and regulations of the board and the laws of this state.

**43-15-41. Board to give notice of refusal or revocation of permits - Appeal.**

If an application for a permit or for a renewal thereof is refused, or a permit or a renewal of permit is revoked, the board shall notify the applicant or permittee by registered or certified mail of such refusal or revocation, with its reasons therefor. The applicant or permittee aggrieved by the refusal or revocation may appeal from the decision or order of the board to the district court of Burleigh County, at any time within thirty days after the receipt of the decision or order appealed from. The appellant shall give bond in the penal sum of two hundred fifty dollars, to be approved by the clerk of the district court, conditioned that appellant will pay all costs if the order or decision of the board is affirmed. With the perfecting of the appeal and the filing of the bond, the decision or order of the board must be stayed pending the determination of the appeal.

**43-15-42. Penalty for violation of rule regulating pharmacies.**

Any person who violates any rule legally adopted by the board pursuant to this chapter is guilty of an infraction.

**43-15-42.1. Penalties - Reinstatement - Criminal prosecutions - Judicial review.**

1. Upon the finding of the existence of grounds for discipline of any person holding, seeking, or renewing a permit or license under this chapter, the board may impose one or more of the following penalties:
  - a. Suspension of the offender's permit or license for a term to be determined by the board.
  - b. Revocation of the offender's permit or license.
  - c. Restriction of the offender's permit or license to prohibit the offender from performing certain acts or from engaging in the practice of pharmacy in a particular manner for a term to be determined by the board.
  - d. Refusal to issue or renew offender's permit or license.
  - e. Placement of the offender or the offender's permit or license under suspension and supervision by the board for a period to be determined by the board.
  - f. Cancellation of the offender's permit or license.
  - g. Reprimand.
  - h. Imposition of a fine not to exceed one thousand dollars for each offense involving diversion of controlled substances or a fine not to exceed five hundred dollars for any other offense, with the sanction that the permit or license may be suspended until the fine is paid to the board.
2. Any person whose permit or license to practice pharmacy in North Dakota has been suspended, revoked, or restricted pursuant to this chapter, whether voluntarily or by action of the board, has the right, at reasonable intervals, to petition the board for reinstatement of such permit or license. A petition must be made in writing and in the form prescribed by the board. Upon investigation and hearing, the board may in its discretion grant or deny such petition, or it may modify its original finding to reflect any circumstances which have changed sufficiently to warrant such modifications.
3. Nothing herein shall be construed as barring criminal prosecutions for violations of this chapter if such violations are deemed as criminal offenses in other statutes of North Dakota or of the United States.
4. All final decisions by the board shall be subject to judicial review pursuant to chapter 28-32.

**43-15-42.2. Impaired pharmacists program.**

1. Any pharmaceutical peer review committee may report relevant facts to the board relating to the acts of any pharmacist in this state if it has knowledge relating to the pharmacist which, in the opinion of the peer review committee, might impair competency due to dependency on alcohol or drugs, abuse of alcohol or drugs, or due to physical or mental illness, or which might endanger the public health and safety or provide grounds for disciplinary action under chapter 43-15.
2. Any committee of a professional association comprised primarily of pharmacists, its staff, or any district or local intervenor participating in a program established to aid pharmacists impaired by substance abuse or mental or physical illness may report in writing to the board the name of the impaired pharmacist together with the pertinent information relating to the impairment. The board may report to any committee of such professional association, or the association's designated staff, information which it may receive with regard to any pharmacist who may be impaired by substance abuse or mental or physical illness.
3. Upon a determination by the board that a report submitted by a peer review committee or professional association committee is without merit, the report must be expunged from the pharmacist's individual record in the board's office. A pharmacist or a pharmacist's authorized representative may, on request, examine the pharmacist's peer review or the pharmaceutical association's committee report submitted to the board and place into the record a statement of reasonable length of the pharmacist's view with respect to any information in the report.
4. Notwithstanding the provisions of section 44-04-18, the records and proceedings of the board, compiled in conjunction with an impaired pharmacist peer review committee, are confidential and are not to be considered public records or open records unless the affected pharmacist so requests; provided, however, the board may disclose this confidential information only if any of the following apply:
  - a. In a disciplinary hearing before the board or in a subsequent trial or appeal of a board action or order.
  - b. To the pharmacist licensing or disciplinary authorities of other jurisdictions.
  - c. Under an order of a court of competent jurisdiction.

5. No employee or member of the board, peer review committee member, pharmaceutical association committee member, or pharmaceutical association district or local intervenor furnishing in good faith information, data, reports, or records for the purposes of aiding the impaired pharmacist may, by reason of furnishing the information, be liable for damages to any person.
6. No employee or member of the board or the committee, staff, or intervenor program is liable for damages to any person for any action taken or recommendations made in good faith by the board, committee, or staff.

#### **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.

#### **43-15-43. Pharmacist negligently endangering life - Penalty.**

Any pharmacist in this state, who in putting up any drug or medicine, willfully or negligently:

1. Omits to label the drug or medicine;
2. Puts an untrue label, stamp, or other designation of contents upon the box, bottle, or package containing the drug or medicine;
3. Substitutes a different article for an article prescribed or ordered;
4. Puts up a greater or less quantity of an article than that prescribed or ordered; or
5. Deviates from the terms of the prescription or order in any manner, in consequence of which human life is endangered, is guilty of a class A misdemeanor.

#### **43-15-44. Penalty for violations.**

Any person who willfully violates any of the provisions of this chapter for which another penalty is not specifically provided is guilty of a class B misdemeanor.

#### **43-15-45. Costs of prosecution - Disciplinary proceedings.**

In any order or decision issued by the board in resolution of a disciplinary proceeding, the board may direct any certificate holder, permitholder, or licenseholder, or any pharmacy or pharmacist found not in compliance, guilty, or in violation of one or more of the grounds set forth in subsection 1 of section 43-15-10, to pay the board a sum not to exceed the reasonable and actual costs of the investigation and prosecution of the case, with the sanction that the certificate of registration, permit, or license may be suspended until the costs are paid to the board.

## CHAPTER 43-15.1 WHOLESALE DRUG DISTRIBUTORS

### **43-15.1-01. Definitions.** As used in this chapter:

1. "Board" means the state board of pharmacy.
2. "Manufacturer" means any person engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.
3. "Pharmacy distributor" means any pharmacy licensed in this state or hospital pharmacy that is engaged in the delivery or distribution of prescription drugs either to any other pharmacy licensed in this state or to any other person or entity, including a wholesale drug distributor, engaged in the delivery or distribution of prescription drugs and involved in the actual, constructive, or attempted transfer of a drug in this state to other than the ultimate consumer, if the financial value of the drugs is equivalent to at least five percent of the total gross sales of the pharmacy distributor.
4. "Prescription drug" means any drug required by federal or state law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the federal Food, Drug, and Cosmetic Act.
5. "Wholesale drug distribution" means sale of prescription drugs to persons other than a consumer or patient. The term does not include:
  - a. Intracompany sale, which is a sale between any division, subsidiary, parent, or affiliated or related company under the common ownership and control of a corporate entity.
  - b. The purchase or other acquisition by a hospital pharmacy or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospital pharmacies or health care entities that are members of such organizations.
  - c. The sale, purchase, or trade of a drug, or an offer to sell, purchase, or trade a drug, by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law.
  - d. The sale, purchase, or trade of a drug, or an offer to sell, purchase, or trade a drug, among hospital pharmacies or other health care entities that are under common control.
  - e. The sale, purchase, or trade of a drug, or an offer to sell, purchase, or trade a drug, for emergency medical reasons.
  - f. The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription.
  - g. A transfer of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.
  - h. A manufacturer or a manufacturer's sales representative or agent.
6. "Wholesale drug distributor" means any person engaged in the wholesale drug distribution, including manufacturers; repackers; own-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; sales agents; prescription drug repackagers; physicians; dentists; veterinarians; birth control and other clinics; individuals; hospital pharmacies; nursing home pharmacies or their providers; health maintenance organizations and other health care providers; and retail and hospital pharmacies that conduct wholesale distributions. The term does not include any common carrier or individual hired solely to transport prescription drugs.

### **43-15.1-02. Prohibited drug purchase or receipt - Penalty.**

No person may knowingly purchase or receive any prescription drug from any source other than a wholesale drug distributor, manufacturer, pharmacy distributor, pharmacy, or other person licensed pursuant to the laws of this state except when otherwise provided. A person violating this section is guilty of a class A misdemeanor. A second violation is a class C felony.



**43-15.1-03. Wholesale drug distributor advisory committee.**

The board shall appoint a wholesale drug distributor advisory committee composed of three members. One member must be a representative of a pharmacy and may be a pharmacy distributor, but may not be an employee of the board. One member must be a representative of wholesale drug distributors. One member must be a representative of drug manufacturers. In making appointments, the board shall consider recommendations received from wholesale drug distributors, pharmacy distributors, and drug manufacturers and shall adopt rules that provide for solicitation of such recommendations. The advisory committee shall review and make recommendations to the board on the merit of rules of the board which deal with wholesale drug distributors, pharmacy distributors, and drug manufacturers. The board may not adopt any rule affecting wholesale drug distributors or pharmacy distributors without first submitting the proposed rule to the committee for review and comment.

**43-15.1-04. Wholesale drug distributor and pharmacy distributor licensing requirements - Penalty.**

1. No person may act as a wholesale drug distributor or pharmacy distributor without first obtaining an annual license to do so from the board and paying the annual fee required by the board.
2. The board may grant a temporary license when the wholesale drug distributor or pharmacy distributor first applies for a license to operate within this state. A temporary license is valid until the board finds that the applicant meets the requirements for regular licensure.
3. The licensee shall operate in a manner prescribed by law and according to the rules adopted by the board.
4. The board may require a separate license for each facility directly or indirectly owned or operated by the same business entity within this state, or for a parent entity with divisions, subsidiaries, or affiliate companies within this state if operations are conducted at more than one location and there exists joint ownership and control among all the entities.
5. An applicant for a license and a licensee shall satisfy the board that the applicant or licensee has and will continuously maintain:
  - a. Adequate storage conditions and facilities;
  - b. Minimum liability and other insurance as may be required under any applicable federal or state law;
  - c. A viable security system that includes afterhours, central alarm, or comparable entry detection capability; restricted premises access; comprehensive employment applicant screening; and safeguards against all forms of employee theft;
  - d. A system of records that describes all wholesale drug distributor and pharmacy distributor activities for at least the most recent two-year period and which is reasonably accessible in any inspection authorized by the board;
  - e. Principals and persons, including officers, directors, primary shareholders, and key management executives, who must at all times demonstrate and maintain their capability of conducting business in conformity with sound financial practices as well as state and federal law;
  - f. Complete, updated information, to be provided the board as a condition for obtaining and retaining a license, about each wholesale drug distributor to be licensed under this chapter, including pertinent licensee corporate, if applicable, or other ownership, principal, key personnel, and facilities information;
  - g. Written policies and procedures that assure reasonable wholesale drug distributor and pharmacy distributor preparation for, protection against, and handling of any facility security or operation problems, including problems caused by natural disaster or government emergency; inventory inaccuracies or product shipping and receiving; outdated product or other unauthorized product control; appropriate disposition of returned goods; and product recalls;
  - h. Sufficient inspection procedures for all incoming and outgoing product shipments; and
  - i. Operations in compliance with all federal legal requirements applicable to wholesale drug distribution.

All requirements by the board under this subsection must conform to wholesale drug distributor licensing guidelines formally adopted by the United States food and drug administration. In case of conflict between any wholesale drug distributor licensing requirement imposed by the board under this subsection and any wholesale drug distributor licensing guideline of the food and drug administration, the guideline controls.

6. An agent or employee of any licensed wholesale drug distributor or pharmacy distributor need not seek licensure under this section and may lawfully possess pharmaceutical drugs when acting in the usual course of business or employment.
7. A person who violates this section is guilty of a class C felony.

**43-15.1-05. Out-of-state wholesale drug distributor and pharmacy distributor licensing requirements - Penalty.**

1. An out-of-state wholesale drug distributor or pharmacy distributor or a principal or agent of the distributor may not conduct any business in this state unless the distributor has obtained a license to do so from the board and paid the fee required by the board.
2. Application for a license under this section must be made on a form furnished by the board.
3. The issuance of a license under this section does not change or affect tax liability imposed by this state on any out-of-state wholesale drug distributor or pharmacy distributor.
4. The board, by rule, may license out-of-state wholesale drug distributors or pharmacy distributors on the basis of reciprocity to the extent that an out-of-state wholesale drug distributor or pharmacy distributor:
  - a. Possesses a valid license granted by another state pursuant to legal standards comparable to those of this state which must be met for obtaining a license under the laws of this state; and
  - b. Shows that the other state would extend reciprocal treatment under its own laws to a wholesale drug distributor or pharmacy distributor of this state.
5. A person who violates this section is guilty of a class C felony.

**43-15.1-06. License renewal procedures.**

The board shall mail an application for license renewal to each licensee before the first day of the month in which the license expires. If application for renewal of the license, along with required fee, is not received by the board before the first day of the following month, the license expires on the last day of that month.

**43-15.1-07. Adoption of rules.**

Every rule adopted by the board with respect to implementation of this chapter must conform to the wholesale drug distributor licensing guidelines formally adopted by the United States food and drug administration. In case of conflict between a rule adopted by the board and a guideline of the food and drug administration, the guideline controls.

**43-15.1-08. Violations of chapter - Effect on licensure.**

If the board determines that a wholesale drug distributor or wholesale pharmacy distributor has committed an act or is engaging in a course of conduct which constitutes a clear and present danger to the public health and safety in this state, the board may restrict or suspend the wholesale drug distributor's or pharmacy distributor's license. The board has the burden of proving that a wholesale drug distributor or wholesale pharmacy distributor is a clear and present danger to the public health and safety.

**43-15.1-09. Inspection powers and access to wholesale drug distributor records - Penalty.**

The board or a designee of the board may conduct inspections during normal business hours upon all open premises purporting or appearing to be used by a wholesale drug distributor or wholesale pharmacy distributor in this state. A distributor who provides adequate documentation of the most recent satisfactory inspection less than three years old by either the United States food and drug administration or a state agency determined to be comparable by the board is exempt from further inspection for a period of time determined by the board. This exemption does not bar the board from initiating an investigation pursuant to a complaint regarding a wholesale drug distributor or pharmacy distributor. A wholesale drug distributor may keep records at a central location apart from the principal office of the wholesale drug distributor or the location at which the drugs were stored and from which they were shipped; provided, that the records are made available for inspection within three business days of a request by the board. The records may be kept in any form permissible under federal law applicable to prescription drugs recordkeeping. A person who fails to provide a duly authorized person the right of entry as provided in this section is guilty of a class A misdemeanor for the first conviction and a class C felony for each subsequent conviction.

**43-15.1-10. Judicial enforcement.**

Upon proper application by the board, a court of competent jurisdiction may grant an injunction, restraining order, or other order as may be appropriate to enjoin a person from offering to engage or engaging in the performance of any acts or practices for which a certificate of registration or authority, permit, or license is required by any applicable state law, including this chapter, upon a showing that the acts or practices were or are likely to be performed or offered to be performed without a certificate of registration or authority, permit, or license. An action authorized under this section is in addition to and not in lieu of any other penalty provided by law and may be brought concurrently with other actions to enforce this chapter.

**CHAPTER 43-15.2****LEGEND DRUG DONATION AND REPOSITORY PROGRAM****43-15.2-01. Definitions.**

In addition to the definitions under section 43-15-01, in this chapter unless the context otherwise requires:

1. "Donor" means a person that donates to the program legend drugs, devices, or supplies needed to administer such drugs.
2. "Participant" means a practitioner or pharmacy that has elected to participate in the program and accepts legend drugs, devices, and supplies from donors for the program.
3. "Program" means the legend drug donation and repository program established under this chapter.
4. "Supplies" means any supplies used in the administration of a legend drug.

**43-15.2-02. Administration.**

1. The state board of pharmacy shall establish and contract with a third party to administer a legend drug donation and repository program.
2. The board may develop and maintain a participant registry for the program. A participant registry created under this subsection must include the name, address, and telephone number of the participants. A participant registry created under this subsection must be available through the board or on the board's website.
3. The board may cooperate with nongovernmental organizations to maintain a web-based list of legend drugs, devices, or supplies that have been donated and are available through the program and the participants from which the donated items may be available.

**43-15.2-03. Conditions for participation.**

1. A donor may donate legend drugs, devices, or supplies to the program through a practitioner or pharmacy that meets the criteria established for such participation. Legend drugs, devices, or supplies may not be donated directly to a specific patient and donated items may not be resold.
2. The items donated to the program may be prescribed for use by an individual by a practitioner who is authorized by law to prescribe and only a participant may dispense donated items.

**43-15.2-04. Conditions for acceptance of a donation.**

1. A drug donated, prescribed, or dispensed under the program must be in the original, unopened, sealed, and tamper-evident unit dose packaging, except a drug packaged in single-unit doses may be accepted and dispensed if the outside packaging has been opened and the single-unit-dose package is unopened.
2. A drug may not be accepted or dispensed under the program if the drug has reached its expiration date or if the drug is adulterated or misbranded as determined under subsection 3.
3. Before being dispensed to an eligible individual, the legend drugs, devices, and supplies donated under the program must be inspected by a pharmacist to determine that the legend drugs, devices, and supplies are not adulterated or misbranded.

**43-15.2-05. Storage, distribution, and dispensing.**

1. A participant that accepts donated legend drugs, devices, or supplies under the program shall comply with all applicable provisions of state and federal law relating to the storage, distribution, and dispensing of the donated legend drugs, devices, or supplies.

2. A participant may charge an individual a handling fee that does not exceed two hundred fifty percent of the Medicaid prescription dispensing fee for dispensing donated legend drugs, devices, or supplies under the program.
3. A dispenser of donated legend drugs, devices, or supplies may not submit a claim or otherwise seek reimbursement from any public or private third-party payer for the cost of donated legend drugs, devices, or supplies dispensed to any eligible individual under the program. A public or private third-party payer is not required to provide reimbursement to a dispenser for the cost of donated legend drugs, devices, or supplies dispensed to any eligible individual under the program.

#### **43-15.2-06. Liability.**

1. A donor of legend drugs, devices, or supplies, or any participant in the program, that exercises reasonable care in donating, accepting, distributing, prescribing, and dispensing legend drugs, devices, or supplies under the program and the rules adopted to implement this chapter is immune from civil or criminal liability and from professional disciplinary action of any kind for any injury, death, or loss to personal property relating to such activities.
2. In the absence of intentional misconduct, a pharmaceutical manufacturer is immune from civil or criminal liability for any claim, injury, death, or loss to person or property arising from transfer, donation, dispensing, or acceptance of any legend drugs, devices, or supplies under this chapter, including liability for failure to transfer or communicate product or consumer information regarding the transferred legend drugs, devices, or supplies as well as the expiration date of the legend drugs, devices, or supplies under the program.

#### **43-15.2-07. Recordkeeping.**

1. A participant shall retain separate records detailing the receipt, distribution, and dispensing of legend drugs, devices, and supplies under this program.
2. The records of receipt must include:
  - a. The name and address of the donor;
  - b. The drug name and strength;
  - c. The manufacturer of the legend drugs, devices, or supplies;
  - d. The manufacturer lot number;
  - e. The drug expiration date;
  - f. The date received; and
  - g. The quantity received.
3. Records of distribution and dispensing must include:
  - a. The name and address of the participant;
  - b. The drug or device name;
  - c. The drug strength;
  - d. The quantity distributed;
  - e. The identity of the manufacturer of the legend drugs, devices, or supplies;
  - f. The manufacturer lot number;
  - g. The expiration date;
  - h. The date of distribution or dispensing; and
  - i. The name and address of the individual to whom the donated item was distributed.
4. Records of dispensing must include:
  - a. The requirements for a prescription label; and
  - b. The manufacturer's lot number.

### **CHAPTER 43-15.3 WHOLESALE DRUG PEDIGREE**

#### **43-15.3-01. Definitions.**

As used in this chapter, unless the context otherwise requires:

1. "Authentication" means to affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

2. "Authorized distributor of record" means a wholesale distributor or a third-party logistics provider with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between the third-party logistics provider and the manufacturer or between the wholesale distributor and a manufacturer when the third-party logistics provider or the wholesale distributor, including any affiliated group of the wholesale distributor as defined in section 1504 of the Internal Revenue Code [26 U.S.C. 1504], complies with the following:
  - a. The wholesale distributor or a third-party logistics provider has a written agreement currently in effect with the manufacturer evidencing the ongoing relationship; and
  - b. The wholesale distributor or a third-party logistics provider is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis.
3. "Board" means the state board of pharmacy.
4. "Broker" means a party that mediates between a buyer and a seller the sale or shipment of prescription drugs, medical gases, or medical equipment.
5. "Chain pharmacy warehouse" means a physical location for prescription drugs, medical gases, or medical equipment which acts as a central warehouse and performs intracompany sales or transfers of the drugs, gases, or equipment to a group of chain pharmacies that have the same common ownership and control.
6. "Colicensed product" means a prescription drug, medical gas, or medical equipment in which two or more parties have the right to engage in the manufacturing or marketing or in the manufacturing and marketing of the drug, gas, or equipment.
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:
  - a. Is recognized in the United States pharmacopeia or the official national formulary is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals, or is intended to affect the structure or any function of the body of humans or other animals;
  - b. Does not achieve its primary intended purposes through chemical action within or on the body of a human or other animal; and
  - c. Is not dependent upon being metabolized for the achievement of its primary intended purposes.
8. "Drop shipment" means the sale of a prescription drug, medical gas, or medical equipment to a wholesale distributor by the manufacturer of the prescription drug, medical gas, or medical equipment or to that manufacturer's colicensed product partner, that manufacturer's third-party logistics provider, or that manufacturer's exclusive distributor, under the terms of which the wholesale distributor or chain pharmacy warehouse takes title but not physical possession of the prescription drug, medical gas, or medical equipment and the wholesale distributor invoices the pharmacy or chain pharmacy warehouse, or other person authorized by law to dispense or administer the drug, gas, or equipment to a patient, and the pharmacy or chain pharmacy warehouse or other authorized person receives delivery of the prescription drug, medical gas, or medical equipment directly from the manufacturer, or that manufacturer's third-party logistics provider, or that manufacturer's exclusive distributor.
9. "Durable medical equipment" means medical devices, equipment, or supplies that may be used in a residence, including oxygen and oxygen delivery systems and supplies, ventilators, respiratory disease management devices, continuous positive airway pressure (CPAP) devices, electronic and computerized wheelchairs and seating systems, apnea monitors, transcutaneous medical nerve stimulator (TENS) units, low air cutaneous pressure management devices, sequential compression devices, feeding pumps, home phototherapy devices, infusion delivery devices, distribution of medical gases to end users for human consumption, hospital beds, nebulizers, and other similar equipment as may be determined by the board by rule.
10. "Facility" means a facility of a wholesale distributor where prescription drugs, medical gases, or medical equipment are stored, handled, repackaged, or offered for sale.
11. "Manufacturer" means a person licensed or approved by the federal food and drug administration to engage in the manufacture of drugs, medical gases, or devices by manufacturing the drugs, gases, or devices at the person's own facility or by contracting for the manufacturing by others.

12. "Manufacturer's exclusive distributor" means any person that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and which takes title to that manufacturer's prescription drug, medical gases, or medical equipment but which does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug, medical gas, or medical equipment. The manufacturer's exclusive distributor must be licensed as a wholesale distributor under this chapter, and to be considered part of the normal distribution channel also must be an authorized distributor of record.
13. "Medical device" means a product or equipment used to diagnose a disease or other condition in order to cure, treat, or prevent disease.
14. "Medical equipment" means equipment prescribed or distributed by a practitioner used in the course of treatment of home care.
15. "Medical gas" means any gaseous substance that meets medical purity standards and has application in a medical environment.
16. "Normal distribution channel" means a chain of custody for a prescription drug which goes, directly or by drop shipment, from a manufacturer of the prescription drug, from that manufacturer to that manufacturer's colicensed partner, from that manufacturer to that manufacturer's third-party logistics provider, or from that manufacturer to that manufacturer's exclusive distributor to:
  - a. A pharmacy, to a patient or other designated person authorized by law to dispense or administer the drug to a patient;
  - b. A wholesale distributor, to a pharmacy, to a patient or other designated person authorized by law to dispense or administer the drug to a patient;
  - c. A wholesale distributor, to a chain pharmacy warehouse, to that chain pharmacy warehouse's intracompany pharmacy, to a patient or other designated person authorized by law to dispense or administer the drug to a patient; or
  - d. A chain pharmacy warehouse, to the chain pharmacy warehouse's intracompany pharmacy, to a patient or other designated person authorized by law to dispense or administer the drug to a patient.
17. "Outsourcing facility" means a facility at one geographic location or address which is engaged in anticipatory compounding of sterile drugs and complies with section 503(b) of the federal Food, Drug, and Cosmetic Act [21 U.S.C. 353(b)].
18. "Pedigree" means a document or an electronic file containing information that records each distribution of any given prescription drug.
19. "Pharmacy distributor" means any pharmacy or hospital pharmacy licensed in this state which is engaged in the delivery or distribution of prescription drugs, medical gases, or medical equipment to any other pharmacy licensed in this state or to any other person, including a wholesale drug distributor, engaged in the delivery or distribution of prescription drugs, medical gases, or medical equipment and involved in the actual, constructive, or attempted transfer of a drug, gas, or equipment in this state to other than the ultimate consumer, when the financial value of the drugs, gases, or equipment is equivalent to at least five percent of the total gross sales of the pharmacy distributor.
20. "Prescription drug" means any drug, including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices, required by federal law, including federal regulation, to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the federal Food, Drug, and Cosmetic Act [21 U.S.C. 353(b)].
21. "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug. The term does not include actions completed by the pharmacists responsible for dispensing product to the patient.
22. "Repackager" means a person that repackages.
23. "Third-party logistics provider" means a person that contracts with a wholesale distributor or a prescription drug, medical gas, or medical equipment manufacturer to provide or coordinate warehousing, wholesale distribution, or other services on behalf of a manufacturer, but does not take title to the prescription drug, medical gas, or medical equipment or have general responsibility to direct the prescription drug's, medical gas's, or medical equipment's sale or disposition. The third-party logistics provider must be licensed independently under this chapter and to be considered part of the normal distribution channel must also be an authorized distributor of record.

24. "Trace" means the capability to identify the historical locations, the records of ownership, and the packaging hierarchy for a particular traceable item. "Trace" answers questions such as where has the item been, who previously owned the item, and in what packaging hierarchy did the product exist at various locations.
25. "Track" means the capability to identify the current, and at the time of shipment the intended future, location, ownership, and packaging hierarchy of a traceable item through the supply chain as the traceable item moves between parties. "Track" addresses both forward and reverse logistics operations. "Track" answers questions such as where is the item currently, who is the next intended recipient, and what is the current packaging hierarchy of the item.
26. "Virtual distributor" means a person that arranges for the distribution of a drug or device and which may or may not take actual possession of the drug or device but contracts with others for the distribution, purchase, and sale.
27. "Virtual manufacturer" means a person that owns the new drug application or abbreviated new drug application for a drug or device and which contracts with others for the actual manufacturing of the drug or device.
28. "Wholesale distribution" means distribution of prescription drugs, medical gases, or medical equipment to persons other than a consumer or patient. The term does not include:
  - a. Intracompany sales of prescription drugs, medical gases, or medical equipment, meaning any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership and control of a corporate entity, or any transaction or transfer between colicensees of a colicensed product.
  - b. The sale, purchase, distribution, trade, or transfer of a prescription drug, medical gas, or medical equipment or the offer to sell, purchase, distribute, trade, or transfer a prescription drug, medical gas, or medical equipment for emergency medical reasons.
  - c. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug, gas, or equipment for the hospital's or health care entity's own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations.
  - d. The sale, purchase, or trade of a drug, gas, or equipment or an offer to sell, purchase, or trade a drug, gas, or equipment by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law.
  - e. The sale, purchase, or trade of a drug, gas, or equipment or an offer to sell, purchase, or trade a drug, gas, or equipment among hospitals or other health care entities that are under common control.
  - f. The distribution of prescription drug samples by manufacturers' representatives.
  - g. Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with title 21, Code of Federal Regulations, section 203.23.
  - h. The sale of minimal quantities of prescription drugs, medical gases, or medical equipment by retail pharmacies to licensed practitioners for office use.
  - i. The sale, purchase, or trade of a drug, gas, or equipment; an offer to sell, purchase, or trade a drug, gas, or equipment; or the dispensing of a drug, gas, or equipment pursuant to a prescription.
  - j. The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy from or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets.
  - k. The sale, purchase, distribution, trade, or transfer of a prescription drug, medical gas, or medical equipment from one authorized distributor of record to one additional authorized distributor of record when the manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply such prescription drug, medical gas, or medical equipment and the supplying authorized distributor of record states in writing that the prescription drug, medical gas, or medical equipment being supplied had until that time been exclusively in the normal distribution channel.

- l. The delivery of, or offer to deliver, a prescription drug, medical gas, or medical equipment by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, medical gases, or medical equipment and the common carrier does not store, warehouse, or take legal ownership of the prescription drug, medical gas, or medical equipment.
  - m. The sale or transfer from a retail pharmacy or chain pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs, medical gases, or medical equipment to the original manufacturer or to a third-party returns processor.
29. "Wholesale distributor" means anyone engaged in the wholesale distribution of prescription drugs, medical gases, or medical equipment, including manufacturers; virtual manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; virtual distributors and warehouses, including manufacturers' and distributors' warehouses; manufacturers' exclusive distributors; authorized distributors of record; drug, gas, or equipment wholesalers or distributors; independent wholesale drug, gas, or equipment traders; specialty wholesale distributors; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution. To be considered part of the normal distribution channel, such wholesale distributor must also be an authorized distributor of record.

#### **43-15.3-02. Rulemaking authority.**

The board shall adopt rules that conform with wholesale distributor licensing guidelines adopted by the federal food and drug administration, including rules necessary to carry out the purposes of this chapter, that incorporate and set detailed standards for meeting each of the license prerequisites set forth in this chapter, and that establish reasonable fees to carry out this chapter.

#### **43-15.3-03. Wholesale distributor licensing requirement - Minimum requirements for licensure.**

1. A wholesale distributor that engages in the wholesale distribution of prescription drugs, medical gases, or medical equipment shall pay the annual fee required by the board, must be licensed by the board under this chapter, and must be properly licensed in any other state in which the wholesale distributor engages in the distribution of prescription drugs, medical gases, or medical equipment before engaging in wholesale distributions of wholesale prescription drugs, medical gases, or medical equipment in this state. The licensee shall operate in a manner prescribed by law and according to rules adopted by the board. However, information and qualification requirements for licensure beyond that required by federal law or regulation do not apply to manufacturers distributing the manufacturers' own United States food and drug administration-approved drugs, gases, or equipment, unless particular requirements are deemed necessary and appropriate following rulemaking. The board may grant a temporary license when the wholesale distributor or pharmacy distributor first applies for a license to operate within this state. A temporary license is valid until the board finds that the applicant meets the requirements for regular licensure.
2. A person may not engage in wholesale distributions of prescription drugs without obtaining and maintaining accreditation or certification from the national association of boards of pharmacy's verified accredited wholesale distributor or an accreditation body approved by the board, obtaining and maintaining a license issued by the board, and paying fees as may be required by the board.
3. The board shall require the following minimum information from each wholesale distributor applying to get a license under subsection 1:
  - a. The name, full business address, and telephone number of the licensee.
  - b. All trade or business names used by the licensee.
  - c. Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs.
  - d. The type of ownership or operation.
  - e. The name of every owner and operator of the licensee, including:
    - (1) If an individual, the name of the individual;
    - (2) If a partnership, the name of each partner, and the name of the partnership;
    - (3) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and
    - (4) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.



- f. A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs, medical gases, or medical equipment.
- g. The name of the applicant's designated representative for the facility and for a prescription drug wholesaler applicant, the personal information statement and fingerprints required pursuant to subdivision h for the individual identified as the prescription drug wholesaler applicant's designated representative for the facility.
- h. Each individual identified by a prescription drug wholesaler applicant as a designated representative for a facility and therefore required by subdivision g to provide a personal information statement and fingerprints shall provide the following information to the state:
  - (1) The individual's places of residence for the past seven years;
  - (2) The individual's date and place of birth;
  - (3) The individual's occupations, positions of employment, and offices held during the past seven years;
  - (4) The principal business and address of any business, corporation, or other organization in which each office of the individual was held or in which each occupation or position of employment was carried on;
  - (5) Whether the individual has been, during the past seven years, the subject of any proceeding for the revocation of any license or any criminal violation and, if so, the nature of the proceeding and the disposition of the proceeding;
  - (6) Whether, during the past seven years, the individual has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs or criminal violations, together with details concerning any of those events;
  - (7) A description of any involvement by the individual with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past seven years, which manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which the businesses were named as a party;
  - (8) A description of any misdemeanor or felony criminal offense of which the individual, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the individual pled guilty or nolo contendere. If the individual indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of that criminal offense, the applicant must, within fifteen days after the disposition of the appeal, submit to the state a copy of the final written order of disposition; and
  - (9) A photograph of the individual taken in the previous one hundred eighty days.
4. The information required under subsection 3 must be provided under oath.
5. The board may not issue a wholesale distributor license to an applicant, unless the board:
  - a. Inspects or appoints a third party recognized by the board for the purpose of inspecting the wholesale distribution operations of the facility before initial licensure and continues to inspect periodically thereafter in accordance with a schedule to be determined by the board, but not less than every three years. Manufacturing facilities are exempt from inspection by the board if the manufacturing facilities are currently registered with the federal food and drug administration in accordance with section 510 of the federal Food, Drug, and Cosmetic Act [21 U.S.C. 301]; and
  - b. Determines that the designated representative meets the following qualifications:
    - (1) Is at least twenty-one years of age;
    - (2) Has been employed full time for at least three years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs, medical gases, or medical equipment;
    - (3) Is employed by the applicant full time in a managerial level position;
    - (4) Is actively involved in and aware of the actual daily operation of the wholesale distributor;
    - (5) Is physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including sick leave and vacation leave;

- (6) Is serving in the capacity of a designated representative for only one applicant at a time, except where more than one licensed wholesale distributor is colocated in the same facility and the wholesale distributors are members of an affiliated group, as defined in section 1504 of the Internal Revenue Code [26 U.S.C. 1504];
  - (7) Does not have any convictions under any federal, state, or local laws relating to wholesale or retail prescription drug, medical gas, or medical equipment distribution or distribution of controlled substances; and
  - (8) Does not have any felony conviction under federal, state, or local laws.
6. The board shall submit the fingerprints provided by an individual with a license application for a statewide and nationwide criminal history background record check. The nationwide criminal history background record check must be conducted in the manner provided in section 12-60-24. All costs associated with the background check are the responsibility of the applicant.
  7. The board shall require every wholesale prescription drug distributor applying for a license to submit a bond of at least one hundred thousand dollars, or other equivalent means of security acceptable to the state, including an irrevocable letter of credit or a deposit in a trust account or financial institution. Obtaining and maintaining accreditation or certification from the national association of boards of pharmacy's verified accredited wholesale distributor satisfies this requirement. A chain pharmacy warehouse that is engaged only in intracompany transfers is not subject to the bond requirement. The purpose of the bond is to secure payment of any fines or penalties imposed by the state and any fees and costs incurred by the state regarding that license which are authorized under state law and which the licensee fails to pay thirty days after the fines, penalties, or costs become final. The state may make a claim against the bond or security until one year after the licensee's license ceases to be valid. A single bond may cover all facilities operated by the applicant in the state. Any chain pharmacy warehouse that is engaged only in intracompany transfers is exempt from the bond requirement.
  8. If a wholesale distributor distributes prescription drugs, medical gases, or medical equipment from more than one facility, the wholesale distributor shall obtain a license for each facility.
  9. If a manufacturer manufactures prescription drugs, medical gases, or medical equipment in more than one facility but does not engage in wholesale distribution to North Dakota from those facilities, the manufacturer is not required to obtain a license for each facility.
  10. The board shall mail or e-mail a notice for license renewal to each licensee before the first day of the month in which the license expires. If application for renewal of the license, along with the required fee, is not received by the board before the first day of the following month, the license expires on the last day of that month. Timely renewal is the responsibility of the licensee.
  11. In accordance with each licensure renewal, the board shall make available on the board's website for each wholesale distributor licensed under this section the information that the wholesale distributor provided pursuant to subsection 3. Within thirty days of receiving the notice, the wholesale distributor shall identify and state under oath to the state licensing authority all changes or corrections to the information that was provided under subsection 3. Changes in, or corrections to, any information in subsection 3 must be submitted to the board as required by that authority. The board may suspend, revoke, or refuse to renew the license of a wholesale distributor if the board determines that the wholesale distributor no longer qualifies for the license issued under this section.
  12. The designated representative identified pursuant to subdivision g of subsection 3 must receive and complete continuing training in applicable federal and state laws governing wholesale distribution of prescription drugs, medical gases, or medical equipment.
  13. Information provided under subdivision h of subsection 3 may not be disclosed to any person other than a government agency that needs the information for licensing or monitoring purposes.

**43-15.3-04. Requirements to distribute prescription drugs, medical gases, or medical equipment.**

1. A person may not engage in wholesale distributions of prescription drugs without obtaining and maintaining accreditation or certification from the national association of boards of pharmacy's verified accredited wholesale distributor or an accreditation body approved by the board under subsection 4, obtaining and maintaining a license issued by the board, and paying any reasonable fee required by the board.

2. The board may not issue or renew the license of a wholesale distributor that does not comply with this chapter. The board shall require a separate license for each facility or location where wholesale distribution operations are conducted. An agent or employee of any licensed wholesale distributor does not need a license and may lawfully possess pharmaceutical drugs, medical gases, or medical equipment when acting in the usual course of business or employment. The issuance of a license under this chapter does not affect tax liability imposed by the tax department on any wholesale distributor.
3. An out-of-state wholesale distributor or pharmacy distributor or a principal or agent of the distributor may not conduct business in this state unless the distributor has obtained the necessary license from the board, paid the fee required by the board, and registered with the secretary of state. Application for a license must be made on a form furnished by the board and when submitted by the applicant to the board must include a copy of the certificate of authority from the secretary of state. The issuance of a license under this section does not affect tax liability imposed by the tax department on any out-of-state wholesale distributor or pharmacy distributor. The board may adopt rules that permit out-of-state wholesale distributors to obtain a license on the basis of reciprocity if an out-of-state wholesale distributor possesses a valid license granted by another state and the legal standards for licensure in the other state are comparable to the standards under this chapter and the other state extends reciprocity to wholesale drug distributors licensed in this state. However, if the requirements for licensure under this chapter are more restrictive than the standards of the other state, the out-of-state wholesale distributor shall comply with the additional requirements of this chapter to obtain a license under this chapter.
4. The board may adopt rules to approve an accreditation body to evaluate a wholesale distributor's operations to determine compliance with professional standards, this chapter, and any other applicable law, and perform inspections of each facility and location where wholesale distribution operations are conducted by the wholesale distributor.
5. The board or a designee of the board may conduct inspections during normal business hours upon all open premises purporting or appearing to be used by a wholesale distributor or pharmacy distributor in this state. A distributor that provides adequate documentation of the most recent satisfactory inspection less than three years old by the United States food and drug administration is exempt from further inspection for a period of time determined by the board. This exemption does not bar the board from initiating an investigation pursuant to a complaint regarding a wholesale distributor or pharmacy distributor. A wholesale distributor or pharmacy distributor may keep records at a central location apart from the principal office of the wholesale distributor or pharmacy distributor or the location at which the drugs are stored and from which they were shipped, provided that the records are made available for inspection within three business days of a request by the board. The records may be kept in any form permissible under federal law applicable to prescription recordkeeping.

#### **43-15.3-05. Restrictions on transactions.**

1. A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse under the terms and conditions of the agreement between the wholesale distributor and the pharmacy or between the wholesale distributor and the chain pharmacy warehouse, including the returns of expired, damaged, and recalled pharmaceutical product to either the original manufacturer or a third-party returns processor, and the returns or exchanges are not subject to the pedigree requirement of section 43-15.3-06 if they are exempt from pedigree under the federal food and drug administration's currently applicable guidance for the federal Prescription Drug Marketing Act of 1987 [Pub. L. 100-293; 102 Stat. 95]. Wholesale distributors and pharmacies must ensure that the aspects of this operation are secure and do not permit the entry of adulterated and counterfeit product.
2. A manufacturer or wholesale distributor shall furnish prescription drugs only to a person licensed by the appropriate state licensing authorities. Before furnishing prescription drugs to a person not known to the manufacturer or wholesale distributor, the manufacturer or wholesale distributor shall affirmatively verify that the person is legally authorized to receive the prescription drugs by contacting the appropriate state licensing authorities.

3. Prescription drugs furnished by a manufacturer or wholesale distributor may be delivered only to the premises listed on the license. The manufacturer or wholesale distributor may furnish prescription drugs to an individual or agent of that individual at the premises of the manufacturer or wholesale distributor if:
  - a. The identity and authorization of the recipient are properly established; and
  - b. This method of receipt is employed only to meet the immediate needs of a particular patient of the authorized individual.
4. Prescription drugs may be furnished to a hospital pharmacy receiving area if a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug so received. Any discrepancy between receipt and the type and quantity of the prescription drug actually received must be reported to the delivering manufacturer or wholesale distributor by the next business day after the delivery to the pharmacy receiving area.
5. A manufacturer or wholesale distributor may not accept payment for or allow the use of a person's credit to establish an account for the purchase of prescription drugs from any individual other than the owner of record, the chief executive officer, or the chief financial officer listed on the license of an individual legally authorized to receive prescription drugs. Any account established for the purchase of prescription drugs must bear the name of the licensee.

**43-15.3-06. Pedigree.**

1. Each person who is engaged in wholesale distribution of prescription drugs, including repackagers but excluding the original manufacturer of the finished form of the prescription drug which leave or have ever left the normal distribution channel, before each wholesale distribution of the drug, must provide a pedigree to the person who receives the drug.
  - a. A retail pharmacy or chain pharmacy warehouse must comply with the requirements of this section only if the pharmacy or chain pharmacy warehouse engages in wholesale distribution of prescription drugs.
  - b. The board shall determine by July 1, 2009, a targeted implementation date for electronic track and trace pedigree technology. The determination must be based on consultation with manufacturers, distributors, and pharmacies responsible for the sale and distribution of prescription drug products in this state. After consultation with interested stakeholders and before implementation of the electronic track and trace pedigree technology, the board must determine that the technology is universally available across the entire prescription pharmaceutical supply chain. The implementation date for the mandated electronic track and trace pedigree technology may not be before July 1, 2010, and may be extended by the board in one-year increments if it appears the technology is not universally available across the entire prescription pharmaceutical supply chain.
2. Each person engaged in the wholesale distribution of a prescription drug, including a repackager but excluding the original manufacturer of the finished form of the prescription drug, that is provided a pedigree for a prescription drug and attempts to further distribute that prescription drug shall verify affirmatively before any distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.
3. The pedigree must:
  - a. Include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer, or the manufacturer's third-party logistics provider, colicensed product partner, or manufacturer's exclusive distributor, through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the drug. At minimum, the necessary chain of distribution information must include:
    - (1) The name, address, telephone number, and if available, the e-mail address, of each owner of the prescription drug, and each wholesale distributor of the prescription drug;
    - (2) The name and address of each location from which the product was shipped, if different from the owner's;
    - (3) The transaction dates; and
    - (4) A certification that each recipient has authenticated the pedigree.
  - b. At minimum, the pedigree must also include the:
    - (1) Name of the prescription drug;
    - (2) Dosage form and strength of the prescription drug;

- (3) Size of the container;
  - (4) Number of containers;
  - (5) Lot number of the prescription drug;
  - (6) Name of the manufacturer of the finished dosage form; and
  - (7) National drug code (NDC) number.
4. Each pedigree or electronic file must be:
    - a. Maintained by the purchaser and the wholesale distributor for three years from the date of sale or transfer; and
    - b. Available for inspection or use within five business days upon a request of an authorized officer of the law or the board.
  5. The board shall adopt rules and a form relating to the requirements of this section.

**43-15.3-07. Order to cease distribution.**

1. The board shall issue an order requiring the appropriate person, including the distributors or retailers of the drug, gas, or equipment to immediately cease distribution of the drug, gas, or equipment within the state if the board finds there is a reasonable probability:
  - a. A wholesale distributor, other than a manufacturer, has violated a provision in this chapter or falsified a pedigree or sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug, medical gas, or medical equipment intended for human use;
  - b. The prescription drug, medical gas, or medical equipment at issue as a result of a violation in subdivision a could cause serious, adverse health consequences or death; and
  - c. Other procedures would result in unreasonable delay.
2. An order under subsection 1 must provide the individual subject to the order with an opportunity for an informal hearing, to be held not later than ten days after the date of the issuance of the order, on the actions required by the order. If, after providing an opportunity for such a hearing, the board determines that inadequate grounds exist to support the actions required by the order, the board shall vacate the order.

**43-15.3-08. Prohibited acts - Penalty.**

1. Except as otherwise provided under section 43-15.3-09, it is a class B misdemeanor for a person to perform or cause the performance of or aid and abet any of the following acts in this state:
  - a. Failing to obtain a license under this chapter or operating without a valid license when a license is required by this chapter.
  - b. If the requirements of subsection 1 of section 43-15.3-05 are applicable and are not met, purchasing or otherwise receiving a prescription drug, medical gas, or medical equipment from a pharmacy.
  - c. If a state license is required under subsection 2 of section 43-15.3-05, selling, distributing, or transferring a prescription drug, medical gas, or medical equipment to a person that is not authorized under the law of the jurisdiction in which the person receives the prescription drug, medical gas, or medical equipment to receive the prescription drug, medical gas, or medical equipment.
  - d. Failing to deliver prescription drugs, medical gases, or medical equipment to specified premises, as required by subsection 3 of section 43-15.3-05.
  - e. Accepting payment or credit for the sale of prescription drugs, medical gases, or medical equipment in violation of subsection 5 of section 43-15.3-05.
  - f. Failing to maintain or provide pedigrees as required by this chapter.
  - g. Failing to obtain, pass, or authenticate a pedigree, as required by this chapter.
  - h. Providing the board or any of the board's representatives or any federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of this chapter.
  - i. Obtaining or attempting to obtain a prescription drug, medical gas, or medical equipment by fraud, deceit, misrepresentation, or engaging in misrepresentation or fraud in the distribution of a prescription drug, medical gas, or medical equipment.

- j. Except for the wholesale distribution by manufacturers of a prescription drug, medical gas, or medical equipment that has been delivered into commerce pursuant to an application approved under federal law by the federal food and drug administration, manufacturing, repacking, selling, transferring, delivering, holding, or offering for sale any prescription drug, medical gas, or medical equipment that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for distribution.
  - k. Except for the wholesale distribution by a manufacturer of a prescription drug, medical gas, or medical equipment that has been delivered into commerce under an application approved under federal law by the federal food and drug administration, adulterating, misbranding, or counterfeiting any prescription drug, medical gas, or medical equipment.
  - l. Receiving any prescription drug, medical gas, or medical equipment that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, and the delivery or proffered delivery of such drug, gas, or equipment for pay or otherwise.
  - m. Altering, mutilating, destroying, obliterating, or removing the whole or any part of the labeling of a prescription drug, medical gas, or medical equipment or the commission of any other act with respect to a prescription drug, medical gas, or medical equipment which results in the prescription drug, medical gas, or medical equipment being misbranded.
2. The prohibited acts in subsection 1 do not include a prescription drug, medical gas, or medical equipment manufacturer or agent of a prescription drug, medical gas, or medical equipment manufacturer obtaining or attempting to obtain a prescription drug, medical gas, or medical equipment for the sole purpose of testing the prescription drug, medical gas, or medical equipment for authenticity.

#### **43-15.3-09. Penalties.**

- 1. The board may impose the following sanctions if, after a hearing under chapter 28-32, the board finds that a person violated section 43-15.3-08:
  - a. Revoke, suspend, or limit the wholesale distributor's license issued under this chapter if the person is a wholesale distributor; or
  - b. Assess a civil penalty against the person. A civil penalty assessed may not exceed ten thousand dollars per violation.
- 2. The board, upon a showing of a violation of this chapter, may revoke, suspend, or limit a license issued under this chapter after a proceeding under chapter 28-32. After a proceeding under chapter 28-32, the board may assess a civil penalty against a licensed wholesale distributor of not more than ten thousand dollars for each occurrence. If the licensed wholesale distributor fails to pay the civil penalty within the time specified by the board, the board may suspend the license without additional proceedings.
- 3. Upon application by the board, a court may grant an injunction, a restraining order, or other order to enjoin a person from offering to engage or engaging in the performance of any practices for which a permit or license is required by any applicable federal or state law including this chapter, upon a showing that the practices were or are likely to be performed or offered to be performed without a permit or license. An action brought under this subsection must be commenced either in the county where the conduct occurred or is likely to occur or in the county in the state where the defendant resides. An action brought under this subsection is in addition to any other penalty provided by law and may be brought concurrently with other actions to enforce this chapter.
- 4. A person that knowingly purchases or receives a prescription drug, medical gas, or medical equipment through any source other than a person licensed under this chapter, including a wholesale distributor, manufacturer, pharmacy distributor, or pharmacy commits a class A misdemeanor. A subsequent unrelated violation of this subsection is a class C felony.
- 5. A person that knowingly fails to provide a duly authorized individual the right of entry as provided in subsection 5 of section 43-15.3-04 is guilty of a class A misdemeanor for the first conviction and a class C felony for each subsequent conviction.

6. A person that knowingly or intentionally engages in the wholesale distribution of a prescription drug, medical gas, or medical equipment without a license issued under this chapter commits a class C felony. A person is guilty of a class C felony if that person engages in the wholesale distribution of a prescription drug and with intent to defraud or deceive fails to obtain or deliver to another person a complete and accurate required pedigree concerning a prescription drug before obtaining the prescription drug from another person or transferring the prescription drug to another person or falsely swears or certifies that the person has authenticated any documents to the wholesale distribution of prescription drugs.
7. A person is guilty of a class C felony if that person engages in the wholesale distribution of a prescription drug, medical gas, or medical equipment and knowingly or intentionally:
  - a. Destroys, alters, conceals, or fails to maintain a complete and accurate required pedigree concerning a prescription drug in the person's possession;
  - b. Purchases or receives prescription drugs, medical gases, or medical equipment from a person not authorized to distribute prescription drugs, medical gases, or medical equipment in wholesale distribution;
  - c. Sells, barter, brokers, or transfers a prescription drug, medical gas, or medical equipment to a person not authorized to purchase the prescription drug, medical gas, or medical equipment in the jurisdiction in which the person receives the prescription drug, medical gas, or medical equipment in a wholesale distribution;
  - d. Forges, counterfeits, or falsely creates a pedigree;
  - e. Falsely represents a factual matter contained in a pedigree; or
  - f. Fails to record material information required to be recorded in a pedigree.
8. A person is guilty of a class C felony if that person engages in the wholesale distribution of a prescription drug and possesses a required pedigree concerning a prescription drug, knowingly or intentionally fails to authenticate the matters contained in the pedigree as required, and distributes or attempts to further distribute the prescription drug.

**43-15.3-10. Retail medical gas retailers - Reciprocity.**

1. A person may not sell or deliver medical gases and related medical equipment directly to a consumer unless licensed by the board as a retail medical gas retailer.
  - a. As a term of licensure under this section, a licensee shall employ or contract with an in-state licensed respiratory therapist or other health care professional authorized by that professional's practice act to prescribe or administer the medical gases and related medical equipment. The applicant shall furnish on the application the name and license number of the individual or licensee the applicant employees or with which the applicant contracts. Within thirty days of a change, a retailer shall provide the board with notice of any change in the licensee.
  - b. A retail medical gas retailer may sell or deliver to a patient's home medical gases and related equipment in accordance with a practitioner's prescription or drug order. The retail medical gas retailer shall keep the original drug order or an electronic copy of each drug order at the licensed location or must have available for inspection an electronic copy of the original drug order or electronic copy of the drug order. A prescription or drug order is not valid after one year, except a prescription or order for maintenance equipment may be perpetual. A retail medical gas retailer shall maintain a prescription or drug order for five years.
2. An out-of-state retail medical gas retailer or a principal or agent of the retailer may not conduct business in this state unless the retailer is licensed by the board as a retail medical gas retailer, paid the fee required by the board, and is registered with the secretary of state. An applicant shall submit an application for a license on a form furnished by the board and the application must be accompanied by a copy of the certificate of authority from the secretary of state. The issuance of a license under this section does not change or affect tax liability imposed by this state on an out-of-state medical gas retailer.

3. The board may adopt rules that permit an out-of-state retail medical gas retailer to obtain a license on the basis of reciprocity if the retailer possesses a valid license granted by another jurisdiction and the legal standards for licensure in the other jurisdiction are comparable to the standards under this chapter and if the other jurisdiction extends reciprocity to retail medical gas retailers licensed in this state. However, if the requirements for licensure under this chapter are more restrictive than the standards of the other jurisdiction, the out-of-state retail medical gas retailer shall comply with the additional requirements of this chapter to obtain a license under this chapter.

**43-15.3-11. Retail durable medical equipment retailers - Reciprocity.**

1. A person may not sell or deliver durable medical equipment directly to a consumer unless licensed by the board as a retail durable medical equipment retailer.
  - a. As a term of licensure under this section, a licensee shall employ or contract with an in-state licensed health care professional authorized by that professional's practice act to prescribe or administer the durable medical equipment. For purposes of this section, a licensed health care professional may include a respiratory therapist, physical therapist, pharmacist, registered nurse, licensed practical nurse, advanced practice registered nurse, physician assistant, and occupational therapist.
    - (1) The licensed health care professional must be on staff to oversee and provide custom orthotics and prosthetics. The board shall establish certification requirements for a qualified health care professional which may include certification through the American board for certification in orthotics and prosthetics or the board for certification in orthotics as a certified orthotist, certified prosthetist, certified prosthetist orthotist, certified orthotic fitter, certified mastectomy fitter, or certified pedorthist.
    - (2) The licensed health care professional must be on staff to oversee and provide complex rehabilitation products and services for seating and mobility systems. The board shall establish certification requirements for a qualified health care professional which may include certification through the rehabilitation engineering and assistive technology society of North America as an assistive technology professional.
    - (3) The applicant shall furnish on the application the name and license number of the individual the licensee employs or with which the applicant contracts. Within thirty days of a change, the licensee shall provide the board with notice of any change in the licensee.
  - b. A durable medical equipment retailer may sell or deliver to a patient's home durable medical-related equipment in accordance with a practitioner's prescription or drug order. The retail durable medical equipment retailer shall keep the original prescription or order or an electronic copy at the licensed location or must have available for inspection an electronic copy of the original order or electronic copy of the order. A prescription or order is not valid after one year, except a prescription or order for repair, maintenance, or replacement of equipment and items designated as thirteen month capped rental items by the center of medicare and medicaid services may be perpetual. A retail durable medical equipment retailer shall maintain a prescription or order for five years. A durable medical equipment retailer may only obtain medical equipment from a manufacturer or wholesaler that is duly licensed by the state.
2. An out-of-state retail durable medical equipment retailer or a principal or agent of the retailer may not conduct business in this state unless the retailer is licensed by the board as a retail durable medical equipment retailer, paid the fee required by the board, and is registered with the secretary of state. An applicant shall submit an application for a license on a form furnished by the board and the applicant must be accompanied by a copy of the certificate of authority from the secretary of state. The issuance of a license under this section does not change or affect tax liability imposed by this state on an out-of-state retail durable medical equipment retailer.



3. The board may adopt rules that permit an out-of-state retail durable medical equipment retailer to obtain a license on the basis of reciprocity if the retailer possesses a valid license granted by another jurisdiction and the legal standards for licensure in the other jurisdiction are comparable to the standards under this chapter and if the other jurisdiction extends reciprocity to retail durable medical equipment retailers licensed in this state. However, if the requirements for licensure under this chapter are more restrictive than the standards of the other jurisdiction, the out-of-state retail durable medical equipment retailer shall comply with the additional requirements of this chapter to obtain a license under this chapter.

#### **43-15.3-12 Fees.**

The board shall charge and collect the following fees under this chapter:

Chain drug warehouse	\$200
Chain pharmacy warehouse	\$200
Durable medical equipment distributor, medical gas distributor, or both	\$200
Durable medical equipment retailer, medical gas retailer and distributor, or both	\$300
Hospital offsite warehouse	\$200
Jobber or broker	\$400
Manufacturer	\$400
Medical gas retailer, durable medical equipment retailer, or both	\$200
Medical gas durable medical equipment distributor and retailer	\$300
Outsourcing facility	\$200
Own label distributor	\$400
Pharmacy distributor	\$200
Private label distributor	\$400
Repackager	\$400
Reverse distributor	\$200
Third-party logistic provider	\$400
Veterinary-only distributor	\$200
Virtual manufacturer	\$400
Virtual wholesaler or distributor	\$400
Wholesaler or distributor	\$400

#### **43-15.3.13 Compounding provided by an outsourcing facility.**

1. A facility may provide, without a patient specific prescription, a nonpatient specific compounded drug preparation for human use only, if the following conditions apply:
  - a. The entity is registered with the United States food and drug administration as an outsourcing facility pursuant to section 503(b) of the federal Food, Drug, and Cosmetic Act [21 U.S.C. 353(b)]; and
  - b. The entity is licensed under this chapter with an outsourcing facility classification, has designated a licensed pharmacist in the state of residence as the responsible person on the license, and the facility meets the standards for licensure set in this chapter.
2. Within forty-eight hours of a request from the board, the facility shall make available to the board any inspection reports, federal food and drug administration reports of objectionable conditions issued against the facility, and lists of distribution of products to the state.
3. The facility shall comply with all labeling and recordkeeping requirements pursuant to section 503(b) of the federal Food, Drug, and Cosmetic Act [21 U.S.C. 353(b)].

#### **43-15.3-14. Third-party logistics providers.**

1. Each third-party logistics provider shall comply with the standards for licensure; requirements to distribute prescription drugs, medical gases, or medical equipment; restrictions on transactions; and pedigree requirements set forward in this chapter.
2. The board shall issue a separate license to each qualified third-party logistics provider applying for licensure.

## CHAPTER 43-15.4 VETERINARY PRESCRIPTION DRUGS

### 43-15.4-01. Definitions.

As used in this chapter:

1. "Board" means the state board of pharmacy.
2. "Compound" means the preparation, mixing, assembling, packaging, or labeling of a drug or device.
3. "Controlled substance" means a drug, substance, or immediate precursor in schedules I through V as set out in chapter 19-03.
4. "Dispensing" means the delivery of a veterinary prescription drug pursuant to the lawful order of a licensed veterinarian and the associated recordkeeping that is relevant to that practice.
5. "Extra-label use" means the use of an approved drug in a manner that is not in accordance with the approved label directions.
6. "Nontraditional livestock" means any wildlife held in a cage, fence, enclosure, or other manmade means of confinement that limits its movement within definite boundaries or an animal that is physically altered to limit movement and facilitate capture.
7. "Veterinary prescription drugs" means drugs that are to be used or prescribed only within the context of a valid veterinarian-client-patient relationship. Veterinary prescription drugs are those drugs restricted by federal law to use by or on the order of a licensed veterinarian.
8. "Veterinarian-client-patient relationship" means:
  - a. A veterinarian has assumed the responsibility for making medical judgments regarding the health of an animal and the need for medical treatment, and the client, who is the owner or other caretaker, has agreed to follow the instructions of the veterinarian.
  - b. There is sufficient knowledge of the animal by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal.
  - c. The practicing veterinarian is readily available for followup in the case of adverse reactions or failure of the regimen of therapy. This relationship exists only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal by virtue of an examination of the animal and by medically appropriate and timely visits to the premises where the animal is kept.
9. "Veterinary dispensing technician" means a nonpharmacist registered by the board to dispense veterinary prescription drugs in a veterinary retail facility.
10. "Veterinary retail facility" means an establishment registered by the board employing a registered veterinary dispensing technician authorized to dispense veterinary prescription drugs pursuant to bona fide orders of veterinarians.

### 43-15.4-02. Exemptions.

The provisions of this chapter do not apply to the following:

1. A pharmacist or a pharmacy participating in the practice of pharmacy.
2. A licensed veterinarian or a veterinarian's practice.

### 43-15.4-03. Veterinary retail facility - Permit required.

A person, copartnership, association, corporation, or limited liability company may not open, establish, operate, maintain, or do business in the state of North Dakota, a veterinary retail facility without first obtaining a permit to do so from the board. Application for a permit must be made upon a form prescribed and furnished by the board and must be accompanied by a fee set by the board not to exceed three hundred dollars. A like fee must be paid upon each annual renewal thereof. Separate applications must be made and separate permits required for each veterinary retail facility opened, established, operated, or maintained by the same owner and for the change of location, name, or ownership of an existing veterinary retail facility.

### 43-15.4-04. Minimum standards for veterinary retail facilities.

The following standards apply to veterinary retail facilities:

1. Veterinary prescription drugs dispensed by a veterinary retail facility pursuant to a licensed veterinarian's prescription are for use on equidae, food-animals, and nontraditional livestock only.

2. Veterinary dispensing technicians may not:
  - a. Dispense controlled substances.
  - b. Compound veterinary prescription drugs for the dispensing of a prescription.
  - c. Repackage veterinary prescription drugs for the dispensing of a prescription, except that a veterinary dispensing technician may break down case lots of veterinary prescription drugs, provided the seals on the individual containers are not broken. Veterinary dispensing technicians may not open a container and count out or measure out any quantity of a veterinary prescription drug.
  - d. Dispense medication for extra-label use.
3. Veterinary prescription drugs returned to a veterinary retail facility from a client must be treated as damaged or outdated drugs. Returned drugs may not be returned to stock or dispensed, distributed, or resold.
4. A veterinary dispensing technician may dispense veterinary prescription drugs for use on equidae, food-animals, and nontraditional livestock on the basis of a written, electronically transmitted, or oral order received from a licensed veterinarian or the authorized agent of a licensed veterinarian. Only a veterinary dispensing technician may receive an orally transmitted new or refill prescription.
5. A veterinary dispensing technician may refill a prescription only if the initial prescription is issued indicating that a specific number of refills are authorized. A prescription may not be refilled twelve or more months after the issuance date of the initial order.
6. A veterinary dispensing technician must file, or cause to be filed, any prescription, or a copy thereof, which has been dispensed in the veterinary retail facility. The prescription or a copy of the prescription must be preserved for at least three years after it has been filled. The veterinary dispensing technician must furnish a copy of any prescription to the party presenting it on the request of such party only.
7. Records of receipt and dispensing of legend drugs must be kept for three years and may be audited by the state board of pharmacy.
8. All veterinary prescription drugs must be properly labeled when dispensed. A complete label must include the following information:
  - a. Name, address, and telephone number of veterinarian.
  - b. Name of client.
  - c. Identification of animals or herds treated.
  - d. Date of treatment, prescribing, or dispensing of drug.
  - e. Name and quantity of the drug to be prescribed or dispensed.
  - f. Dosage and duration directions for use.
  - g. Cautionary statements, as needed.
  - h. Expiration date.

If that information is included in a manufacturer's label, it is unnecessary to repeat it on the prescription label. If there is inadequate space on the label for complete instructions, the veterinary dispensing technician shall provide additional information to accompany the drug dispensed or prescribed.
9. Veterinary prescription drugs must be stored separately from over-the-counter drugs. Drugs must be stored under conditions recommended by the manufacturer.

#### **43-15.4-05. Veterinary dispensing technicians - Educational requirements.**

To be eligible to be registered by the board as a veterinary dispensing technician, an individual must meet one of the following requirements:

1. Successful completion of an academic program approved by the state board of pharmacy;
2. Successful completion of a certification program approved by the state board of pharmacy; or
3. Be licensed as a veterinary technician by the state board of veterinary medical examiners.

#### **43-15.4-06. Veterinary dispensing technicians - Registration requirements.**

1. A veterinary dispensing technician must register with the state board of pharmacy on an annual basis.
2. A veterinary dispensing technician must be assigned a registration number.
3. The state board of pharmacy shall provide the veterinary dispensing technician with an annual registration card and pocket identification card.

4. The veterinary dispensing technician certificate and annual registration card must be displayed and visible to the public in the veterinary retail facility where the veterinary dispensing technician is employed.
5. The veterinary dispensing technician must wear a name badge while in the veterinary retail facility which clearly identifies the person as a "veterinary dispensing technician".
6. Every registered veterinary dispensing technician, within fifteen days after changing address or place of employment, shall notify the board of the change. The board shall make the necessary changes in the board's records.
7. A veterinary dispensing technician holding a certificate of registration as a veterinary dispensing technician in this state may go on inactive status and continue to hold a certificate of registration in this state provided the technician on inactive status may not practice within this state. A veterinary dispensing technician on inactive status may not be required to meet the continuing education requirements of the board under section 43-15.4-08. In order for a veterinary dispensing technician to change an inactive status of registration to an active status of registration, the veterinary dispensing technician must complete eight hours of approved continuing education and thereafter comply with the continuing education requirements of the board.

**43-15.4-07. Veterinary dispensing technician continuing education.**

1. Each registered veterinary dispensing technician shall complete at least eight hours of approved continuing education every year as a condition of renewal of a registration as a veterinary dispensing technician in this state. Of the required eight hours of continuing education, at least four hours must be of pharmacy technician continuing education approved by the state board of pharmacy and at least four hours must be of veterinary technician continuing education approved by the state board of veterinary medical examiners.
2. There may be no carryover or extension of continuing education units with the exception that continuing education units obtained twelve months prior to the beginning of each annual reporting period may be used in the current annual reporting period which begins March first of each year and ends the last day of February, or the previous reporting period. However, the units may not be counted as credit in both reporting periods. Failure to obtain the required eight hours of continuing education by the renewal date may result in suspension for a minimum of thirty days or a maximum of the period ending the date the continuing education is completed.
3. Veterinary dispensing technicians shall maintain their own records on forms supplied by the board. The records must be maintained for a two-year period.
4. The requirements of this section do not apply to a veterinary dispensing technician applying for a first renewal of a registration.
5. A veterinary dispensing technician registered with the board may make application to the board for a waiver of compliance with the continuing education requirements and may be granted an exemption by the board.
6. Upon request of the board, proof of compliance must be furnished to the board.

**43-15.4-08. Penalties for violation of rule regulating veterinary dispensing technicians.**

1. The registration of a veterinary dispensing technician violating drug laws or rules may be revoked by the state board of pharmacy, and the veterinary dispensing technician may be subject to the penalties of section 43-15-42.1.
2. The license of a veterinary retail facility violating drug laws or rules may be revoked by the state board of pharmacy and the veterinary retail facility may be subject to the penalties of section 43-15-42.1.

**CHAPTER 43-51**

**PROFESSIONAL AND OCCUPATIONAL LICENSING**

**43-51-01. Definitions.**

As used in this chapter, unless the context indicates otherwise:

1. "Board" means a board, commission, or other agency of state government created or identified in this title to regulate a particular occupation or profession. a. The term does not include the:
  - a. State board of accountancy;
  - b. State electrical board;

- c. North Dakota real estate appraiser qualifications and ethics board;
- d. State real estate commission;
- e. Secretary of state with respect to contractor licensing;
- f. North Dakota board of medicine; and
- g. State board of dental examiners.

"Board" also includes any agency of state government which is created or identified outside this title to regulate a particular occupation or profession if the agency elects, by administrative rule, to invoke the authority in this chapter.

- 2. "Foreign practitioner" means an individual who currently holds and maintains a license in good standing to engage in an occupation or profession in a state or jurisdiction other than this state and who is not the subject of a pending disciplinary action in any state or jurisdiction.
- 3. "Good standing" means a foreign practitioner holds a current license that is not issued on a temporary or restricted basis, is not encumbered or on probation, and is not suspended or revoked.
- 4. "License" means a license, certificate, permit, or similar authorization to practice an occupation or profession which is issued by a government agency in another state or jurisdiction that imposes requirements for obtaining and maintaining a license which are at least as stringent as the requirements imposed in this state to obtain and maintain a license to practice the same profession or occupation.
- 5. "Military spouse" means a foreign practitioner who is the spouse of a member of the armed forces of the United States or a reserve component of the armed forces of the United States stationed in this state in accordance with military orders or stationed in this state before a temporary assignment to duties outside of this state.
- 6. "Occupation or profession" means activity for which a license is required from a board or similar activity for which a license is required in another state or jurisdiction.

#### **43-51-02. Location of practice of an occupation or profession.**

The provision of services to an individual in this state which fall within the standard of practice of a profession or occupation regulated by a board, regardless of the means by which the services are provided or the physical location of the person providing those services, constitutes the practice of that occupation or profession in this state and is subject to regulation by the appropriate board in this state.

#### **43-51-03. Indirect practice without a license.**

- 1. A foreign practitioner may provide services in this state which fall within the scope of practice designated by the foreign practitioner's license and by this title without obtaining a license from the appropriate board if the services are provided through consultation with the person licensed by the board and if the foreign practitioner has no direct communication in this state with the individual receiving the services except in the presence of the individual who is licensed by the board. Both the foreign practitioner and the individual licensed by the board are responsible for the services provided under this subsection.
- 2. A foreign practitioner may provide services in this state which fall within the scope of practice designated by the foreign practitioner's license and by this title without obtaining a license from the appropriate board if the services are provided through a remote means and are a continuation of an existing relationship between the foreign practitioner and the individual receiving the services which was formed in the state or jurisdiction in which the foreign practitioner is currently licensed.

**43-51-04. Emergency practice without a license.**

Upon prior written notice to the appropriate board, a foreign practitioner may provide services in this state which fall within the scope of practice designated by the foreign practitioner's license and by this title without obtaining a license from the board, if the services are provided for a period of time not to exceed sixty consecutive days in a calendar year and are provided in response to a disaster declared by the appropriate authority in this state. The notice provided by a foreign practitioner under this section must include verified documentation from the appropriate licensing authority which identifies the requirements for licensure in that jurisdiction and which confirms that the practitioner is licensed and in good standing in that jurisdiction and any other information requested by the board. A notice provided under this section, if accompanied by sufficient documentation, is deemed to be accepted unless denied by the board. If a notice under this section is denied, the foreign practitioner immediately shall cease providing services under this section and may not resume providing services until after a successful appeal of the board's decision under chapter 28-32 or after an application for privileges under this section is reviewed and approved by the board.

**43-51-05. Limited practice without a license.**

Upon prior written application to the appropriate board, a foreign practitioner may provide services in this state which fall within the scope of practice designated by the foreign practitioner's license and by this title without obtaining a license from the board if the services are provided for no more than thirty full or partial days per year. The one-year period commences on the date the written application is approved by the board. An application from a foreign practitioner under this section must include verified documentation from the appropriate licensing authority which identifies the requirements for licensure in that jurisdiction and which confirms that the practitioner is licensed and in good standing in that jurisdiction and any other information requested by the board. The board may require payment of a fee of twenty-five dollars or other fee established by the board by administrative rule, not to exceed the higher of twenty-five dollars or one-tenth of the fee for an annual license from the board, as a condition of approving an application under this section.

**43-51-06. Licensure without examination.**

A board may issue a license, without examination, to any foreign practitioner who has practiced the occupation or profession for which the practitioner is licensed at least two years prior to submitting the application to the board, or for any shorter period of time provided in this title or established by the board by administrative rule, and who meets the other requirements for a license. A board is not prohibited from issuing a license under this section to a foreign practitioner if the state or jurisdiction in which the individual is licensed does not extend similar privileges to individuals licensed in this state. This section does not prohibit a board from requiring a foreign practitioner to take an examination regarding the laws of this state and the rules established by the board.

**43-51-07. License compacts.**

A board may establish, by administrative rule, conditions and procedures for foreign practitioners to practice in this state pursuant to written compacts or agreements between the board and one or more other states or jurisdictions or pursuant to any other method of license recognition that ensures the health, safety, and welfare of the public. Any compact or agreement by a board does not become binding on this state until implemented by administrative rules under this section.

**43-51-08. Discipline.**

A foreign practitioner's authority to practice an occupation or profession under this chapter is subject to denial, probation, suspension, revocation, or other form of discipline for the same grounds as individuals licensed by the appropriate board in this state. In addition to other grounds for disciplinary action authorized by law, a person who holds a license issued by a board may be subject to disciplinary action in this state for:

1. Failing to adequately review services provided by a foreign practitioner under this chapter;
2. Unauthorized practice of the person's occupation or profession in another state or jurisdiction, including the delivery of services by a licenseholder in this state to a recipient of services in another state or jurisdiction;

3. Acts occurring in another state or jurisdiction which could subject the person to disciplinary action if those acts occurred in this state; or
4. Acts occurring in another state or jurisdiction which could subject the person to disciplinary action if the person held a license in that state or jurisdiction.

A disciplinary action under this section against a foreign practitioner is subject to chapter 28-32.

#### **43-51-09. Jurisdiction - Service of process.**

A foreign practitioner who provides services in this state without a license as permitted in this chapter shall be deemed to have consented to the jurisdiction of this state and the appropriate board, to be bound by the laws of this state and the rules established by the appropriate board, and to have appointed the secretary of state as the foreign practitioner's agent upon whom process may be served in any action or proceeding against the practitioner arising out of the practitioner's activities in this state.

Service on the secretary of state of any process, notice, or demand is deemed personal service upon the foreign practitioner and must be made by filing with the secretary of state an original and two copies of the process, notice, or demand, with the filing fee of twenty-five dollars. A member of the legislative assembly or a state or county officer may not be charged for filing any process, notice, or demand for service. The secretary of state shall immediately forward a copy of the process, notice, or demand by registered mail, addressed to the foreign practitioner at the address provided by the filer.

#### **43-51-10. Application with other laws.**

This chapter applies notwithstanding any other limitation in state law on the practice of an occupation or profession. This chapter supplements and does not repeal the authority provided to each board. Nothing in this chapter prohibits a board from imposing conditions on foreign practitioners by administrative rule or compact which are more restrictive than those imposed in this chapter, if those restrictions are enacted to ensure the health, safety, and welfare of the public. Rules under this section may be adopted as emergency rules under chapter 28-32. Nothing in this chapter alters the scope of practice of a particular occupation or profession as defined by law.

#### **43-51-11. Members of military - License renewal.**

1. A board shall adopt rules to provide for or shall grant on a case-by-case basis exceptions to the board's license renewal requirements in order to address renewal compliance hardships that may result from:
  - a. Activation of more than thirty days of a licensee who is a member of the national guard or armed forces of the United States.
  - b. Service in the theater or area of armed conflict by a licensee who is a member of the regular active duty armed forces of the United States.
2. For purposes of this section, the term board includes the state board of accountancy, state electrical board, North Dakota real estate appraiser qualifications and ethics board, state real estate commission, secretary of state with respect to contractor licensing, North Dakota board of medicine, and state board of dental examiners.

##### **43-51-11.1. Military spouses - Licensure.**

1. A board shall adopt rules regarding licensure of a military spouse or shall grant on a case-by-case basis exceptions to the board's licensing standards to allow a military spouse to practice the occupation or profession in the state if upon application to the board:
  - a. The military spouse demonstrates competency in the occupation or profession through methods or standards determined by the board which must include experience in the occupation or profession for at least two of the four years preceding the date of application under this section;
  - b. The military spouse pays any fees required by the board from which the applicant is seeking a license; and
  - c. The board determines the exception will not substantially increase the risk of harm to the public.

2. Under subsection 1, a board may issue a provisional license or temporary permit to a military spouse for which one or more of the licensure requirements have not been met. A provisional license or temporary permit issued under this subsection remains valid while the military spouse is making progress toward satisfying the necessary unmet licensure requirements. A military spouse may practice under a provisional license or temporary permit issued under this subsection until any of the following occurs:
  - a. The board grants or denies the military spouse a North Dakota license under subsection 1 or grants a North Dakota license under the traditional licensure method;
  - b. The provisional license or temporary permit expires; or
  - c. The military spouse fails to comply with the terms of the provisional license or temporary permit.
3. A board that is exempted from this chapter under subdivision a of subsection 1 of section 43-51-01 may issue a license, provisional license, or temporary permit to a military spouse in the same manner as provided under subsections 1 and 2. A board that may elect to subject the board to this chapter under subdivision b of subsection 1 of section 43-51-01 may issue a license, provisional license, or temporary permit to a military spouse in the same manner as provided under subsections 1 and 2 regardless of whether the board has adopted rules to subject the board to this chapter. The state board of architecture and landscape architecture is exempt from the mandate in subsection 1; however, the board voluntarily may issue a license, provisional license, or temporary permit under subsections 1 and 2.
4. A military spouse issued a license under this section has the same rights and duties as a licensee issued a license under the traditional licensure method.

**43-51-12. Foreign practitioners - Emergency practice exemption.**

Notwithstanding contrary provisions of law, a foreign practitioner may practice in an emergency in this state, practice as a member of an organ harvesting team, or practice on board an ambulance as part of the ambulance treatment team.

**TITLE 19  
FOODS, DRUGS, OILS, AND COMPOUNDS  
CHAPTER 19-01  
ADMINISTRATION**

**19-01-01. Definitions of terms used in title.**

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

1. "Department" means the state department of health.
2. "Person" includes both the singular and the plural, as the case demands, and includes individuals, partnerships, corporations, limited liability companies, companies, and associations, or two or more individuals having a joint or common interest.

**19-01-02. Consolidated laboratories branch - Members, duties, meetings.**

[Repealed by S.L. 1993, ch. 218, § 10.]

**19-01-02.1. Legislative intent.**

It is the intent of the legislative assembly that the department provide consumer protection services to the public by means of laboratory sampling, laboratory testing, onsite inspecting, and public information services within its jurisdiction.

**19-01-03. Director of department - Appointment, bond, oath, salary.**

[Repealed by S.L. 1987, ch. 263, § 30.]

**19-01-04. Assistant director - Qualifications, appointment, bond, salary, duties.**

[Repealed by S.L. 1987, ch. 263, § 30.]

**19-01-05. Sheriff as local inspector - Compensation, duties.**

[Repealed by S.L. 2013, ch. 179, § 2.]

**19-01-06. Offices of department - Employees - Equipment.**

[Repealed by S.L. 1987, ch. 263, § 30.]



**19-01-07. Contract services.**

Funds may be accepted by the department from cities, counties, states, federal agencies, and private organizations for contract services of analytical and inspection work. Such funds must be remitted by the department to the state treasurer and deposited in the operating fund of the state department of health.

**19-01-08. Expenses - How paid.**

[Repealed by S.L. 1987, ch. 263, § 30.]

**19-01-09. Right of inspection - Penalty.**

For obtaining information regarding suspected violations of any provision contained in this title, the department, its inspectors and agents, shall have free access to all places, except private homes, and all vehicles of transportation where and in which any of the products, articles, compositions, or things designated in any chapter in this title are manufactured, stored, sold, exposed for sale, prepared for sale, held, or transported. Such inspectors and other agents of the department may open any car, vehicle, package, can, jar, tub, tank, or other receptacle containing any such product, articles, composition, or thing, for the purpose of inspection, and may take therefrom such sample as may be required to permit such contents to be inspected and analyzed, upon paying or offering to pay to the person entitled thereto the full value of the sample so taken. Agents, bookkeepers, transportation officers, and other employees connected with or having control over any place or vehicle in which any such products, articles, compositions, or things, are manufactured, stored, sold, exposed for sale, prepared for sale, held, or transported, shall render all assistance and aid within their power to inspectors and agents of the department in carrying out the provisions of any chapter contained in this title. Any person obstructing any such agent or inspector of the department in making the entry or inspection or in taking the samples authorized under the provisions of this section or failing upon request to assist therein is guilty of a class A misdemeanor.

**19-01-10. Department to make analyses, inspections, and examinations - Report of examination as evidence - Publication of report.**

The department shall make, or cause to be made, analyses, examinations, and inspections of all products, articles, compositions, or things included under this title whenever such analyses, inspections, or examinations are necessary to determine whether any of such products, articles, compositions, or things violate this title relating to the products, articles, compositions, or things in question, or violate any definition, standard, tolerance, rule, or regulation issued with regard to such products, articles, compositions, or things pursuant to any provision contained in this title. However, the state crime laboratory shall make or cause to be made, analysis, examination, inspection, or test of any product, article, composition, or thing at the request of any prosecutor, defense counsel, or law enforcement officer in the state of North Dakota when such analysis, examination, inspection, or test is made in connection with an investigation into violations of the criminal law of this state. A copy of any report issued by the department or the state crime laboratory, or electronically posted by the director of the state crime laboratory or the director's designee on the crime laboratory information management system and certified by a law enforcement officer or individual who has authorized access to the crime laboratory information management system through the criminal justice data information sharing system, of the examination or analyses of any product, article, composition, or thing, duly authenticated by the person making the analysis or examination, when given under oath, is prima facie evidence in all courts of the matters and facts therein contained. The department may collect samples of any product, article, composition, or thing for the purpose of making analyses, inspections, and investigations in connection with research carried on by it and may publish the reports thereof for the information of the public.

**19-01-11. Possession of prohibited or regulated products, articles, compositions, or things as prima facie evidence.**

Possession of any product, article, composition, or thing, the manufacture, sale, or use of which is restricted, regulated, or forbidden by any provision of this title, is prima facie evidence of the intent to sell, manufacture, transport, possess, or use the same in violation of the provisions of this title relating to such product, article, composition, or thing, as the case may be.

**19-01-12. Seizure of unlawful products - Search warrant.**

A search warrant may be issued by any judge, including a district or municipal judge, whenever probable cause is shown by affidavit or deposition under oath that any article, product, composition, or thing is being kept or is present upon certain premises which shall be particularly described or is in possession of any person who shall be named in the affidavit or deposition, and that such article, product, composition, or thing, is not in compliance with, or is being used or possessed contrary to, any applicable provision of this title or of any rule, regulation, standard, tolerance, or definition issued pursuant thereto. The search warrant must be in substantially the form described in the North Dakota Rules of Criminal Procedure. It must particularly describe the premises or the person who has possession of such article and must be signed by the judge with the name of the judge's office, and must be directed to any peace officer of the county or to the department or any of its agents. The warrant shall command the peace officer or agent of the department to search the persons or places named and to seize all and any products, articles, compositions, or things of the kind described therein which may be held in violation of any applicable provision of this title and to bring such products, articles, compositions, or things before the judge.

**19-01-13. Department may seize unlawful products, articles, compositions, or things without search warrant.**

The department may seize any product, article, composition, or thing which is manufactured, sold, used, transported, kept, or offered for sale, use, or transportation, or which is held in possession with intent to use, sell, or transport the same, in violation of any provision of this title applicable to such product, article, composition, or thing, or in violation of any rule, regulation, standard, or definition relating to the product, article, composition, or thing established pursuant to any provision of this title. The employees of the department have the powers of a peace officer. A seizure may be made without warrant, but, as soon as practicable, the person suspected of violation must be arrested and prosecuted for the violation.

**19-01-14. Service and return of search warrant and proceedings thereon.**

The provisions of sections 29-29-01 and 29-29-18 and rule 41 of the North Dakota Rules of Criminal Procedure, as to the service and return of a search warrant, and hearing, and return thereon to the district court, govern in cases of search warrants issued pursuant to the provisions of this chapter except that testimony of witnesses need not be reduced to writing. If the magistrate finds that the property seized is property of the kind described in the search warrant and that there is probable cause to believe that the grounds on which the search warrant was issued existed, the magistrate shall send the property so seized to the district court, together with the magistrate's return. If the magistrate finds that there is not probable cause to believe that the grounds on which the search warrant was issued existed, the magistrate shall order the property returned to the person from whom it was taken.

**19-01-15. Agent is punishable for violation of any provision of title.**

[Repealed by S.L. 1975, ch. 106, § 673.]

**19-01-16. Enforcement by department - Duty of state's attorney to prosecute.**

The department shall enforce the provisions contained in this title and may prevent the manufacture or sale of products, articles, compositions, or things not complying with any provisions of this title applicable thereto. The department shall report each violation of any such provision to the state's attorney of the county within which such violation occurred. Any state's attorney to whom the department or any of its inspectors or agents shall report any such violation, without delay, shall cause appropriate proceedings to be instituted for the enforcement of the appropriate penalty.

**19-01-17. Form of license to be issued.**

All licenses and permits issued by the department must be uniform insofar as practicable and must be on a suitable blank provided and prescribed by the department. If two or more licenses or permits are issued to the same person or corporation, they must be on one and the same blank when possible and practicable.

**19-01-18. Duties as to weights and measures.**

[Repealed by S.L. 2013, ch. 179, § 2.]

## **19-01-19. Administrative procedure and judicial review.**

Any proceeding under this title for issuing or modifying rules and regulations and determining compliance with rules and regulations of the department must be conducted in accordance with chapter 28-32 and appeals may be taken as provided in chapter 28-32.

### **CHAPTER 19-02 FOOD AND DRUG LAW**

[Repealed by S.L. 1949, ch. 169, § 1; 1967, ch. 168, § 24; 1969, ch. 322, § 10; 1989, ch. 316, § 4; and by omission]

### **CHAPTER 19-02.1 NORTH DAKOTA FOOD, DRUG, AND COSMETIC ACT**

#### **19-02.1-01. Definitions.**

For the purpose of this chapter:

1. "Advertisement".means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics.
2. "Color" includes black, white, and intermediate grays.
3. "Color additive" means a material which:
  - a. Is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity from a vegetable, animal, mineral, or other source; or
  - b. When added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable, alone or through reaction with other substance, of imparting color thereto, except that such term does not include any material which has been or hereafter is exempted under the federal act.
4. "Contaminated with filth" applies to any food, drug, device, or cosmetic not securely protected from dust, dirt, and as far as may be necessary by all reasonable means, from all foreign or injurious contaminations.
5. "Cosmetic" means:
  - a. Articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance; or
  - b. Articles intended for use as a component of any such articles, except that such term does not include soap.
6. "Department" means the state department of health.
7. "Device", except when used in the first paragraph following subsection 21 of this section and in subsection 10 of section 19-02.1-02, subsection 6 of section 19-02.1-10, subsections 3 and 16 of section 19-02.1-14, and subsection 3 of section 19-02.1-18, means instruments, apparatus and contrivances, including their components, parts, and accessories, intended:
  - a. For use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or
  - b. To affect the structure or any function of the body of man or other animals.
8. "Drug" means:
  - a. Articles recognized in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, 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 animals;
  - c. Articles, other than food, intended to affect the structure or any function of the body of man or other animals; or

- d. Articles intended for use as a component of any article specified in subdivision a, b, or c, but does not include devices or their components, parts, or accessories. Provided, however, that "drug", for the purpose of this chapter, and as defined by this subsection, does not include those controlled substances or drugs regulated by or under the authority of the Uniform Controlled Substances Act, with respect to such drugs, the Uniform Controlled Substances Act takes precedence over and supplants the provisions of this chapter only so far as its authority and control is synonymous with the provisions of this chapter.
9. "Federal act" means the federal Food, Drug, and Cosmetic Act, as amended [21 U.S.C. 301 et seq.].
10. "Food" means:
  - a. Articles used for food or drink for man or other animals;
  - b. Chewing gum; and
  - c. Articles used for components of any such article.
11. "Food additive" means any substance, the intended use of which results or may be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use, if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures, or, in the case of a substance used in a food prior to January 1, 1958, through either scientific procedures or experience based on common use in food, to be safe under the conditions of its intended use, except that such term does not include:
  - a. A pesticide chemical in or on a raw agricultural commodity;
  - b. A pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity;
  - c. A color additive; or
  - d. Any substance used in accordance with a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958, pursuant to the federal act; the Poultry Products Inspection Act [21 U.S.C. 451 et seq.]; or the Meat Inspection Act of March 4, 1907 [34 Stat. 1260, as amended and extended, 21 U.S.C. 71 et seq.].
12. "Immediate container" does not include package liners.
13. "Label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appearing on the label may not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.
14. "Labeling" means all labels and other written, printed, or graphic matter:
  - a. Upon an article or any of its containers or wrappers; or
  - b. Accompanying such article.
15. "Manufacture, compound, or process" includes repackaging or otherwise changing the container, wrapper, or labeling of any drug package in the furtherance of the distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer, and the term "manufacturers, compounders, and processors" must be deemed to refer to persons engaged in such defined activities.
16. "New drug" means:
  - a. Any drug the composition of which is such that such drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; or
  - b. Any drug the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

17. "Official compendium" means the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, official national formulary, or any supplement to any of them.
18. "Person" includes individual, partnership, corporation, limited liability company, and association.
19. "Pesticide chemical" means any substance which, alone, in chemical combination, or in formulation with one or more other substances is a pesticide within the meaning of chapter 19-18, and which is used in the production, storage, or transportation of raw agricultural commodities.
20. "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 which are subject to this chapter.
21. "Raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

If an article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then in determining whether the labeling or advertisement is misleading, there must be taken into account, among other things, not only representations made or suggested by statement, word, design, device, sound, or in any combination thereof, but also the extent to which the labeling or advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual.

The representation of a drug, in its labeling or advertisement, as an antiseptic must be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

The provisions of this chapter regarding the selling of food, drugs, devices, or cosmetics must be considered to include the manufacture, production, processing, packing, exposure, offer, possession, and holding of any such article for sale; and the sale, dispensing, and giving of any such article and the supplying or applying of any such articles in the conduct of any food, drug, or cosmetic establishment.

Nothing in subsection 21 may be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological process of produce of the soil and thereby affecting its color, whether before or after harvest.

#### **19-02.1-02. Prohibited acts.**

The following acts and the causing thereof within the state of North Dakota are hereby prohibited:

1. The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded.
2. The adulteration or misbranding of any food, drug, device, or cosmetic.
3. The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.
4. The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of section 19-02.1-11 or 19-02.1-16.
5. The dissemination of any false advertisement.
6. The refusal to permit entry or inspection, or to permit the taking of a sample, as authorized by section 19-02.1-21.
7. The giving of a guaranty or undertaking which guaranty or undertaking is false, except by a person who relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of the person residing in the state of North Dakota from whom the person received in good faith the food, drug, device, or cosmetic.
8. The removal or disposal of a detained or embargoed article in violation of section 19-02.1-05.
9. The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device, or cosmetic, if such act is done while such article is held for sale and results in such article being adulterated or misbranded.

10. Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of this chapter or of the federal act.
11. The using, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under section 19-02.1-16 or that such drug complies with the provisions of such section.
12. In the case of a prescription drug distributed or offered for sale in this state, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved under the federal act. Nothing in this subsection may be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter.
13. Placing or causing to be placed upon any drug or device or container thereof, with intent to defraud, the trade name or other identifying mark, or imprint of another or any likeness of any of the foregoing; selling, dispensing, disposing of, or causing to be sold, dispensed, or disposed of, or concealing or keeping in possession, control, or custody, with intent to sell, dispense, or dispose of, any drug, device, or any container thereof, with knowledge that the trade name or other identifying mark or imprint of another or any likeness of any of the foregoing has been placed thereon in a manner prohibited by this subsection; or making, selling, disposing of, or causing to be made, sold, or disposed of, or keeping in possession, control, or custody, or concealing, with intent to defraud, any punch, die, plate, or other thing designed to print, imprint, or reproduce that trade name or other identifying mark or imprint of another or any likeness of any of the foregoing upon any drug, device, or container thereof.
14. Dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without the express permission in each case of the person ordering or prescribing.
15. The manufacture of drugs, or the supplying of drugs at wholesale or retail, unless a license or permit to do so has first been obtained from the state board of pharmacy after application to the state board of pharmacy and the payment of a fee set by the state board of pharmacy.
16. The filling or refilling of any prescription in violation of subsection 1 of section 19-02.1-15.

#### **19-02.1-03. Injunction proceedings.**

In addition to the remedies hereinafter provided, the department is hereby authorized to apply to the district court of Burleigh County for, and such court shall have jurisdiction upon hearing and for cause shown to grant, a temporary or permanent injunction restraining any person from violating any provision of section 19-02.1-02, irrespective of whether or not there exists an adequate remedy at law.

#### **19-02.1-04. Penalties and guaranty.**

1. Any person who violates any of the provisions of subsections 1 through 16 of section 19-02.1-02 is guilty of a class B misdemeanor.
2. No person shall be subject to the penalties of subsection 1, for having violated subsection 1 or 3 of section 19-02.1-02 if the person established a guaranty or undertaking signed by, and containing the name and address of, the person residing in the state of North Dakota from whom the person received in good faith the article, to the effect that such article is not adulterated or misbranded within the meaning of this chapter, designating this chapter.
3. No publisher, radio-broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, packer, distributor, or seller of the article to which a false advertisement relates, shall be liable under this section by reason of the dissemination by the person of such false advertisement, unless the person has refused, on the request of the department, to furnish the department the name and post-office address of the manufacturer, packer, distributor, seller, or advertising agency residing in the state of North Dakota who caused the person to disseminate such advertisement.
4. Repealed by S.L. 1971, ch. 235, § 49.

**19-02.1-05. Seizure.**

1. Whenever a duly authorized agent of the department finds or has probable cause to believe that any food, drug, device, or cosmetic is adulterated or so misbranded as to be dangerous or fraudulent, within the meaning of this chapter, the authorized agent shall affix to such article a tag or other appropriate marking, giving notice that such article is, or is suspected of being, adulterated or misbranded and has been detained or embargoed, and warning all persons not to remove or dispose of such article by sale or otherwise until permission for removal or disposal is given by such agent or the court. It is unlawful for any person to remove or dispose of such detained or embargoed article by sale or otherwise without such permission.
2. When an article detained or embargoed under subsection 1 has been found by such agent to be adulterated or misbranded, the authorized agent shall petition the judge of the district court in the county in which the article is detained or embargoed for a libel for condemnation of such article. When such agent has found that an article so detained or embargoed is not adulterated or misbranded, the authorized agent shall remove the tag or other marking.
3. If the court finds that a detained or embargoed article is adulterated or misbranded, such article must, after entry of the decree, be destroyed at the expense of the claimant thereof, under the supervision of such agent, and all court costs and fees, and storage and other proper expenses, must be taxed against the claimant of such article or the claimant's agent; provided, that when the adulteration or misbranding can be corrected by proper labeling or processing of the article, the court, after entry of the decrees and after such costs, fees, and expenses have been paid and a good and sufficient bond, conditioned that such article must be so labeled or processed, has been executed, may by order direct that such article be delivered to the claimant thereof for such labeling or processing under the supervision of an agent of the department. The expense of such supervision must be paid by the claimant. Such must be returned to the claimant of the article on the representation to the court by the department that the article is no longer in violation of this chapter, and that the expenses of such supervision have been paid.
4. Whenever an authorized agent of the department finds in any room, building, vehicle of transportation or other structure, any meat, seafood, poultry, vegetable, fruit, or other perishable articles which are unsound, or contain any filthy, decomposed, or putrid substance, or that may be poisonous or deleterious to health or otherwise unsafe, the same being hereby declared to be a nuisance, the department's authorized agent shall forthwith condemn or destroy the same, or in any other manner render the same unsalable as human food.
5. Any person, firm, corporation, or limited liability company having an interest in the alleged article, equipment, or other thing proceeded against, or any person, firm, corporation, or limited liability company against whom a civil or criminal liability would exist if said merchandise is in violation of section 19-02.1-02 may, within twenty days following the seizure, appear and file answer to the complaint. The answer must allege the interest or liability of the party filing it. In all other respects, the issue must be made up as in other civil actions.
  - a. Any article, equipment, conveyance, or other thing condemned under this section must, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, must be paid to the treasurer of the state; but such article, equipment, or other thing may not be sold under such decree contrary to provisions of this chapter.
6. Whenever in any proceedings under this section the condemnation of any equipment or conveyance or other thing, other than a drug, is decreed, the court shall allow the claim of any claimant, to the extent of such claimant's interest, for remission or mitigation of such forfeiture if such claimant proves to the satisfaction of the court all of the following:
  - a. The claimant has not committed or caused to be committed any prohibited act referred to in chapter 19-03.1 and has no interest in any drug or controlled substance referred to therein.
  - b. The claimant has an interest in such equipment, or other thing as owner or lienor or otherwise, acquired by the claimant in good faith.

- c. The claimant at no time had any knowledge or reason to believe that such equipment, conveyance, or other thing was being or would be used in, or to facilitate, the violation of the laws of this state relating to depressant, stimulant, or hallucinogenic drugs or counterfeit drugs.
7. When a decree of condemnation is entered against the article, equipment, conveyance, or other thing, court costs and fees and storage and other proper expenses must be awarded against the person, if any, intervening as claimant of the article.

**19-02.1-06. Prosecutions - State's attorney.**

It is the duty of each state's attorney, to whom the department or state board of pharmacy reports any violation of this chapter occurring in the state's attorney's county, to cause appropriate proceedings to be instituted in the proper courts without delay and to be prosecuted in the manner required by law.

**19-02.1-07. Minor violations.**

Nothing in this chapter may be construed as requiring the state department of health or the state board of pharmacy to report minor violations of this chapter for the institution of proceedings under this chapter whenever the state department of health or the state board of pharmacy believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.

**19-02.1-08. Food - Definitions and standards.**

Whenever in the judgment of the department such action will promote honesty and fair dealing in the interest of consumers, the department shall promulgate regulations fixing and establishing for any food or class of food a reasonable definition and standard of identity or reasonable standard of quality or fill of container. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the department shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which must be named on the label. The definitions and standards so promulgated must conform so far as practicable to the definitions and standards promulgated under authority of the federal act.

**19-02.1-09. Food - Adulteration defined.**

A food must be deemed to be adulterated for any of the following reasons:

1. If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food may not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.
2. If it bears or contains any added poisonous or added deleterious substance, other than one which is:
  - a. A pesticide chemical in or on a raw agricultural commodity;
  - b. A food additive; or
  - c. A color additive which is unsafe within the meaning of subsection 1 of section 19-02.1-12.
3. If it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of subsection 1 of section 19-02.1-12.
4. If it is or bears or contains, any food additive which is unsafe within the meaning of subsection 1 of section 19-02.1-12. Provided, that when a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or tolerance prescribed under subsection 1 of section 19-02.1-12, and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food may not, notwithstanding the provisions of section 19-02.1-12 and this subsection, be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of such residue in the processed food when ready-to-eat, is not greater than the tolerance prescribed for the raw agricultural commodity.
5. If it consists in whole or in part of a diseased, contaminated, filthy, putrid, or decomposed substance or if it is otherwise unfit for food.
6. If it has been produced, prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered diseased, unwholesome, or injurious to health.



7. If it is the product of a diseased animal or an animal which has died otherwise than by slaughter or that has been fed upon the uncooked offal from a slaughterhouse.
8. If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.
9. If any valuable constituent has been in whole or in part omitted or abstracted therefrom.
10. If any substance has been substituted wholly or in part therefor.
11. If damage or inferiority has been concealed in any manner.
12. If any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight or reduce its quality or strength or make it appear better or of greater value than it is.
13. If it is confectionery and has partially or completely imbedded therein any nonnutritive object. This subsection does not apply in the case of any nonnutritive object if, in the judgment of the department as provided by rules, the object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health. This subsection does not apply to any confectionery, by reason of its containing less than one-half of one percent by volume of alcohol derived solely from the use of flavoring extracts. This subsection does not apply to a nonnutritive substance that is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this chapter. To avoid or resolve uncertainty as to the application of this subsection, the department may issue rules allowing or prohibiting use of particular nonnutritive substances.
14. If it is or bears or contains any color additive which is unsafe within the meaning of subsection 1 of section 19-02.1-12.
15. If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to federal law.

**19-02.1-10. Food - Misbranding defined.**

A food must be deemed to be misbranded:

1. If its labeling is false or misleading in any particular.
2. If it is offered for sale under the name of another food.
3. If it is an imitation of another food for which a definition and standard of identity has been prescribed by regulations as provided by section 19-02.1-08 or if it is an imitation of another food that is not subject to subsection 7, unless its label bears in type of uniform size and prominence the word imitation and immediately thereafter the name of the food imitated.
4. If its container is so made, formed, or filled as to be misleading.
5. If in package form, unless it bears a label containing:
  - a. The name and place of business of the manufacturer, packer, or distributor;
  - b. An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; and
  - c. In the case of beverages that are manufactured, distributed, and sold under a franchise or trademark name indicated thereon, whereby the person, firm, corporation, or limited liability company owning the franchise or trademark has control over the distribution, such beverages may be exempt from this subsection, if a certified statement is filed with the state department of health, stating the name and address of the manufacturer or distributor, and a statement signed by the manufacturer or distributor that they assume all responsibility and liability for the product named, which is being sold, or offered for sale, under such name within the area of the state designated, which certificate must be in the following form:

NORTH DAKOTA STATE DEPARTMENT OF HEALTH  
BISMARCK, NORTH DAKOTA  
BEVERAGE LABELING EXEMPTIONS CERTIFICATE

I, \_\_\_\_\_, the undersigned, an agent of and having authority to sign, do hereby certify that the following information is correct:

Name and address of company requesting exemption

\_\_\_\_\_  
Name \_\_\_\_\_

Street Address \_\_\_\_\_  
 City or Town \_\_\_\_\_  
 State \_\_\_\_\_  
 Name of Product \_\_\_\_\_  
 Brand Name \_\_\_\_\_

In order to be exempt from subdivisions a and b of subsection 5 of section 19-02.1-10 of the North Dakota Century Code, relating to misbranding of food, which requires the name and address of the real manufacturer or other persons responsible for placing the product upon the market, I, the undersigned, do bind the company listed above by agreeing to assume all responsibility for the product named in this certificate which is being sold, or offered for sale under such name and brand name within the area consisting of \_\_\_\_\_ in the State of North Dakota.

Note: The area must be designated by counties or other legal subdivisions of the city, county, or state.

Firm \_\_\_\_\_  
 Signed \_\_\_\_\_  
 Title \_\_\_\_\_  
 Address \_\_\_\_\_

Note: If signed by a person other than an officer of the company, authorization for signature must accompany this form. This certificate must be acknowledged. Provided, that under subdivision b reasonable variations must be permitted, and exemptions as to small packages must be established, by regulations prescribed by the department.

6. If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness, as compared with other words, statements, designs, or devices, in the labeling, and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
7. If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 19-02.1-08 unless it conforms to such definition and standard, its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients, other than spices, flavoring, and coloring, present in such food.
8. If it purports to be or is represented as:
  - a. A food for which a standard of quality has been prescribed by regulations as provided by section 19-02.1-08 and its quality falls below such standard unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or
  - b. A food for which a standard or standards of fill of container have been prescribed by regulation as provided by section 19-02.1-08, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.
9. If it is not subject to the provisions of subsection 7, unless it bears labeling clearly giving:
  - a. The common or usual name of the food, if any there be; and
  - b. The common or usual name of each such ingredient, in case it is fabricated from two or more ingredients, except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each; provided, that to the extent that compliance with the requirements of this subdivision is impracticable or results in deception or unfair competition, exemptions must be established by regulations promulgated by the department and, provided further, that the requirements of this subdivision do not apply to food products which are packaged at the direction of purchasers at retail at the time of sale, the ingredients of which are disclosed to the purchasers by other means in accordance with regulations promulgated by the department.
10. If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the department determines to be, and by regulations prescribes as, necessary in order to fully inform purchasers as to its value for such uses.

11. If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact; provided, that the extent that compliance with the requirements of this subsection is impracticable, exemptions must be established by regulations promulgated by the department.
12. If it is a product intended as an ingredient of another food and when used according to the directions of the purveyor will result in the final food product being adulterated or misbranded.
13. If it is a color additive unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive prescribed under the provisions of the federal act.
14. If it is a raw agricultural commodity that is the produce of the soil, bearing or containing a pesticide chemical applied after harvest, unless the shipping container of the commodity bears labeling that declares the presence of the chemical in or on the commodity and the common or usual name and the function of the chemical. No such declaration is required while the commodity, having been removed from the shipping container, is being held or displayed for sale at retail out of the container in accordance with the custom of the trade.
15. If its packaging or labeling is in violation of an applicable regulation issued under section 3 or 4 of the Poison Prevention Packaging Act of 1970.

**19-02.1-11. Emergency permit control.**

Whenever the department finds after investigation that the distribution in the state of North Dakota of any class of food may, by reason of contamination with micro-organisms during manufacture, processing, or packing thereof in any locality, be injurious to health and that such injurious nature cannot be adequately determined after such articles have entered commerce, it then, and in such case only, shall promulgate regulations providing for the issuance, to manufacturers, processors, or packers of such class of food in such locality, of permits to which must be attached such conditions governing the manufacture, processing, or packaging, or packing of such class of food, for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulations, and during such temporary period, no person may introduce or deliver for introduction into commerce any such food manufactured, processed, or packed by any such manufacturer, processor, or packer unless such manufacturer, processor, or packer holds a permit issued by the department as provided by such regulations.

The department is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended is privileged at any time to apply for the reinstatement of such permit, and the department shall, immediately after prompt hearing and inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued, or as amended.

Any officer or employee duly designated by the department shall have access to any factory or establishment, the operator of which holds a permit from the department for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection is grounds for suspension of the permit until such access is freely given by the operator.

**19-02.1-12. Food - Tolerances for added poisonous ingredients.**

1. Any added poisonous or deleterious substance, any food additive, any pesticide chemical in or on a raw agricultural commodity, or any color additive shall with respect to any particular use or intended use be deemed unsafe for the purpose of application of subsection 2 of section 19-02.1-09 with respect to any food, subsection 1 of section 19-02.1-13 with respect to any drug or device, or subsection 1 of section 19-02.1-17 with respect to any cosmetic, unless there is in effect a regulation pursuant to subsection 2 limiting the quantity of such substance, and the use or intended use of such substance conforms to the terms prescribed by such regulation. While such regulation relating to such substance is in effect, a food, drug, or cosmetic may not, by reason of bearing or containing such substance in accordance with the regulation, be considered adulterated within the meaning of subsection 1 of section 19-02.1-09, subsection 1 of section 19-02.1-13, or subsection 1 of section 19-02.1-17.

2. The department, whenever public health or other considerations in the state so require, is authorized to adopt, amend, or repeal regulations whether or not in accordance with regulations promulgated under the federal act prescribing therein tolerances for any added poisonous or deleterious substances, for food additives, for pesticide chemicals in or on raw agricultural commodities, or for color additives, including zero tolerances, and exemptions from tolerances in the case of pesticide chemicals in or on raw agricultural commodities, and prescribing the conditions under which a food additive or a color additive may be safely used and exemptions when such food additive or color additive is to be used solely for investigational or experimental purposes, upon its own motion or upon the petition of any interested party requesting that such a regulation be established, and it is incumbent upon such petitioner to establish by data submitted to the department that a necessity exists for such regulation, and that its effect will not be detrimental to the public health. If the data furnished by the petitioner is not sufficient to allow the department to determine whether such regulation should be promulgated, the department may require additional data to be submitted and failure to comply with the request is sufficient grounds to deny the request. In adopting, amending, or repealing regulations relating to such substances, the department shall consider among other relevant factors the following which the petitioner, if any, shall furnish:
  - a. The name and all pertinent information concerning such substance, including where available, its chemical identity and composition, a statement of the conditions of the proposed use, including directions, recommendations, and suggestions and including specimens of proposed labeling, and all relevant data bearing on the physical or other technical effect and the quantity required to produce such effect;
  - b. The probable composition of any substance formed in or on a food, drug, or cosmetic resulting from the use of such substance;
  - c. The probable consumption of such substance in the diet of man and animals taking into account any chemically or pharmacologically related substance in such diet;
  - d. Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of such substances for the use or uses for which they are proposed to be used, are generally recognized as appropriate for the use of animal experimentation data;
  - e. The availability of any needed practicable methods of analysis for determining the identity and quantity of such substance in or on an article, any substance formed in or on such article because of the use of such substance, and the pure substance and all intermediates and impurities; and
  - f. Facts supporting a contention that the proposed use of such substance will serve a useful purpose.

#### **19-02.1-13. Drugs and devices - Adulteration defined.**

A drug or device must be deemed to be adulterated:

1. If it consists in whole or in part of any filthy, putrid, or decomposed substance.
2. If it has been produced, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.
3. If it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.
4. If it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.
5. If it is a drug and it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of subsection 1 of section 19-02.1-12 or it is a color additive, the intended use of which in or on drugs is for purposes of coloring only, and is unsafe within the meaning of subsection 1 of section 19-02.1-12.

6. If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity must be made in accordance with the tests or methods of assay set forth in such compendium or, in the absence of or inadequacy of such tests or methods of assay, those prescribed under authority of the federal act. No drug defined in an official compendium may be deemed to be adulterated under this subsection because it differs from the standard of strength, quality, or purity therefor set forth in such compendium if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States pharmacopoeia and the homeopathic pharmacopoeia of the United States it is subject to the requirements of the United States pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it is subject to the provisions of the homeopathic pharmacopoeia of the United States and not to those of the United States pharmacopoeia.
7. If it is not subject to the provisions of subsection 6 and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.
8. If it is a drug and any substance has been mixed or packed therewith so as to reduce its quality or strength or substituted wholly or in part therefor.

#### **19-02.1-14. Drugs and devices - Misbranding defined.**

A drug or device must be deemed to be misbranded:

1. If its labeling is false or misleading in any particular.
2. If in package form unless it bears a label containing:
  - a. The name and place of business of the manufacturer, packer, or distributor; and
  - b. An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; provided, that under this subdivision reasonable variations must be permitted, and exemptions as to small packages must be allowed, in accordance with regulations prescribed by the department or issued under the federal act.
3. If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness, as compared with other words, statements, designs, or devices in the labeling, and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
4. If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote, or sulfonmethane, or any chemical derivative of such substance, which derivative, after investigation, has been found to be and designated as, habit-forming, by regulations issued by the department under this chapter, or by regulations issued pursuant to section 502(d) of the federal act, unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning - May be habit-forming".
5. If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name, except the applicable systematic chemical name or the chemical formula:
  - a. The established name, as defined in subsection 6, of the drug, if such there be; and
  - b. The established name and quantity of each active ingredient, in case it is fabricated from two or more ingredients, including the kind and quantity or proportion of any alcohol, and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein.
  - c. Provided, that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subsection applies only to prescription drugs; provided, further, that to the extent that compliance with the requirements of subdivision b of subsection 6 is impracticable, exemptions must be allowed under regulations promulgated by the department, or under the federal act.

6. As used in subsections 5 and 6, the term "established name", with respect to a drug or ingredient thereof, means:
  - a. The applicable official name designated pursuant to section 508 of the federal act;
  - b. If there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium; or
  - c. If neither subdivision a nor b applies, then the common or usual name, if any, of such drug or of such ingredient.
  - d. Provided, further, that when subdivision b applies to an article recognized in the United States pharmacopeia and in the homeopathic pharmacopeia under different official titles, the official title used in the United States pharmacopeia applies unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the homeopathic pharmacopeia applies.
7. Unless its labeling bears:
  - a. Adequate directions for use; and
  - b. Such adequate warnings against use in those pathological conditions or by children when its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users.
  - c. Provided, that if any requirement of subdivision a, as applied to any drug or device, is not necessary for the protection of the public health, the department shall promulgate regulations exempting such drug or device from such requirements; provided, further, that articles exempted under regulations issued under section 502(f) of the federal act may also be exempt.
8. If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein; provided, that the method of packing may be modified with the consent of the department, or if consent is obtained under the federal act. Whenever a drug is recognized in both the United States pharmacopeia and the homeopathic pharmacopeia of the United States, it is subject to the requirements of the United States pharmacopeia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it is subject to the provisions of the homeopathic pharmacopeia of the United States and not to those of the United States pharmacopeia; provided, further, that in the event of inconsistency between the requirements of this subsection and those of subsections 5 and 6 as to the name by which the drug or its ingredients must be designated, the requirements of subsections 5 and 6 must prevail.
9. If it has been found by the department or under the federal act to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the regulations issued by the department or under the federal act require as necessary for the protection of public health. No such regulation may be established for any drug recognized in an official compendium until the department shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.
10. If it is a drug and:
  - a. Its container is so made, formed, or filled as to be misleading;
  - b. If it is an imitation of another drug; or
  - c. If it is offered for sale under the name of another drug.
11. If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.
12. If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless it is from a batch with respect to which a certificate or release has been issued pursuant to section 506 of the federal act, and such certificate or release is in effect with respect to such drug.

13. If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof, unless it is from a batch with respect to which a certificate or release has been issued pursuant to section 507 of the federal act, and such certificate or release is in effect with respect to such drug; provided, that this subsection does not apply to any drug or class of drugs exempted by regulations promulgated under section 507(c) or (d) of the federal act. For the purpose of this subsection, the term "antibiotic drug" means any drug intended for use by man containing any quantity of any chemical substance which is produced by a micro-organism and which has the capacity to inhibit or destroy micro-organisms in dilute solution, including the chemically synthesized equivalent of any such substance.
14. If it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, prescribed under the provisions of subsection 2 of section 19-02.1-12 or of the federal act.
15. In the case of any prescription drug distributed or offered for sale in this state, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of the established name as defined in subsection 6, the formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502(e) of the federal act, and such other information in brief summary relating to side effects, contraindications, and effectiveness as are required in regulations issued under the federal act.
16. If a trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of the foregoing has been placed thereon or upon its container with intent to defraud.
17. Drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed are exempt from any labeling or packaging requirements of this chapter; provided, that such drugs and devices are being delivered, manufactured, processed, labeled, repacked, or otherwise held in compliance with regulations issued by the department, or under the federal act.
18. If it is a device and it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name, as defined in subsection 6, prominently printed in type at least half as large as that used thereon for any proprietary name or designation for the device, except that to the extent compliance with the requirements of this subsection is impracticable, exemptions will be established by rules adopted by the department. As used in this subsection, the term "established name" with respect to a device means:
  - a. The applicable official name of the device designated pursuant to federal law.
  - b. If there is no official name of the device designated pursuant to federal law and the device is an article recognized in an official compendium, then the official title of the device in the compendium.
  - c. If neither subdivision a nor subdivision b applies, then any common or usual name of the device.
19. If it is a device subject to a performance standard established under federal law, unless it bears labeling prescribed in the performance standard.

**19-02.1-14.1. Definitions - Label of prescription drugs - Selecting and dispensing generic name drugs - Identification of prescription drugs.**

1. As used in this section, unless the subject matter or context otherwise requires:
  - a. "Brand name" means the registered trademark name given to a drug or medicine by its manufacturer, labeler, or distributor.
  - b. "Code imprint" means a series of letters or numbers assigned by the manufacturer or distributor to a specific drug, or marks or monograms unique to the manufacturer or distributor of the drug, or both.
  - c. "Distributor" means a person who distributes for resale a drug in solid dosage form under that person's own label even though that person is not the actual manufacturer of the drug.
  - d. "Generic name" means the established name or official chemical name of the drug, drug product, or medicine.

- e. "Prescription drug" means a drug defined by section 503(b) of the federal Act and under which definition its label is required to bear the statement "Caution: Federal law prohibits dispensing without prescription" or "Rx Only".
  - f. "Solid dosage form" means capsules or tablets intended for oral use.
  - g. "Therapeutically equivalent" means a generic name drug product that would elicit the same therapeutic response from the same person as a brand name drug product.
2. Drugs or medicines dispensed pursuant to a prescription must bear a label permanently affixed to the immediate container in which the drug or medicine is dispensed or delivered and which is received by the purchaser or patient. The label must bear the brand name or the generic name, strength, quantity, serial number, date of dispensing, patient name, and directions for use of the drug or medicine, except when the physician or other health care provider authorized by law to prescribe drugs or medicine has notified the pharmacist that the appearance of the name on the label would be alarming to or detrimental to the well-being of the purchaser of the prescription.
  3. If a practitioner prescribes a drug by its brand name, the pharmacist may exercise professional judgment in the economic interest of the patient by selecting a drug product with the same generic name and demonstrated therapeutical equivalency as the one prescribed for dispensing and sale to the patient unless the practitioner specifically indicates in the practitioner's own handwriting "brand medically necessary" on a written prescription or expressly indicates that an oral prescription is to be dispensed as communicated. If the prescription is created electronically by the prescriber, the required legend must appear on the practitioner's screen. The practitioner must take a specific overt action to include the "brand medically necessary" language with the electronic transmission. The pharmacist shall note the instructions on the file copy of the prescription, or maintain the digital record as transmitted if it is an electronic prescription. A reminder legend must be placed on all prescription forms or appear on the computer screen of the electronic prescribing system. The legend must state "In order to require that a brand name product be dispensed, the practitioner must handwrite the words 'brand medically necessary'.". The legend printed on the prescription form or appearing on the prescriber's computer screen must be in at least six-point uppercase print or font. The pharmacist may not substitute a generic name drug product unless its price to the purchaser is less than the price of the prescribed drug product. In addition, a pharmacist may not substitute drug products in the following dosage forms: enteric coated tablets, controlled release products, injectable suspensions other than antibiotics, suppositories containing active ingredients for which systemic absorption is necessary for therapeutic activity, and different delivery systems for aerosol and nebulizer drugs. In the event that any drug listed above is, subsequent to January 1, 1982, determined to be therapeutically equivalent, then the previously mentioned substitution ban is automatically removed for that drug. The pharmacist shall inform the person receiving the drug when a prescription for a brand name drug product does not require that the prescribed drug be dispensed and of the person's right to refuse a generic name drug product selected by the pharmacist. The pharmacy file copy of every prescription must include the brand name, if any, or the name of the manufacturer, packer, or distributor of the generic name drug dispensed. A pharmacist who selects and dispenses a therapeutically equivalent generic name drug product shall assume no greater liability for selecting the dispensed drug product than would be incurred in filling a prescription for a drug product prescribed by its generic name. The practitioner is not liable for the substitution made by a pharmacist.
  4. In the case of a prescription for which a maximum allowable cost program for purposes of reimbursement has been established under title XIX of the federal Social Security Act, the following also apply:
    - a. If the practitioner has instructed the pharmacist to dispense as written, the words "brand medically necessary" must also be written on the prescription in the practitioner's own handwriting, or appear as part of the electronic prescription as noted in subsection 3. The pharmacist may dispense a therapeutically equivalent generic name drug product if this handwritten or electronic instruction does not appear on the prescription.
    - b. If the pharmacist is instructed orally to dispense a brand name drug as prescribed, the pharmacist shall reduce the prescription to writing and shall note the instructions on the file copy of the prescription.



- c. If the practitioner has not instructed the pharmacist to dispense a brand name drug or medicine and the patient specifically requests a brand name drug or medicine, the patient shall pay the difference between the price to the patient of the brand name drug or medicine and the therapeutically equivalent generic name drug or medicine if the price of the brand name drug or medicine is higher.
5. A pharmacist may not select and dispense a different drug product for a prescribed drug product unless it has been manufactured with the following minimum manufacturing standards and practices by a manufacturer who:
  - a. Marks capsules and tablets with identification code or monogram.
  - b. Labels products with their expiration date.
  - c. Provides reasonable services to accept return goods that have reached their expiration date.
  - d. Provides the pharmacist with information from which it can be determined whether a drug product is therapeutically equivalent.
  - e. Maintains recall capabilities for unsafe or defective drugs.
6. No prescription drug in solid dosage form may be manufactured or distributed in this state unless it is clearly marked or imprinted with a code imprint identifying the drug and the manufacturer or distributor of the drug.
7. All manufacturers and distributors of prescription drugs in solid dosage form shall provide to the department or state board of pharmacy, upon request, a listing of all such prescription drugs identifying by code imprint the manufacturer and the specific type of drug. The listing must at all times be kept current by all manufacturers and distributors subject to the provisions of this section.
8. The state board of pharmacy may grant exemptions from the requirements of this section upon application by any drug manufacturer or distributor which shows size, physical characteristics, or other unique characteristics of a drug that render the use of a code imprint on the drug impracticable or impossible. Any exemption granted by the state board of pharmacy must be included by the manufacturer or distributor in the listing required by this section. The listing must describe the physical characteristics and type of drug to which the exemption relates.
9. All prescription drugs in solid dosage form that are possessed, distributed, sold, or offered for sale in violation of the provisions of this section must be deemed misbranded and must be seized by the department or state board of pharmacy.

**19-02.1-14.2. Maximum allowable cost lists for pharmaceuticals - Pharmacy benefits managers - Penalty.**

1. For the purposes of this section:
  - a. "Determination" means a decision that settles and ends a controversy or the resolution of a question through appeal.
  - b. "Maximum allowable cost price" means a maximum reimbursement amount for a group of therapeutically equivalent and pharmaceutically equivalent multiple source drugs.
  - c. "Multiple source drug" means a therapeutically equivalent drug that is available from at least two manufacturers.
  - d. "Pharmacy benefits manager" has the same meaning as in section 19-03.6-01.
2. With respect to each contract between a pharmacy benefits manager and a pharmacy, each pharmacy benefits manager shall:
  - a. Provide to the pharmacy, at the beginning of each contract and contract renewal, the sources utilized to determine the maximum allowable cost pricing of the pharmacy benefits manager.
  - b. Update any maximum allowable cost price list at least every seven business days, and provide prompt notification of the pricing changes to network pharmacies.
  - c. Disclose the sources utilized for setting maximum allowable cost price rates on each maximum allowable cost price list included under the contract and identify each maximum allowable cost price list that applies to the contracted pharmacy. A pharmacy benefits manager shall make the list of the maximum allowable costs available to a contracted pharmacy in a format that is readily accessible and usable to the contracted pharmacy.
  - d. Ensure maximum allowable cost prices are not set below sources utilized by the pharmacy benefits manager.

- e. Provide a reasonable administrative appeals procedure to allow a dispensing pharmacy provider to contest a listed maximum allowable price rate. The pharmacy benefits manager shall provide a determination to a provider that has contested a maximum allowable price rate within seven business days. If an update to the maximum allowable price rate for an appealed drug is warranted, the pharmacy benefits manager shall make the change based on the date of the determination and make the adjustment effective for all similarly situated pharmacy providers in this state within the network.
- f. Ensure dispensing fees are not included in the calculation of maximum allowable cost price reimbursement to pharmacy providers.
3. A pharmacy benefits manager may not place a prescription drug on a maximum allowable price list unless:
  - a. The drug has at least two nationally available, therapeutically equivalent, multiple source drugs or a generic drug is available only from one manufacturer;
  - b. The drug is listed as therapeutically equivalent and pharmaceutically equivalent or "A" or "B" rated in the United States food and drug administration's most recent version of the "Orange Book" or the drug is "Z" rated; and
  - c. The drug is generally available for purchase by pharmacies in the state from national or regional wholesalers and not obsolete.
4. This section does not apply to state medicaid programs.
5. A pharmacy benefits manager that violates this section is guilty of a class B misdemeanor.

**19-02.1-14.3. Biosimilar biological products.**

1. In this section:
  - a. "Biological product", "biosimilar", "interchangeable", "interchangeable biological product", "license", and "reference product" mean the same as these terms mean under section 351 of the Public Health Service Act [42 U.S.C. 262].
  - b. "Prescription" means a product that is subject to section 503(b) of the federal Food, Drug, and Cosmetic Act [21 U.S.C. 353(b)].
2. A pharmacy may substitute a prescription biosimilar product for a prescribed product only if:
  - a. The biosimilar product has been determined by the United States food and drug administration to be interchangeable with the prescribed product;
  - b. The prescribing practitioner does not specifically indicate in the practitioner's own handwriting "brand medically necessary" on a written prescription, does not expressly indicate that an oral prescription is to be dispensed as communicated, or has not taken a specific overt action to include the "brand medically necessary" language with an electronically transmitted prescription;
  - c. The pharmacist informs the individual receiving the biological product that the biological product may be substituted with a biosimilar product and that the individual has a right to refuse the biosimilar product selected by the pharmacist and the individual chooses not to refuse;
  - d. The pharmacist notifies the prescribing practitioner orally, in writing, or by electronic transmission within twenty-four hours of the substitution; and
  - e. The pharmacy and the prescribing practitioner retain a record of the interchangeable biosimilar substitution for a period of no less than five years.
3. The board of pharmacy shall maintain on its public website a current list, or an internet link to a United States food and drug administration-approved list, of biosimilar biological products determined to be interchangeable under subdivision a of subsection 2.

**19-02.1-15. Drugs limited to dispensing on prescription.**

1. Except as authorized and provided in chapter 19-03.1, a depressant, stimulant, or hallucinogenic drug; or a drug intended for use by man which is a habit-forming drug to which subsection 4 of section 19-02.1-14 applies; or a drug that, because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner; or a drug limited by an approved application under section 505 of the federal act or section 19-02.1-16 to use under the professional supervision of a practitioner, must be dispensed by prescription of a practitioner, and such prescription may not be filled or refilled after one year from the date on which such prescription was issued; except that nothing herein may be construed as preventing a practitioner from issuing a new prescription for the same drug either in writing or orally. Any oral prescription for such drug must be promptly reduced to writing and filed by the pharmacist.
2. Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug is exempt from the requirements of section 19-02.1-14, except subsection 1, subdivisions b and c of subsection 10, subsections 12 and 13, and the packaging requirements of subsections 8 and 9 of section 19-02.1-14, if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption does not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or electronic means, or to a drug dispensed in violation of subsection 1.
3. The department may, by regulation, remove drugs subject to subsection 4 of section 19-02.1-14 and section 19-02.1-16 from the requirements of subsection 1 when such requirements are not necessary for the protection of the public health. Drugs removed from the prescription requirements of the federal act by regulations issued thereunder may also, by regulations issued by the department, be removed from the requirements of subsection 1.
4. A drug which is subject to subsection 1 must be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal Law Prohibits Dispensing Without Prescription", "Rx Only", or "Caution: State Law Prohibits Dispensing Without Prescription". A drug to which subsection 1 does not apply must be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.
5. Nothing in this section may be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications of narcotic drugs or marijuana as defined in the applicable federal and state laws relating to narcotic drugs and marijuana.

**19-02.1-15.1. Requirements for dispensing controlled substances and specified drugs - Penalty.**

1. As used in this section:
  - a. "Controlled substance" has the meaning set forth in section 19-03.1-01.
  - b. "Deliver, distribute, or dispense by means of the internet" refers, respectively, to delivery, distribution, or dispensing of a controlled substance or specified drug that is caused or facilitated by means of the internet.
  - c. "In-person medical evaluation" means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other practitioners, and must include one of the following actions:
    - (1) The prescribing practitioner examines the patient at the time the prescription or drug order is issued;
    - (2) The prescribing practitioner has performed a prior examination of the patient within twelve months;
    - (3) Another prescribing practitioner practicing within the same health system, group, or clinic as the prescribing practitioner has examined the patient within twelve months;
    - (4) A consulting practitioner to whom the prescribing practitioner has referred the patient has examined the patient within twelve months; or

- (5) The referring practitioner has performed an examination in the case of a consultant practitioner issuing a prescription or drug order when providing services by means of telemedicine.
  - d. "Internet" and "practice of telemedicine" have the meanings set forth in the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 [Pub. L. 110-425; 21 U.S.C. 802-803].
  - e. "Specified drugs" mean:
    - (1) A skeletal muscle relaxant containing carisoprodol, chlorphenesin, chlorzoxazone, metaxalone, or methocarbamol;
    - (2) A centrally acting analgesic with opioid activity such as tapentadol or tramadol;
    - (3) A drug containing butalbital; and
    - (4) Phosphodiesterase type 5 inhibitors when used to treat erectile dysfunction.
  - f. "Valid prescription" means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by a practitioner who has conducted an in-person medical evaluation of the patient.
2. A controlled substance or specified drug may not be delivered, distributed, or dispensed without a valid prescription. It is also unlawful for a person to knowingly or intentionally aid or abet in these activities. An example of such an activity includes knowingly or intentionally serving as an agent, intermediary, or other entity that causes the internet to be used to bring together a buyer and seller to engage in the dispensing of a controlled substance or specified drug.
  3. This section applies to the delivery, distribution, and dispensing of a controlled substance or specified drug by means of the internet or any other electronic means from a location whether within or outside this state to a person or an address in this state.
  4. Nothing in this section may be construed:
    - a. To apply to the delivery, distribution, or dispensing of a controlled substance or specified drug by a practitioner engaged in the practice of telemedicine in accordance with applicable federal and state laws;
    - b. To prohibit or limit the use of electronic prescriptions for a controlled substance or any other drug;
    - c. To prohibit a physician from prescribing a controlled substance or specified drug through the use of a guideline or protocol established with an allied health professional, resident, or medical student under the direction and supervision of the physician;
    - d. To prohibit a practitioner from issuing a prescription or dispensing a controlled substance or specified drug in accordance with administrative rules adopted by a state agency authorizing expedited partner therapy in the management of a sexually transmitted disease; or
    - e. To limit prescription, administration, or dispensing of a controlled substance or specified drug through a distribution mechanism approved by the state health officer in order to prevent, mitigate, or treat a pandemic illness, infectious disease outbreak, or intentional or accidental release of a biological, chemical, or radiological agent.
  5. A person who violates this section is guilty of a class C felony.

#### **19-02.1-16. New drugs.**

1. No person may sell, deliver, offer for sale, hold for sale, or give away any new drug unless:
  - a. An application with respect thereto has been approved and said approval has not been withdrawn under section 505 of the federal act; or
  - b. When not subject to the federal act, unless such drug has been tested and has been found to be safe for use and effective in use under the conditions prescribed, recommended, or suggested in the labeling thereof, and prior to selling or offering for sale such drug, there has been filed with the department an application setting forth:
    - (1) Full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use.
    - (2) A full list of the articles used as components of such drug.
    - (3) A full statement of the composition of such drug.
    - (4) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drugs.

- (5) Such samples of such drug and of the articles used as components thereof as the department may require.
- (6) Specimens of the labeling proposed to be used for such drug.
- 2. An application provided for in subdivision b of subsection 1 becomes effective on the one hundred eightieth day after the filing thereof, except that if the department finds, after due notice to the applicant and giving the applicant an opportunity for a hearing, that the drug is not safe or not effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof, the state department of health shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.
- 3. An order refusing to permit an application under this section to become effective may be revoked by the department.
- 4. This section does not apply:
  - a. To a drug intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs, provided the drug is plainly labeled in compliance with regulations issued by the department or pursuant to section 505(i) or 507(d) of the federal act;
  - b. To a drug sold in this state at any time prior to the enactment of this chapter or introduced into interstate commerce at any time prior to the enactment of the federal act;
  - c. To any drug which is licensed under the Virus, Serum, and Toxin Act of July 1, 1902, U.S.C. 1958 ed. Title 42 Chapter 6A Sec. 262; or
  - d. To any drug which is subject to subsection 5 of section 19-02.1-14.
- 5. The provisions of subsection 16 of section 19-02.1-01 do not apply to any drug which, on October 9, 1962, or on the date immediately preceding the enactment of this subsection:
  - a. Was commercially sold or used in this state or in the United States;
  - b. Was not a new drug as defined by subsection 16 of section 19-02.1-01 as then in force; and
  - c. Was not covered by an effective application under section 19-02.1-16 or under section 505 of the federal act, when such drug is intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug.

**19-02.1-17. Cosmetics - Adulteration defined.**

A cosmetic must be deemed to be adulterated:

- 1. If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling or advertisement thereof, or under such conditions of use as are customary or usual; provided, that this provision does not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution - This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness", and the labeling of which bears adequate directions for such preliminary testing. For the purpose of this subsection and subsection 5, the term "hair dye" does not include eyelash dyes or eyebrow dyes.
- 2. If it consists in whole or in part of any filthy, putrid, or decomposed substance.
- 3. If it has been produced, prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.
- 4. If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.
- 5. If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of subsection 1 of section 19-02.1-12.

**19-02.1-18. Cosmetics - Misbranding defined.**

A cosmetic must be deemed to be misbranded:

- 1. If its labeling is false or misleading in any particular.

2. If in package form unless it bears a label containing:
  - a. The name and place of business of the manufacturer, packer, or distributor; and
  - b. An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; provided, that under this subdivision reasonable variations must be permitted, and exemptions as to small packages must be established by regulations prescribed by the department.
3. If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness, as compared with other words, statements, designs, or devices, in the labeling, and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
4. If its container is so made, formed, or filled as to be misleading.
5. If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive prescribed under the provisions of the federal act. This subsection does not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes, as defined in the last sentence of subsection 1 of section 19-02.1-17.
6. If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

#### **19-02.1-19. False advertising.**

1. An advertisement of a food, drug, device, or cosmetic is false if it is false or misleading in any particular.
2. For the purpose of this chapter, the advertisement of a drug or device representing it to have any effect in albuminuria, appendicitis, arteriosclerosis, blood poison, bone disease, Bright's disease, cancer, carbuncles, cholecystitis, diabetes, diphtheria, dropsy, erysipelas, gallstones, heart and vascular diseases, high blood pressure, mastoiditis, measles, meningitis, mumps, nephritis, otitis media, paralysis, pneumonia, poliomyelitis (infantile paralysis), prostate gland disorders, pyelitis, scarlet fever, sexual impotence, sexually transmitted disease, sinus infection, smallpox, tuberculosis, tumors, typhoid, or uremia is also false, except that no advertisement not in violation of subsection 1 is false under this subsection if it is disseminated only to members of the medical, dental, pharmaceutical, or veterinary professions, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of such drugs or devices; provided, that whenever the department determines that an advance in medical science has made any type of self-medication safe as to any of the diseases named above, the department by rule shall authorize the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the department may deem necessary in the interests of public health; and provided, further, that this subsection may not be construed as indicating that self-medication for diseases other than those named herein is safe or efficacious.

#### **19-02.1-20. Rules.**

The authority to adopt rules for the efficient enforcement of this chapter is hereby vested in the department. The department is hereby authorized to make the rules adopted under this chapter conform, insofar as practicable, with those adopted under the federal act. Rules must conform and be consistent with the provisions of the Uniform Controlled Substances Act. When adopting any rules under this chapter, the department shall follow the procedures under chapter 28-32.

#### **19-02.1-21. Inspections - Examinations.**

The department has free access at all reasonable hours to any factory, warehouse, or establishment in which foods, drugs, devices, or cosmetics are manufactured, processed, packed, or held for introduction into commerce, or to enter any vehicle being used to transport or hold such foods, drugs, devices, or cosmetics in commerce, for the purpose of inspecting such factory, warehouse, establishment, or vehicle to determine if this chapter is being violated and to secure samples or specimens of any food, drug, device, or cosmetic after paying or offering to pay for such sample.

The department shall make or cause to be made examinations of samples secured under this section to determine whether or not this chapter is being violated.

Inspections of slaughterhouses, meatpacking, and meat processing plants where cattle, swine, sheep, goats, farmed elk, horses, or other equines are slaughtered for human food or where the carcass or the

parts thereof, meat, or meat food products are salted, canned, packed, smoked, cured, rendered, or otherwise processed or prepared for human food may not be performed under this chapter if the slaughterhouses, meatpacking, or meat processing plants are inspected under the North Dakota Meat Inspection Act, or the Federal Meat Inspection Act, as amended [34 Stat. 1260-65; 21 U.S.C. 71-91].

#### **19-02.1-22. Publicity.**

The department may cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this chapter, including the nature of the charge and the disposition thereof.

The department may also cause to be disseminated such information regarding food, drugs, devices, and cosmetics as the department deems necessary in the interest of public health and the protection of the consumer against fraud. Nothing in this section may be construed to prohibit the department from collecting, reporting, and illustrating the results of the investigations of the department.

#### **19-02.1-23. Prohibition against manufacture of drugs - Exceptions.**

[Repealed by S.L. 1971, ch. 235, § 49.]

#### **19-02.1-24. Sale of prepackaged food from vending machines - License - Rules - Inspections.**

1. An establishment may not sell any type of prepackaged food from a food vending machine without first obtaining a license from the department. The license expires on June thirtieth of each year. The department may adopt rules establishing the amount and the procedures for the collection of license fees. License fees collected pursuant to this section must be deposited in the department's operating fund in the state treasury and any expenditure from the fund is subject to appropriation by the legislative assembly.
2. The department may, in accordance with chapter 28-32, revoke an establishment's license if the establishment fails to comply with the rules adopted pursuant to subsection 3.
3. The department may adopt, in accordance with chapter 28-32, rules which define "food vending machine" for the purposes of this section and rules governing the sanitation, maintenance, and construction of such vending machines and exempting certain types of machines from this section, if it is deemed appropriate and not materially detrimental to public health.
4. The department may inspect any food vending machine for compliance with the rules and for the presence of a license required by this section.

#### **19-02.1-25. Country of origin labels.**

Each retailer shall indicate, by label, to customers the country of origin of fresh beef, lamb, and pork available for sale to customers. For purposes of this section, a label means a clearly visible printed or written indication that is placed in the immediate vicinity of the food product. This section does not apply to a restaurant, cafeteria, prepared food service establishment, or mobile food unit.

#### **19-02.1-26. Limitation on exemplary damages.**

1. Exemplary damages may not be awarded against the manufacturer or seller of a product or device that caused the harm claimed by the plaintiff if:
  - a. The product or device was subject to approval under 21 U.S.C. 355 or premarket approval under 21 U.S.C. 360e by the food and drug administration with respect to the safety of formulation or performance of the aspect of the product or device that caused the harm, or by the adequacy of the packaging or labeling of the product or device; or
  - b. The product or device was approved by the food and drug administration.
2. Subsection 1 does not apply in a case in which it is determined on the basis of clear and convincing evidence that the defendant:
  - a. Withheld from or misrepresented to the food and drug administration information concerning the product or device which is required to be submitted under the federal act which is material and relevant to the harm suffered by the claimant;
  - b. Made an illegal payment to an official of the food and drug administration for the purpose of securing approval of the product or device;

- c. Failed to use reasonable care to comply with the food and drug administration regulations concerning the manufacture of, or the investigation and correction of defects in design or manufacture of, a medical device, and the failure to comply has caused the harm suffered by the plaintiff;
- d. Made a significant or knowing departure from official food and drug administration requirements;
- e. Acted with conscious disregard for human safety.

## **CHAPTER 19-03 NARCOTICS**

[Repealed by S.L. 1971, ch. 235, § 49]

### **CHAPTER 19-03.1 UNIFORM CONTROLLED SUBSTANCES ACT**

#### **19-03.1-01. Definitions.**

As used in this chapter and in chapters 19-03.2 and 19-03.4, unless the context otherwise requires:

1. "Administer" means to apply a controlled substance, whether by injection, inhalation, ingestion, or any other means, directly to the body of a patient or research subject by:
  - a. A practitioner or, in the practitioner's presence, by the practitioner's authorized agent; or
  - b. The patient or research subject at the direction and in the presence of the practitioner.
2. "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.
3. "Anabolic steroids" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, and corticosteroids.
4. "Board" means the state board of pharmacy.
5. "Bureau" means the drug enforcement administration in the United States department of justice or its successor agency.
6. "Controlled substance" means a drug, substance, or immediate precursor in schedules I through V as set out in this chapter.
7. "Controlled substance analog":
  - a. Means a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance in a schedule I or II and:
    - (1) Which has a stimulant, depressant, or hallucinogenic effect on the central nervous system which is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or
    - (2) With respect to a particular individual, which the individual represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II.
  - b. Does not include:
    - (1) A controlled substance;
    - (2) Any substance for which there is an approved new drug application; or
    - (3) With respect to a particular individual, any substance, if an exemption is in effect for investigational use, for that individual, under section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355] to the extent conduct with respect to the substance is pursuant to the exemption.
8. "Counterfeit substance" means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person who in fact manufactured, distributed, or dispensed the substance.
9. "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a controlled substance whether or not there is an agency relationship.
10. "Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.



11. "Dispenser" means a practitioner who dispenses.
12. "Distribute" means to deliver other than by administering or dispensing a controlled substance.
13. "Distributor" means a person who distributes.
14. "Drug" means:
  - a. Substances recognized as drugs in the official United States pharmacopeia national formulary, or the official homeopathic pharmacopeia of the United States, or any supplement to any of them;
  - b. Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in individuals or animals;
  - c. Substances, other than food, intended to affect the structure or any function of the body of individuals or animals; and
  - d. Substances intended for use as a component of any article specified in subdivision a, b, or c. The term does not include devices or their components, parts, or accessories.
15. "Hashish" means the resin extracted from any part of the plant cannabis with or without its adhering plant parts, whether growing or not, and every compound, manufacture, salt, derivative, mixture, or preparation of the resin.
16. "Immediate precursor" means a substance:
  - a. That the board has found to be and by rule designates as being the principal compound commonly used or produced primarily for use in the manufacture of a controlled substance;
  - b. That is an immediate chemical intermediary used or likely to be used in the manufacture of the controlled substance; and
  - c. The control of which is necessary to prevent, curtail, or limit the manufacture of the controlled substance.
17. "Manufacture" means the production, preparation, propagation, compounding, conversion, or processing of a controlled substance, 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 substance or labeling or relabeling of its container. The term does not include the preparation or compounding of a controlled substance by an individual for the individual's own use or the preparation, compounding, packaging, or labeling of a controlled substance:
  - a. By a practitioner as an incident to the practitioner's administering or dispensing of a controlled substance in the course of the practitioner's professional practice; or
  - b. By a practitioner, or by the practitioner's authorized agent under the practitioner's supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale.
18. "Marijuana" means all parts of the plant cannabis whether growing or not; the seeds thereof; the resinous product of the combustion of the plant cannabis; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds. The term does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of mature stalks, fiber, oil, or cake, or the sterilized seed of the plant which is incapable of germination.
19. "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:
  - a. Opium and opiate and any salt, compound, derivative, or preparation of opium or opiate.
  - b. Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subdivision a, but not including the isoquinoline alkaloids of opium.
  - c. Opium poppy and poppy straw.
  - d. Coca leaves and any salt, compound, derivative, or preparation of coca leaves, any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions of coca leaves which do not contain cocaine or ecgonine.

20. "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. The term does not include, unless specifically designated as controlled under section 19-03.1-02, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). The term includes its racemic and levorotatory forms.
21. "Opium poppy" means the plant of the species *papaver somniferum* L., except its seeds.
22. "Over-the-counter sale" means a retail sale of a drug or product other than a controlled, or imitation controlled, substance.
23. "Person" means individual, corporation, limited liability company, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.
24. "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.
25. "Practitioner" means:
  - a. A physician, dentist, veterinarian, pharmacist, scientific investigator, or other person licensed, registered, or otherwise permitted by the jurisdiction in which the individual is practicing to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research.
  - b. A pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state.
26. "Production" includes the manufacturing, planting, cultivating, growing, or harvesting of a controlled substance.
27. "Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by a person, whether as principal, proprietor, agent, servant, or employee.
28. "Scheduled listed chemical product" means a product that contains ephedrine, pseudoephedrin, or phenylpropanolamine, or each of the salts, optical isomers, and salts of optical isomers of each chemical, and that may be marketed or distributed in the United States under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] as a nonprescription drug unless prescribed by a licensed physician.
29. "State" when applied to a part of the United States includes any state, district, commonwealth, territory, insular possession thereof, and any area subject to the legal authority of the United States.
30. "Ultimate user" means an individual who lawfully possesses a controlled substance for the individual's own use or for the use of a member of the individual's household or for administering to an animal owned by the individual or by a member of the individual's household.

#### **19-03.1-01.1. Board - Agreements - Gifts.**

1. In carrying out its duties under this chapter, the board shall consult with representatives of each of the following interests: North Dakota board of medicine, board of dental examiners, board of registry in podiatry, board of veterinary medical examiners, board of nursing, the college of pharmacy, and the school of medicine.
2. To carry out its duties under this chapter, the board may enter into agreements or memorandums of understanding with the interests named in subsection 1. Additionally, the board may contract for and accept private contributions, gifts, and grants-in-aid from the federal government, private industry, and other sources. The income received from these sources must be spent for the purpose designated in the gift, grant, or donation.

#### **19-03.1-02. Authority to control.**

1. The board shall administer this chapter and may add substances to or delete or reschedule all substances enumerated in the schedules in sections 19-03.1-05, 19-03.1-07, 19-03.1-09, 19-03.1-11, or 19-03.1-13 pursuant to the procedures of chapter 28-32. In making a determination regarding a substance, the board shall consider the following:
  - a. The actual or relative potential for abuse;
  - b. The scientific evidence of its pharmacological effect, if known;
  - c. The state of current scientific knowledge regarding the substance;
  - d. The history and current pattern of abuse;

- e. The scope, duration, and significance of abuse;
  - f. The risk to the public health;
  - g. The potential of the substance to produce psychic or physiological dependence liability; and
  - h. Whether the substance is an immediate precursor of a substance already controlled under this chapter.
2. After considering the factors enumerated in subsection 1, the board shall make findings with respect thereto and issue a rule controlling the substance if it finds the substance has a potential for abuse.
  3. If the board designates a substance as an immediate precursor, substances which are precursors of the controlled precursor are not subject to control solely because they are precursors of the controlled precursor.
  4. If any substance is designated, rescheduled, or deleted as a controlled substance under federal law and notice thereof is given to the board, the board shall similarly control the substance under this chapter after the expiration of thirty days from publication in the federal register of a final order designating a substance as a controlled substance or rescheduling, or deleting a substance, unless within that thirty-day period, the board objects to inclusion, rescheduling, or deletion. In that case, the board shall publish the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall publish its decision, which is final unless altered by statute. Upon publication of objection to inclusion, rescheduling, or deletion under this chapter by the board, control under this chapter is stayed until the board publishes its decision.
  5. Authority to control under this section does not extend to distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in title 5.

#### **19-03.1-03. Nomenclature.**

The controlled substances listed or to be listed in the schedules in sections 19-03.1-05, 19-03.1-07, 19-03.1-09, 19-03.1-11, and 19-03.1-13 are included by whatever official, common, usual, chemical, or trade name designated.

#### **19-03.1-034. Schedule I tests.**

The board shall place a substance in schedule I if it finds that the substance:

1. Has high potential for abuse; and
2. Has no accepted medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision.

#### **19-03.1-05. Schedule I.**

1. The controlled substances listed in this section are included in schedule I.
2. Schedule I consists of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.
3. Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of those isomers, esters, ethers, and salts is possible within the specific chemical designation:
  - a. Acetyl-alpha-methylfentanyl (also known as N-[1-(1-methyl-2-phenethyl)-4piperidiny]-N-phenylacetamide).
  - b. Acetylfentanyl (also known as N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide).
  - c. Acetylmethadol.
  - d. Allylprodine.
  - e. Alphacetylmethadol.
  - f. Alphameprodine.
  - g. Alphamethadol.
  - h. Alpha-methylfentanyl (also known as N-[1-(alpha-methyl-beta-phenyl)ethyl-4piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine).
  - i. Alpha-methylthiofentanyl (also known as N-[1-methyl-2- (2-thienyl)ethyl-4piperidiny]-N-phenylpropanamide).
  - j. Benzethidine.
  - k. Betacetylmethadol.

- l. Beta-hydroxyfentanyl (also known as N-[1-(2-hydroxy-2- phenethyl)-4-piperidiny]N-phenylpropanamide).
  - m. Beta-hydroxy-3-methylfentanyl (also known as N-[1-(2-hydroxy-2- phenethyl)-3methyl-4-piperidiny]-N-phenylpropanamide).
  - n. Betameprodine.
  - o. Betamethadol.
  - p. Betaprodine.
  - q. Clonitazene.
  - r. Dextromoramide.
  - s. Diampromide.
  - t. Diethylthiambutene.
  - u. Difenoxin.
  - v. Dimenoxadol.
  - w. Dimepheptanol.
  - x. Dimethylthiambutene.
  - y. Dioxaphetyl butyrate.
  - z. Dipipanone.
  - aa. Ethylmethylthiambutene.
  - bb. .Etonitazene.
  - cc. Etoxeridine.
  - dd. Furethidine.
  - ee. Hydroxypethidine.
  - ff. Ketobemidone.
  - gg. Levomoramide.
  - hh. Levophenacylmorphane.
  - ii. 3-Methylfentanyl (also known as N-[3-methyl-1-(2-phenylethyl) 4-piperidyl]-Nphenylpropanamide).
  - jj. 3-Methylthiofentanyl (also known as N-[3-methyl-1-(2- thienyl)ethyl-4-piperidiny]N-phenylpropanamide).
  - kk. Morpheridine.
  - ll. MPPP (also known as 1-methyl-4-phenyl-4-propionoxypiperidine).
  - mm. Noracymethadol.
  - nn. Norlevorphanol.
  - oo. Normethadone.
  - pp. Norpipanone.
  - qq. Para-fluorofentanyl (also known as N-(4-fluorophenyl)-N-[1-(2- phenethyl)-4piperidiny]propanamide).
  - rr. PEPAP (1-(2-Phenylethyl)-4-Phenyl-4-acetoxypiperidine).
  - ss. Phenadoxone.
  - tt. Phenampromide.
  - uu. Phenomorphan.
  - vv. Phenoperidine.
  - ww. Piritramide.
  - xx. Proheptazine
  - yy. Properidine.
  - zz. Propiram.
  - aaa. Racemoramide.
  - bbb. Thiofentanyl (also known as N-phenyl-N-[1-(2-thienyl)ethyl-4- piperidiny]propanamide).
  - ccc. Tilidine.
  - ddd. Trimeperidine.
4. Opium derivatives. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
- a. Acetorphine.
  - b. Acetyldihydrocodeine.

- c. Benzylmorphine.
  - d. Codeine methylbromide.
  - e. Codeine-N-Oxide.
  - f. Cyprenorphine.
  - g. Desomorphine.
  - h. Dihydromorphine.
  - i. Drotebanol.
  - j. Etorphine (except hydrochloride salt).
  - k. Heroin.
  - l. Hydromorphenol.
  - m. Methyldesorphine.
  - n. Methyldihydromorphine.
  - o. Morphine methylbromide.
  - p. Morphine methylsulfonate.
  - q. Morphine-N-Oxide.
  - r. Myrophine.
  - s. Nicocodeine.
  - t. Nicomorphine.
  - u. Normorphine.
  - v. Pholcodine.
  - w. Thebacon.
5. Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any quantity of the following hallucinogenic substances, including their salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this subsection only, the term "isomer" includes the optical, position, and geometric isomers):
- a. Alpha-ethyltryptamine, its optical isomers, salts, and salts of isomers (also known as etryptamine;  $\alpha$ -ethyl-1H-indole-3-ethanamine; 3-(2-aminobutyl) indole).
  - b. Alpha-methyltryptamine.
  - c. 4-methoxyamphetamine (also known as 4-methoxy- $\alpha$ -methylphenethylamine; paramethoxyamphetamine; PMA).
  - d. N-hydroxy-3,4-methylenedioxyamphetamine (also known as N-hydroxy- $\alpha$ -methyl-3,4(methylenedioxy)phenylamine, and N-hydroxy MDA).
  - e. Hashish.
  - f. Ibogaine (also known as 7-Ethyl-6, 6B, 7, 8, 9, 10, 12, 13-octahydro-2-methoxy-6, 9-methano-5 H-pyrido [1', 2':1,2] azepino (5,4-b) indole; Tabernanthe iboga).
  - g. Lysergic acid diethylamide.
  - h. Marijuana.
  - i. Parahexyl (also known as 3-Hexyl-1-hydroxy-7,8,9,10-tetrahydro- 6,6,9-trimethyl6H-dibenzol[b,d]pyran; Synhexyl).
  - j. Peyote (all parts of the plant presently classified botanically as *Lophophora williamsii* Lemaire, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture, or preparation of such plant, its seeds, or its extracts).
  - k. N-ethyl-3-piperidyl benzilate.
  - l. N-methyl-3-piperidyl benzilate.
  - m. Psilocybin.
  - n. Tetrahydrocannabinols, meaning tetrahydrocannabinols naturally contained in a plant of the genus *Cannabis* (cannabis plant), as well as synthetic equivalents of the substances contained in the cannabis plant, or in the resinous extractives of such plant, including synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, such as the following:

- (1) Delta-1 cis or trans tetrahydrocannabinol, and their optical isomers. Other names: Delta-9-tetrahydrocannabinol.
  - (2) Delta-6 cis or trans tetrahydrocannabinol, and their optical isomers.
  - (3) Delta-3,4 cis or trans tetrahydrocannabinol, and its optical isomers. (Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)
- o. Cannabinoids, synthetic. It includes the chemicals and chemical groups listed below, including their homologues, salts, isomers, and salts of isomers. The term "isomer" includes the optical, position, and geometric isomers.
- (1) Indole carboxaldehydes. Any compound structurally derived from 1H-indole3-carboxaldehyde or 1H-2-carboxaldehyde substituted in both of the following ways: at the nitrogen atom of the indole ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3- morpholinyl)methyl, tetrahydropyranylmethyl, benzyl, or halo benzyl group; and, at the hydrogen of the carboxaldehyde by a phenyl, benzyl, naphthyl, adamantyl, cyclopropyl, or propionaldehyde group whether or not the compound is further modified to any extent in the following ways:
    - (a) Substitution to the indole ring to any extent; or
    - (b) Substitution to the phenyl, benzyl, naphthyl, adamantyl, cyclopropyl, or propionaldehyde group to any extent; or
    - (c) A nitrogen heterocyclic analog of the indole ring; or
    - (d) A nitrogen heterocyclic analog of the phenyl, benzyl, naphthyl, adamantyl, or cyclopropyl ring.
  - (e) Examples include:
    - [1] 1-Pentyl-3-(1-naphthoyl) indole - Other names: JWH-018 and AM-678.
    - [2] 1-Butyl-3-(1-naphthoyl) indole - Other names: JWH-073.
    - [3] 1-Pentyl-3-(4-methoxy-1-naphthoyl) indole - Other names: JWH-081.
    - [4] 1-[2-(4-morpholinyl) ethyl]-3-(1-naphthoyl) indole - Other names: JWH-200.
    - [5] 1-Propyl-2-methyl-3-(1-naphthoyl) indole - Other names: JWH-015.
    - [6] 1-Hexyl-3-(1-naphthoyl) indole - Other names: JWH-019.
    - [7] 1-Pentyl-3-(4-methyl-1-naphthoyl) indole - Other names: JWH-122.
    - [8] 1-Pentyl-3-(4-ethyl-1-naphthoyl) indole - Other names: JWH-210.
    - [9] 1-Pentyl-3-(4-chloro-1-naphthoyl) indole - Other names:
    - [10] JWH-398.
    - [11] 1-(5-fluoropentyl)-3-(1-naphthoyl) indole - Other names: AM-2201.
    - [12] 1-(2-cyclohexylethyl)-3-(2-methoxyphenylacetyl) indole - Other names: RCS-8.
    - [13] 1-Pentyl-3-(2-methoxyphenylacetyl) indole - Other names: JWH-250.
    - [14] 1-Pentyl-3-(2-methylphenylacetyl) indole - Other names: JWH-251.
    - [15] 1-Pentyl-3-(2-chlorophenylacetyl) indole - Other names: JWH203.
    - [16] 1-Pentyl-3-(4-methoxybenzoyl) indole - Other names: RCS-4.
    - [17] (1-(5-fluoropentyl)-3-(2-iodobenzoyl) indole) - Other names: AM-694.
    - [18] (4-Methoxyphenyl)-[2-methyl-1-(2-(4-morpholinyl) ethyl)indol-3yl]methanone - Other names: WIN 48,098 and Pravadoline.
    - [19] (1-Pentylindol-3-yl) -(2,2,3,3-tetramethylcyclopropyl)methanone -- Other names: UR-144.
    - [20] (1-(5-fluoropentyl) indol-3-yl)-(2,2,3,3tetramethylcyclopropyl)methanone - Other names: XLR-11.
    - [21] (1-(2-morpholin-4-ylethyl)-1H-indol-3-yl) -(2,2,3,3tetramethylcyclopropyl)methanone - Other names: A-796,260.
    - [22] (1-(5-fluoropentyl)-1H-indazol-3-yl) (naphthalen-1-yl)methanone -- Other names: THJ-2201.
    - [23] 1-naphthalenyl(1-pentyl-1H-indazol-3-yl)-methanone -- Other names: THJ-018.
    - [24] (1-(5-fluoropentyl)-1H-benzo[d]imidazol-2-yl) (naphthalen-1-yl)methanone - Other names: FUBIMINA.

- [25] 1-[(N-methylpiperidin-2-yl) methyl]-3-(adamant-1-yl) indole - Other names: AM-1248.
- [26] 1-Pentyl-3-(1-adamantyl) indole - Other names: AB-001 and JWH-018 adamantyl analog.
- (2) Indole carboxamides. Any compound structurally derived from 1H-indole-3carboxamide or 1H-2-carboxamide substituted in both of the following ways: at the nitrogen atom of the indole ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, tetrahydropyranylmethyl, benzyl, or halo benzyl group; and, at the nitrogen of the carboxamide by a phenyl, benzyl, naphthyl, adamantyl, cyclopropyl, or propionaldehyde group whether or not the compound is further modified to any extent in the following ways:
- (a) Substitution to the indole ring to any extent; or
  - (b) Substitution to the phenyl, benzyl, naphthyl, adamantyl, cyclopropyl, or propionaldehyde group to any extent; or
  - (c) A nitrogen heterocyclic analog of the indole ring; or
  - (d) A nitrogen heterocyclic analog of the phenyl, benzyl, naphthyl, adamantyl, or cyclopropyl ring.
- (e) Examples include:
- [1] N-Adamantyl-1-pentyl-1H-indole-3-carboxamide - Other names: JWH-018 adamantyl carboxamide, APICA, SDB-001, and 2NE1.
  - [2] N-Adamantyl-1-fluoropentylindole-3-carboxamide - Other names: STS-135.
  - [3] N-Adamantyl-1-pentyl-1H-Indazole-3-carboxamide - Other names: AKB 48 and APINACA.
  - [4] N-1-naphthalenyl-1-pentyl-1H-indole-3-carboxamide - Other names: NNEI and MN-24.
  - [5] N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indole-3carboxamide - Other names: ADBICA.
  - [6] (S)-N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole3-carboxamide - Other names: AB-PINACA.
  - [7] N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-[(4fluorophenyl)methyl]-1H-indazole-3-carboxamide - Other names: AB-FUBINACA.
  - [8] (S)-N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1Hindazole-3-carboxamide - Other names: 5-Fluoro AB-PINACA.
  - [9] N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole3-carboxamide - Other names: ADB-PINACA.
  - [10] N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-(cyclohexylmethyl)1H-indazole-3-carboxamide - Other names: AB-CHMINACA.
  - [11] N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1Hindazole-3-carboxamide - Other names: ADB-FUBINACA.
  - [12] N-((3s,5s,7s)-adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3carboxamide - Other names: FUB-AKB48 and AKB48 N-(4fluorobenzyl) analog.
  - [13] 1-(5-fluoropentyl)-N-(quinolin-8-yl)-1H-indazole-3-carboxamide - Other names: 5-fluoro-THJ.
  - [14] (S)-methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3methylbutanoate - Other names: 5-fluoro AMB.
  - [15] methyl (1-(4-fluorobenzyl)-1H-indazole-3-carbonyl)-L-valinate - Other names: FUB-AMB.
- (3) Indole carboxylic acids. Any compound structurally derived from 1H-indole3-carboxylic acid or 1H-2-carboxylic acid substituted in both of the following ways: at the nitrogen atom of the indole ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3- morpholinyl)methyl, tetrahydropyranylmethyl, benzyl, or halo benzyl group; and, at the hydroxyl group of the carboxylic acid by a phenyl, benzyl, naphthyl, adamantyl, cyclopropyl, or propionaldehyde group whether or not the compound is further modified to any extent in the following ways:

- (a) Substitution to the indole ring to any extent; or
- (b) Substitution to the phenyl, benzyl, naphthyl, adamantyl, cyclopropyl, propionaldehyde group to any extent; or
- (c) A nitrogen heterocyclic analog of the indole ring; or
- (d) A nitrogen heterocyclic analog of the phenyl, benzyl, naphthyl, adamantyl, or cyclopropyl ring.
- (e) Examples include:
  - [1] 1-(cyclohexylmethyl)-1H-indole-3-carboxylic acid 8-quinolinyl ester - Other names: BB-22 and QUCHIC.
  - [2] naphthalen-1-yl 1-(4-fluorobenzyl)-1H-indole-3-carboxylate - Other names: FDU-PB-22.
  - [3] 1-pentyl-1H-indole-3-carboxylic acid 8-quinolinyl ester - Other names: PB-22 and QUPIC.
  - [4] 1-(5-Fluoropentyl)-1H-indole-3-carboxylic acid 8-quinolinyl ester - Other names: 5-Fluoro PB-22 and 5F-PB-22.
  - [5] quinolin-8-yl-1-(4-fluorobenzyl)-1H-indole-3-carboxylate - Other names: FUB-PB-22.
  - [6] naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate - Other names: NM2201.
- (4) Naphthylmethylindeles. Any compound containing a 1H-indol-3-yl-(1naphthyl)methane structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, or (tetrahydropyran-4-yl)methyl group whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples include:
  - (a) 1-Pentyl-1H-indol-3-yl-(1-naphthyl) methane - Other names: JWH-175.
  - (b) 1-Pentyl-1H-indol-3-yl-(4-methyl-1-naphthyl) methane - Other names: JWH-184.
- (5) Naphthoylpyrroles. Any compound containing a 3-(1-naphthoyl) pyrrole structure with substitution at the nitrogen atom of the pyrrole ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, or (tetrahydropyran-4-yl)methyl group whether or not further substituted in the pyrrole ring to any extent, whether or not substituted in the naphthyl ring to any extent. Examples include: (5-(2-fluorophenyl)-1-pentylpyrrol-3-yl)-naphthalen-1-ylmethanone - Other names: JWH-307.
- (6) Naphthylmethylindenes. Any compound containing a naphthylideneindene structure with substitution at the 3-position of the indene ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl) methyl, 2 (4 morpholinyl)ethyl, 1-(N-methyl-2pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, or (tetrahydropyran-4-yl)methyl group whether or not further substituted in the indene ring to any extent, whether or not substituted in the naphthyl ring to any extent. Examples include: E-1-[1-(1-Naphthalenylmethylene)-1H-inden-3-yl] pentane - Other names: JWH-176.
- (7) Cyclohexylphenols. Any compound containing a 2-(3-hydroxycyclohexyl) phenol structure with substitution at the 5-position of the phenolic ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, or (tetrahydropyran-4-yl)methyl group whether or not substituted in the cyclohexyl ring to any extent. Examples include:
  - (a) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol - Other names: CP 47,497.
  - (b) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol - Other names: Cannabicyclohexanol and CP 47,497 C8 homologue.
  - (c) 5-(1,1-dimethylheptyl)-2-[(1R,2R)-5-hydroxy-2-(3hydroxypropyl) cyclohexyl]-phenol - Other names: CP 55,940.
- (8) Others specifically named:
  - (a) (6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-
  - (b) 6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol - Other names: HU-210.
  - (c) (6aS,10aS)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol - Other names: Dexanabinol and HU-211.



- (d) 2,3-Dihydro-5-methyl-3-(4-morpholinylmethyl) pyrrolo[1,2,3-de]-1,4benzoxazin-6-yl]-1-naphthalenylmethanone - Other names: WIN 55,212-2.
- (e) Naphthalen-1-yl-(4-pentyloxynaphthalen-1-yl)methanone - Other names: CB-13.
- p. Substituted phenethylamines. This includes any compound, unless specifically excepted, specifically named in this schedule, or listed under a different schedule, structurally derived from phenylethan-2-amine by substitution on the phenyl ring in any of the following ways, that is to say, by substitution with a fused methylenedioxy ring, fused furan ring, or fused tetrahydrofuran ring; by substitution with two alkoxy groups; by substitution with one alkoxy and either one fused furan, tetrahydrofuran, or tetrahydropyran ring system; or by substitution with two fused ring systems from any combination of the furan, tetrahydrofuran, or tetrahydropyran ring systems.
- (1) Whether or not the compound is further modified in any of the following ways, that is to say:
- (a) By substitution of phenyl ring by any halo, hydroxyl, alkyl,
  - (b) trifluoromethyl, alkoxy, or alkylthio groups;
  - (c) By substitution at the 2-position by any alkyl groups; or
  - (d) By substitution at the 2-amino nitrogen atom with alkyl, dialkyl, benzyl, hydroxybenzyl, methylenedioxybenzyl, or methoxybenzyl groups.
- (2) Examples include:
- (a) 2-(4-Chloro-2,5-dimethoxyphenyl) ethanamine (also known as 2C-C or 2,5-Dimethoxy-4-chlorophenethylamine).
  - (b) 2-(2,5-Dimethoxy-4-methylphenyl) ethanamine (also known as 2C-D or 2,5-Dimethoxy-4-methylphenethylamine).
  - (c) 2-(2,5-Dimethoxy-4-ethylphenyl) ethanamine (also known as 2C-E or 2,5-Dimethoxy-4-ethylphenethylamine).
  - (d) 2-(2,5-Dimethoxyphenyl) ethanamine (also known as 2C-H or 2,5-Dimethoxyphenethylamine).
  - (e) 2-(4-Iodo-2,5-dimethoxyphenyl) ethanamine (also known as 2C-I or 2,5-Dimethoxy-4-iodophenethylamine).
  - (f) 2-(2,5-Dimethoxy-4-nitro-phenyl) ethanamine (also known as 2C-N or 2,5-Dimethoxy-4-nitrophenethylamine).
  - (g) 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (also known as 2C-P or 2,5-Dimethoxy-4-propylphenethylamine).
  - (h) 2-[4-(Ethylthio)-2,5-dimethoxyphenyl] ethanamine (also known as 2CT-2 or 2,5-Dimethoxy-4-ethylthiophenethylamine).
  - (i) 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl] ethanamine (also known as 2C-T-4 or 2,5-Dimethoxy-4-isopropylthiophenethylamine).
  - (j) 2-(4-bromo-2,5-dimethoxyphenyl) ethanamine (also known as 2C-B or 2,5-Dimethoxy-4-bromophenethylamine).
  - (k) 2-(2,5-dimethoxy-4-(methylthio) phenyl) ethanamine (also known as 2C-T or 4-methylthio-2,5-dimethoxyphenethylamine).
  - (l) 1-(2,5-dimethoxy-4-iodophenyl)-propan-2-amine (also known as DOI or 2,5-Dimethoxy-4-iodoamphetamine).
  - (m) 1-(4-Bromo-2,5-dimethoxyphenyl)-2-aminopropane (also known as DOB or 2,5-Dimethoxy-4-bromoamphetamine).
  - (n) 1-(4-chloro-2,5-dimethoxy-phenyl) propan-2-amine (also known as DOC or 2,5-Dimethoxy-4-chloroamphetamine).
  - (o) 2-(4-bromo-2,5-dimethoxyphenyl)-N-[(2methoxyphenyl)methyl]ethanamine (also known as 2C-B-NBOMe;
  - (p) 2,5B-NBOMe or 2,5-Dimethoxy-4-bromo-N-(2methoxybenzyl)phenethylamine).
  - (q) 2-(4-iodo-2,5-dimethoxyphenyl)-N-[(2
  - (r) -methoxyphenyl)methyl]ethanamine (also known as 2C-I-NBOMe;
  - (s) 2,5I-NBOMe or 2,5-Dimethoxy-4-iodo-N-(2methoxybenzyl)phenethylamine).
  - (t) N-(2-Methoxybenzyl)-2-(3,4,5-trimethoxyphenyl) ethanamine (also known as mescaline-NBOMe or 3,4,5-trimethoxy-N-(2methoxybenzyl)phenethylamine).

- (u) 2-(4-chloro-2,5-dimethoxyphenyl)-N-[(2-methoxyphenyl)methyl]ethanamine (also known as 2C-C-NBOMe;
  - (v) 2,5C-NBOMe or 2,5-Dimethoxy-4-chloro-N-(2-methoxybenzyl)phenethylamine).
  - (w) 2-(7-Bromo-5-methoxy-2,3-dihydro-1-benzofuran-4-yl)ethanamine (also known as 2CB-5-hemiFLY).
  - (x) 2-(8-bromo-2,3,6,7-tetrahydrofuro [2,3-f][1]benzofuran-4yl)ethanamine (also known as 2C-B-FLY).
  - (y) 2-(10-Bromo-2,3,4,7,8,9-hexahydropyrano[2,3-g]chromen-5yl)ethanamine (also known as 2C-B-butterFLY).
  - (z) N-(2-Methoxybenzyl)-1-(8-bromo-2,3,6,7-tetrahydrobenzo[1,2-b:4,5b']difuran-4-yl)-2-aminoethane (also known as 2C-B-FLY-NBOMe).
  - (aa) 1-(4-Bromofuro[2,3-f][1]benzofuran-8-yl)propan-2-amine (also known as bromo-benzodifuran-yl-isopropylamine or bromo-dragonFLY).
  - (bb) N-(2-Hydroxybenzyl)-4-iodo-2,5-dimethoxyphenethylamine (also known as 2C-I-NBOH or 2,5I-NBOH).
  - (cc) 5-(2-Aminopropyl)benzofuran (also known as 5-APB).
  - (dd) 6-(2-Aminopropyl)benzofuran (also known as 6-APB).
  - (ee) 5-(2-Aminopropyl)-2,3-dihydrobenzofuran (also known as 5-APDB).
  - (ff) 6-(2-Aminopropyl)-2,3-dihydrobenzofuran (also known as 6-APDB).
  - (gg) 2,5-dimethoxy-amphetamine (also known as 2,5-dimethoxy-amethylphenethylamine; 2,5-DMA).
  - (hh) 2,5-dimethoxy-4-ethylamphetamine (also known as DOET).
  - (ii) 2,5-dimethoxy-4-(n)-propylthiophenethylamine (also known as 2C-T-7).
  - (jj) 5-methoxy-3,4-methylenedioxy-amphetamine.
  - (kk) 4-methyl-2,5-dimethoxy-amphetamine (also known as 4-methyl-2,5dimethoxy-a-methylphenethylamine; DOM and STP).
  - (ll) 3,4-methylenedioxy amphetamine (also known as MDA).
  - (mm) 3,4-methylenedioxymethamphetamine (also known as MDMA).
  - (nn) 3,4-methylenedioxy-N-ethylamphetamine (also known as N-ethylalpha-methyl-3,4(methylenedioxy)phenethylamine, MDE, MDEA).
  - (oo) 3,4,5-trimethoxy amphetamine.
  - (pp) Mescaline (also known as 3,4,5-trimethoxyphenethylamine).
- q. Substituted tryptamines. This includes any compound, unless specifically excepted, specifically named in this schedule, or listed under a different schedule, structurally derived from 2-(1H-indol-3-yl)ethanamine (i.e., tryptamine) by mono- or di-substitution of the amine nitrogen with alkyl or alkenyl groups or by inclusion of the amino nitrogen atom in a cyclic structure whether or not the compound is further substituted at the alpha-position with an alkyl group or whether or not further substituted on the indole ring to any extent with any alkyl, alkoxy, halo, hydroxyl, or acetoxy groups. Examples include:
- (1) 5-methoxy-N,N-diallyltryptamine (also known as 5-MeO-DALT).
  - (2) 4-acetoxy-N,N-dimethyltryptamine (also known as 4-AcO-DMT or O-Acetylpsilocin).
  - (3) 4-hydroxy-N-methyl-N-ethyltryptamine (also known as 4-HO-MET).
  - (4) 4-hydroxy-N,N-diisopropyltryptamine (also known as 4-HO-DIPT).
  - (5) 5-methoxy-N-methyl-N-isopropyltryptamine (also known as 5-MeO-MiPT).
  - (6) 5-methoxy-N,N-dimethyltryptamine (also known as 5-MeO-DMT).
  - (7) Bufotenine (also known as 3-(Beta-Dimethyl-aminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N,Ndimethyltryptamine; mappine).
  - (8) 5-methoxy-N,N-diisopropyltryptamine (also known as 5-MeO-DiPT).
  - (9) Diethyltryptamine (also known as N,N-Diethyltryptamine; DET).
  - (10) Dimethyltryptamine (also known as DMT).
  - (11) Psilocyn.
6. 1-[3-(trifluoromethylphenyl)]piperazine (also known as TFMPP).
7. 1-[4-(trifluoromethylphenyl)]piperazine.

8. 6,7-dihydro-5H-indeno-(5,6-d)-1,3-dioxol-6-amine (also known as 5,6Methylenedioxy-2-aminoindane or MDAI).
9. 2-(Ethylamino)-2-(3-methoxyphenyl)cyclohexanone (also known as Methoxetamine or MXE).
10. Ethylamine analog of phencyclidine (also known as N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl) ethylamine, cyclohexamine, PCE).
12. Pyrrolidine analog of phencyclidine (also known as 1-(1-phenylcyclohexyl)pyrrolidine, PCPy, PHP).
13. Thiophene analog of phencyclidine (also known as (1-[1-(2-thienyl) cyclohexyl] piperidine; 2-Thienylanalog of phencyclidine; TPCP, TCP).
14. 1-[1-(2-thienyl)cyclohexyl]pyrrolidine (also known as TCPy).
15. Salvia divinorum, salvinorin A, or any of the active ingredients of salvia divinorum.
16. Depressants. Unless specifically excepted or unless listed in another schedule, any material compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
  - a. Flunitrazepam.
  - a. Gamma-hydroxybutyric acid.
  - b. Mecloqualone.
  - c. Methaqualone.
17. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:
  - a. Aminorex (also known as 2-amino-5-phenyl-2-oxazoline, or 4,5-dihydro-5-phenyl-2-oxazolamine).
  - b. Cathinone.
  - c. Substituted cathinones. Any compound, material, mixture, preparation, or other product, unless listed in another schedule or an approved food and drug administration drug (e.g., bupropion, pyrovalerone), structurally derived from 2aminopropan-1-one by substitution at the 1-position with either phenyl, naphthyl, or thiophene ring systems, whether or not the compound is further modified in any of the following ways:
    - (1) By substitution in the ring system to any extent with alkyl, alkylenedioxy, alkoxy, haloalkyl, hydroxyl, or halide substituents, whether or not further substituted in the ring system by one or more other univalent substituents;
    - (2) By substitution at the 3-position with an acyclic alkyl substituent;
    - (3) By substitution at the 2-amino nitrogen atom with alkyl, dialkyl, benzyl, or methoxybenzyl groups; or
    - (4) By inclusion of the 2-amino nitrogen atom in a cyclic structure. Some trade or other names:
      - (a) 3,4-Methylenedioxy-alpha-pyrrolidinopropiophenone (also known as MDPPP).
      - (b) 3,4-Methylenedioxy-N-ethylcathinone (also known as Ethylone, MDEC, or bk-MDEA).
      - (c) 3,4-Methylenedioxy-N-methylcathinone (also known as Methylone or bk-MDMA).
      - (d) 3,4-Methylenedioxypyrovalerone (also known as MDPV).
      - (e) 3,4-Dimethylmethcathinone (also known as 3,4-DMMC).
      - (f) 2-(methylamino)-1-phenylpentan-1-one (also known as Pentedrone).
      - (g) 2-Fluoromethcathinone.
      - (h) 3-Fluoromethcathinone.
      - (i) 4-Methylethcathinone (also known as 4-MEC).
      - (j) 4-Fluoromethcathinone (also known as Flephedrone).
      - (k) 4-Methoxy-alpha-pyrrolidinopropiophenone (also known as MOPPP).
      - (l) 4-Methoxymethcathinone (also known as Methedrone; bk-PMMA).
      - (m) 4'-Methyl-alpha-pyrrolidinobutiophenone (also known as MPBP).
      - (n) Alpha-methylamino-butyrophenone (also known as Buphedrone or MABP).
      - (o) Alpha-pyrrolidinobutiophenone (also known as alpha-PBP).
      - (p) Alpha-pyrrolidinopropiophenone (also known as alpha-PPP).
      - (q) Alpha-pyrrolidinopentiophenone (also known as Alphapyrrolidinovalerophenone or alpha-PVP).
      - (r) Beta-keto-N-methylbenzodioxolylbutanamine (also known as Butylone or bk-MBDB).

- (s) Ethcathinone (also known as N-Ethylcathinone).
- (t) 4-Methylmethcathinone (also known as Mephedrone or 4-MMC).
- (u) Methcathinone.
- (v) N,N-dimethylcathinone (also known as metamfepramone).
- (w) Naphthylpyrovalerone (naphyrone).
- d. Fenethylamine.
- e. Fluoroamphetamine.
- f. Fluoromethamphetamine.
- g. (±)cis-4-methylaminorex (also known as (±)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazoline).
- h. N-Benzylpiperazine (also known as BZP, 1-benzylpiperazine).
- i. N-ethylamphetamine.
- j. N, N-dimethylamphetamine (also known as N,N-α-trimethylbenzeneethanamine; N,N-α-trimethylphenethylamine).

#### **19-03.1-06. Schedule II tests.**

The board shall place a substance in schedule II if it finds that:

1. The substance has high potential for abuse;
2. The substance has currently accepted medical use in treatment in the United States or currently accepted medical use with severe restrictions; and
3. The abuse of the substance may lead to severe psychic or physical dependence.

#### **19-03.1-07. Schedule II.**

1. The controlled substances listed in this section are included in schedule II.
2. Schedule II consists of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.
3. Substances, vegetable origin or chemical synthesis. Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:
  - a. Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, dextrophan, nalbuphine, nalmeferine, naloxone, and naltrexone and their respective salts, but including the following:
    - (1) Codeine.
    - (2) Dihydroetorphine.
    - (3) Ethylmorphine.
    - (4) Etorphine hydrochloride.
    - (5) Granulated opium.
    - (6) Hydrocodone.
    - (7) Hydromorphone.
    - (8) Metopon.
    - (9) Morphine.
    - (10) Opium extracts.
    - (11) Opium fluid.
    - (12) Oripavine.
    - (13) Oxycodone.
    - (14) Oxymorphone.
    - (15) Powder opium.
    - (16) Raw opium.
    - (17) Thebaine.
    - (18) Tincture of opium.
  - b. Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subdivision a, but not including the isoquinoline alkaloids of opium.
  - c. Opium poppy and poppy straw.

- d. Coca leaves and any salt, compound, derivative, or preparation of coca leaves, including cocaine and ecgonine and their salts, isomers, derivatives, and salts of isomers and derivatives, and any salt, compound, derivative, or preparation thereof that is chemically equivalent or identical with any of these substances, except that the nondosage substances must include decocainized coca leaves or extractions of coca leaves which do not contain cocaine or ecgonine.
- e. Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrine alkaloids of the opium poppy).
4. Opiates. Unless specifically excepted or unless in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of those isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrophan and levopropoxyphene excepted:
  - a. Alfentanil.
  - b. Alphaprodine.
  - c. Anileridine.
  - d. Bezitramide.
  - e. Bulk dextropropoxyphene (nondosage forms).
  - f. Carfentanil.
  - g. Dihydrocodeine.
  - h. Diphenoxylate.
  - i. Fentanyl.
  - j. Isomethadone.
  - k. Levo-alphaacetylmethadol (LAAM).
  - l. Levomethorphan.
  - m. Levorphanol.
  - n. Metazocine.
  - o. Methadone.
  - p. Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane.
  - q. Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.
  - r. Pethidine (also known as meperidine).
  - s. Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.
  - t. Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.
  - u. Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.
  - v. Phenazocine.
  - w. Priminodine.
  - x. Racemethorphan.
  - y. Racemorphan.
  - z. Remifentanil.
  - aa. Sufentanil.
  - bb. Tapentadol.
5. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:
  - a. Amphetamine, its salts, optical isomers, and salts of its optical isomers.
  - b. Lisdexamfetamine, its salts, isomers, and salts of isomers.
  - c. Methamphetamine, its salts, isomers, and salts of isomers.
  - d. Phenmetrazine and its salts.
  - e. Methylphenidate.
6. Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
  - a. Amobarbital.
  - b. Glutethimide.

- c. Pentobarbital.
- d. Phencyclidine.
- e. Secobarbital.
- 7. Hallucinogenic substances. Nabilone [another name for nabilone ( $\pm$ )-trans-3-(1, 1-dimethylheptyl)-6, 6a, 7, 8, 10, 10a-hexahydro-1-hydroxy-6, 6-dimethyl-9Hdibenzo [b, d] pyran-9-one].
- 8. Immediate precursors. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances:
  - a. Immediate precursor to amphetamine and methamphetamine: Phenylacetone. Some trade or other names: phenyl-2-propanone; P2P, benzyl methyl ketone; methyl benzyl ketone.
  - b. Immediate precursors to phencyclidine (PCP):
    - (1) 1-phenylcyclohexylamine.
    - (2) 1-piperidinocyclohexanecarbonitrile (PCC).
  - c. Immediate precursors to fentanyl: 4-anilino-N-phenethyl-4-piperidine (ANPP).

#### 19-03.1-08. Schedule III tests.

The board shall place a substance in schedule III if it finds that:

- 1. The substance has a potential for abuse less than the substances listed in schedules I and II;
- 2. The substance has currently accepted medical use in treatment in the United States; and
- 3. Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

#### 19-03.1-09. Schedule III.

- 1. The controlled substances listed in this section are included in schedule III.
- 2. Schedule III consists of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.
- 3. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
  - a. Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in schedule II and any other drug of the quantitative composition shown in that schedule for those drugs or which is the same except that it contains a lesser quantity of controlled substances.
  - b. Benzphetamine.
  - c. Chlorphentermine.
  - d. Clortermine.
  - e. Phendimetrazine.
- 4. Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a depressant effect on the central nervous system:
  - a. Any compound, mixture, or preparation containing:
    - (1) Amobarbital;
    - (2) Secobarbital; (3) Pentobarbital; or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule.
  - b. Any suppository dosage form containing:
    - (1) Amobarbital;
    - (2) Secobarbital; (3) Pentobarbital; or any salt of any of these drugs and approved by the food and drug administration for marketing only as a suppository.
  - c. Any substance that contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid, except those substances which are specifically listed in other schedules thereof.
  - d. Chlorhexadol.
  - e. Embutramide.
  - f. Gamma-hydroxybutyric acid in a United States food and drug administration approved drug product.
  - g. Ketamine.

- h. Lysergic acid.
  - i. Lysergic acid amide.
  - j. Methyprylon.
  - k. Perampanel.
  - l. Sulfondiethylmethane.
  - m. Sulfonethylmethane.
  - n. Sulfonmethane.
  - o. Tiletamine and zolazepam or any salt thereof. Some trade or other names for a tiletamine-zolazepam combination product: Telazol. Some trade or other names for tiletamine: 2-(ethylamino)-2-(2-thienyl)-cyclohexanone. Some trade or other names for zolazepam: 4-2(2-fluorophenyl)-6, 8-dihydro-1,3,8-trimethylpyrazolo[3,4-e][1,4]-diazepin-7(1H)-one, flupyrzapon.
5. Nalorphine.
6. Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:
- a. (1) Not more than 1.80 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.
    - (1) Not more than 1.80 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
    - (2) Not more than 1.80 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
    - (3) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
    - (4) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
    - (5) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
  - b. Buprenorphine.
7. Anabolic steroids. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any of the following anabolic steroids:
- a. 3beta,17-dihydroxy-5a-androstane;
  - b. 3alpha,17beta-dihydroxy-5a-androstane;
  - c. 5alpha-androstan-3,17-dione;
  - d. 1-androstenediol (3beta,17beta-dihydroxy-5alpha-androst-1-ene);
  - e. 1-androstenediol (3alpha,17beta-dihydroxy-5alpha-androst-1-ene);
  - f. 4-androstenediol (3beta,17beta-dihydroxy-4-ene);
  - g. 5-androstenediol (3beta,17beta-dihydroxy-androst-5-ene);
  - h. 1-androstenedione ([5alpha]-androst-1-en-3,17-dione);
  - i. 4-androstenedione (androst-4-en-3,17-dione);
  - j. 5-androstenedione (androst-5-en-3,17-dione);
  - k. Bolasterone (7alpha,17alpha-dimethyl-17beta-hydroxyandrost-4-en-3-one);
  - l. Boldenone (17beta-hydroxyandrost-1,4,-diene-3-one);
  - m. Boldione (androsta-1,4-diene-3,17-dione);
  - n. Calusterone (7beta,17alpha-dimethyl-17beta-hydroxyandrost-4-en-3-one);
  - o. Clostebol (4-chloro-17beta-hydroxyandrost-4-en-3-one);
  - p. Dehydrochloromethyltestosterone (4-chloro-17beta-hydroxy-17alpha-methylandrost-1,4-dien-3-one);
  - q. Delta-1-dihydrotestosterone (also known as '1-testosterone') (17beta-hydroxy-5alpha-androst-1-en-3-one);
  - r. Desoxymethyltestosterone (17a-methyl-5a-androst-2-en-17ol) (also known as madol);

- s. 4-dihydrotestosterone (17beta-hydroxy-androstan-3-one);
- t. Drostanolone (17beta-hydroxy-2alpha-methyl-5alpha-androstan-3-one);
- u. Ethylestrenol (17alpha-ethyl-17beta-hydroxyestr-4-ene);
- v. Fluoxymesterone (9-fluoro-17alpha-methyl-11beta, 17beta-dihydroxyandrost-4-en-3-one);
- w. Formebolone (2-formyl-17alpha-methyl-11alpha, 17beta-dihydroxyandrost-1,4dien-3-one);
- x. Furazabol (17alpha-methyl-17beta-hydroxyandrostan-2,3-c-furazan);
- y. 13beta-ethyl-17alpha-hydroxygon-4-en-3-one;
- z. 4-hydroxytestosterone (4,17beta-dihydroxy-androst-4-en-3-one);
- aa. 4-hydroxy-19-nortestosterone (4,17beta-dihydroxy-estr-4-en-3-one);
- bb. Mestanolone (17alpha-methyl-17beta-hydroxy-5-androstan-3-one);
- cc. Mesterolone (1alpha-methyl-17beta-hydroxy-[5alpha]-androstan-3-one);
- dd. Methandienone (17alpha-methyl-17beta-dihydroxyandrost-1,4-dien-3-one);
- ee. Methandriol (17alpha-methyl-3beta,17beta-dihydroxyandrost-5-ene);
- ff. Methasterone (2[alpha],17[alpha]-dimethyl-5[alpha]-androstan-17[beta]-ol-3-one);
- gg. Methenolone (1-methyl-17beta-hydroxy-5alpha-androst-1-en-3-one);
- hh. 17alpha-methyl-3beta,17beta-dihydroxy-5a-androstane;
- ii. 17alpha-methyl-3alpha,17beta-dihydroxy-5a-androstane;
- jj. 17alpha-methyl-3beta,17beta-dihydroxyandrost-4-ene;
- kk. 17alpha-methyl-4-hydroxynandrolone (17alpha-methyl-4-hydroxy-17betahydroxyestr-4-en-3-one);
- ll. Methyldienolone (17alpha-methyl-17beta-hydroxyestra-4,9(10)-dien-3-one);
- mm. Methyltrienolone (17alpha-methyl-17beta-hydroxyestra-4,9(11)-trien-3-one);
- nn. Methyltestosterone (17alpha-methyl-17beta-hydroxyandrost-4-en-3-one);
- oo. Mibolerone (7alpha,17alpha-dimethyl-17beta-hydroxyestr-4-en-3-one);
- pp. 17alpha-methyl-delta1-dihydrotestosterone (17beta-hydroxy-17alpha-methyl-5alpha-androst-1-en-3-one) (also known as '17-alpha-methyl-1-testosterone');
- qq. Nandrolone (17beta-hydroxyestr-4-en-3-one);
- rr. 19-nor-4-androstenediol (3beta,17beta-dihydroxyestr-4-ene);
- ss. 19-nor-4-androstenediol (3alpha,17beta-dihydroxyestr-4-ene);
- tt. 19-nor-5-androstenediol (3beta,17beta-dihydroxyestr-5-ene);
- uu. 19-nor-5-androstenediol (3alpha,17-beta-dihydroxyester-5-ene);
- vv. 19-nor-4-androstenedione (estr-4-en-3,17-dione);
- ww. 19-nor-4,9(10)-androstadienedione (estra-4,9(10)-diene-3,17-dione);
- xx. 19-nor-5-androstenedione (estr-5-en-3,17-dione);
- yy. Norbolethone (13beta,17alpha-diethyl-17beta-hydroxygon-4-en-3-one);
- zz. Norclostebol (4-chloro-17beta-hydroxyestr-4-en-3-one);
- aaa. Norethandrolone (17alpha-ethyl-17beta-hydroxyestr-4-en-3-one);
- bbb. Normethandrolone (17alpha-methyl-17beta-hydroxyestr-4-en-3-one);
- ccc. Oxandrolone (17alpha-methyl-17beta-hydroxy-2-oxa-[5alpha]-androstan-3-one);
- ddd. Oxymesterone (17alpha-methyl-4-17beta-dihydroxyandrost-4-en-3-one);
- eee. Oxymetholone (17alpha-methyl-2-hydroxymethylene-17beta-hydroxy [5alpha]androstan-3-one);
- fff. Stanozolol (17alpha-methyl-17beta-hydroxy[5alpha]-androst-2-eno[3,2-c]pyrazole);
- ggg. Stenbolone (17beta-hydroxy-2-methyl-[5alpha]-androst-1-en-3-one);
- hhh. Prostanazol (17[beta]-hydroxy-5[alpha]-androstan-2,3-c-pyrazole);
- iii. Testolactone (13-hydroxy-3-oxo-13,17-secoandrost-1,4-dien-17-oic acid lactone);
- jjj. Testosterone (17beta-hydroxyandrost-4-en-3-one);
- kkk. Tetrahydrogestrinone (13beta,17alpha-diethyl-17beta-hydroxygon-4,9,11-trien-3-one);
- lll. Trenbolone (17beta-hydroxyestr-4,9,11-trien-3-one); or any salt, ester, or isomer of a drug or substance described or listed in this subsection, if that salt, ester, or isomer promotes muscle growth.

The term does not include an anabolic steroid that is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the secretary of health and human services for administration unless any person prescribes, dispenses, possesses, delivers, or distributes for human use.



8. Hallucinogenic substances.
  - a. Dronabinol (synthetic) [(-)-delta-9-(trans)-tetrahydrocannabinol] in sesame oil and encapsulated in a soft gelatin capsule in a United States food and drug administration-approved drug product.
  - b. Any product in hard or soft gelatin capsule form containing natural dronabinol (derived from the cannabis plant) or synthetic dronabinol (produced from synthetic materials) in sesame oil, for which an abbreviated new drug application has been approved by the food and drug administration under section 505(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(j)] which references as its listed drug the drug product referred to in subdivision a.
9. The board may except by rule any compound, mixture, or preparation containing any stimulant or depressant substance listed in subsections 3 and 4 from the application of all or any part of this chapter if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a stimulant or depressant effect on the central nervous system.

#### **19-03.1-10. Schedule IV tests.**

The board shall place a substance in schedule IV if it finds that:

1. The substance has a low potential for abuse relative to substances in schedule III;
2. The substance has currently accepted medical use in treatment in the United States; and
3. Abuse of the substance may lead to limited physical dependence or psychological dependence relative to the substances in schedule III.

#### **19-03.1-11. Schedule IV.**

1. The controlled substances listed in this section are included in schedule IV.
2. Schedule IV consists of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.
3. Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:
  - a. Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.
  - b. Dextropropoxyphene (also known as alpha-(+)-4-dimethylamino- 1,2-diphenyl-3methyl-2-propionoxybutane).
  - c. Tramadol.
4. Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any quantity of the following substances, including their salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:
  - a. Alprazolam.
  - b. Alfaxalone.
  - c. Barbitol.
  - d. Bromazepam.
  - e. Camazepam.
  - f. Carisoprodol.
  - g. Chloral betaine.
  - h. Chloral hydrate.
  - i. Chlordiazepoxide.
  - j. Clobazam.
  - k. Clonazepam.
  - l. Clorazepate.
  - m. Clotiazepam.
  - n. Cloxazolam.
  - o. Delorazepam.
  - p. Diazepam.
  - q. Dichloralphenazone.

- r. Estazolam.
  - s. Ethchlorvynol.
  - t. Ethinamate.
  - u. Ethyl loflazepate.
  - v. Fludiazepam.
  - w. Flurazepam.
  - x. Fospropofol.
  - y. Halazepam.
  - z. Haloxazolam.
  - aa. Indiplon.
  - bb. Ketazolam.
  - cc. Loprazolam.
  - dd. Lorazepam.
  - ee. Lorcaserin.
  - ff. Lormetazepam.
  - gg. Mebutamate.
  - hh. Medazepam
  - ii. Meprobamate.
  - jj. Methohexital.
  - kk. Methylphenobarbital (also known as mephobarbital).
  - ll. Midazolam.
  - mm. Nimetazepam
  - nn. Nitrazepam.
  - oo. Nordiazepam.
  - pp. Oxazepam.
  - qq. Oxazolam.
  - rr. Paraldehyde.
  - ss. Petrichloral.
  - tt. Phenobarbital.
  - uu. Pinazepam.
  - vv. Propofol.
  - ww. Prazepam.
  - xx. Quazepam.
  - yy. Suvorexant.
  - zz. Temazepam.
  - aaa. Tetrazepam
  - bbb. Triazolam.
  - ccc. Zaleplon.
  - ddd. Zolpidem.
  - eee. Zopiclone.
5. Fenfluramine. Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible:  
Fenfluramine.
  6. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:
    - a. Cathine.
    - b. Diethylpropion.
    - c. Fencamfamin.
    - d. Fenproporex.
    - e. Mazindol.
    - f. Mefenorex.
    - g. Modafinil.

- h. Pemoline (including organometallic complexes and chelates thereof).
  - i. Phentermine.
  - j. Pipradrol.
  - k. Sibutramine.
  - l. SPA ((-)-1-dimethylamino-1, 2-diphenylethane).
7. Other substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of:
    - a. Pentazocine, including its salts.
    - b. Butorphanol, including its optical isomers.
  8. The board may except by rule any compound, mixture, or preparation containing any depressant substance listed in subsection 2 from the application of all or any part of this chapter if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a depressant effect on the central nervous system.

#### **19-03.1-12. Schedule V tests.**

The board shall place a substance in schedule V if it finds that:

1. The substance has low potential for abuse relative to the controlled substances listed in schedule IV;
2. The substance has currently accepted medical use in treatment in the United States; and
3. The substance has limited physical dependence or psychological dependence liability relative to the controlled substances listed in schedule IV.

#### **19-03.1-13. Schedule V.**

1. The controlled substances listed in this section are included in schedule V.
2. Schedule V consists of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.
3. Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs and their salts.
4. Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below, which includes one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone.
  - a. Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.
  - b. Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.
  - c. Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.
  - d. Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.
  - e. Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.
  - f. Not more than 0.5 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.
5. Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible:
  - a. Ezogabine N-[2-amino-4-(4-fluorobenzylamino)-phenyl]-carbamic acid ethyl ester.
  - b. Lacosamide [(R)-2-acetoamido-N-benzyl-3-methoxy-propionamide].
  - c. Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid].
6. Stimulants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation containing any quantity of the following substances having a stimulant effect on the central nervous system, including their salts, isomers, and salts of isomers:
 

Pyrovalerone.

**19-03.1-14. Republishing of schedules.**

The board shall revise and republish the schedules annually.

**19-03.1-15. Rules.**

The board may adopt rules pursuant to chapter 28-32 and charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances within this state.

**19-03.1-16. Registration requirements.**

1. Every person who manufactures, distributes, or dispenses any controlled substance within this state or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance within this state shall obtain annually a registration issued by the board in accordance with its rules.
2. Persons registered by the board under this chapter to manufacture, distribute, dispense, or conduct research with controlled substances may possess, manufacture, distribute, dispense, or conduct research with those substances to the extent authorized by their registration and in conformity with the other provisions of this chapter.
3. The following persons need not register and may lawfully possess controlled substances under this chapter:
  - a. An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance if an agent or employee is acting in the usual course of an agent's or employee's business or employment.
  - b. A common or contract carrier or warehouseman, or an employee thereof, whose possession of any controlled substance is in the usual course of business or employment.
  - c. An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a practitioner or in lawful possession of a schedule V substance.
4. The board may waive by rule the requirement for registration of certain manufacturers, distributors, or dispensers if it finds it consistent with the public health and safety.
5. A separate registration is required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances.
6. The board may inspect the establishment of a registrant or applicant for registration in accordance with the rules of the board.

**19-03.1-17. Registration.**

1. The board shall register an applicant to manufacture or distribute controlled substances included in sections 19-03.1-05, 19-03.1-07, 19-03.1-09, 19-03.1-11, and 19-03.1-13 unless it determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the board shall consider the following factors:
  - a. Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;
  - b. Compliance with applicable state and local laws;
  - c. Any convictions of the applicant under any federal and state laws relating to any controlled substance;
  - d. Past experience in the manufacture or distribution of controlled substances and the existence in the applicant's establishment of effective controls against diversion;
  - e. Furnishing by the applicant of false or fraudulent material in any application filed under this chapter;
  - f. Suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law; and
  - g. Any other factors relevant to and consistent with the public health and safety.
2. Registration under subsection 1 does not entitle a registrant to manufacture and distribute controlled substances in schedule I or II other than those specified in the registration.

3. Practitioners must be registered to dispense any controlled substances or to conduct research with controlled substances in schedules II through V if they are authorized to dispense or conduct research under the laws of this state. The board need not require separate registration under this chapter for practitioners engaging in research with nonnarcotic controlled substances in schedules II through V where the registrant is already registered under this chapter in another capacity. Practitioners registered under federal law to conduct research with schedule I substances may conduct research with schedule I substances within this state upon furnishing the state department of health evidence of that federal registration.
4. Compliance by manufacturers and distributors with the provisions of the federal law respecting registration (excluding fees) entitles them to be registered under this chapter.

**19-03.1-17.1. Criminal history record checks.**

The board may require an applicant for registration or a registrant whose registration is subject to revocation or suspension or employees or officers of an applicant or registrant to submit to a statewide and nationwide criminal history record check. The nationwide criminal history record check must be conducted in the manner provided by section 12-60-24. All costs associated with obtaining a background check are the responsibility of the applicant or registrant.

**19-03.1-18. Revocation and suspension of registration.**

1. A registration under section 19-03.1-17 to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the board upon a finding that the registrant:
  - a. Has furnished false or fraudulent material information in any application filed under this chapter;
  - b. Has been convicted of a felony under any state or federal law relating to any controlled substance; or
  - c. Has had the registrant's federal registration suspended or revoked to manufacture, distribute, or dispense controlled substances.
2. The board may limit revocation or suspension of a registration to the particular controlled substance with respect to which grounds for revocation or suspension exist.
3. If the board suspends or revokes a registration, all controlled substances owned or possessed by the registrant at the time of suspension or the effective date of the revocation order may be placed under seal. No disposition may be made of substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application therefor, orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all controlled substances may be forfeited to the state.
4. The board shall promptly notify the bureau of all orders suspending or revoking registration and all forfeitures of controlled substances.

**19-03.1-19. Order to show cause.**

1. Before denying, suspending, or revoking a registration, or refusing a renewal of registration, the board shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended, or why the renewal should not be refused. The order to show cause must contain a statement of the basis therefor and must call upon the applicant or registrant to appear before the board at a time and place not less than thirty days after the date of service of the order, but in the case of a denial or renewal of registration the show cause order must be served not later than thirty days before the expiration of the registration. These proceedings must be conducted in accordance with chapter 28-32 without regard to any criminal prosecution or other proceeding. Proceedings to refuse renewal of registration do not abate the existing registration which remains in effect pending the outcome of the administrative hearing.
2. The board may suspend, without an order to show cause, any registration simultaneously with the institution of proceedings under section 19-03.1-18, or where renewal of registration is refused, if it finds that there is an imminent danger to the public health or safety which warrants this action. The suspension continues in effect until the conclusion of the proceedings, including judicial review thereof, unless sooner withdrawn by the board or dissolved by a court of competent jurisdiction.

**19-03.1-20. Records of registrants.**

Persons registered to manufacture, distribute, or dispense controlled substances under this chapter shall keep records and maintain inventories in conformance with the recordkeeping and inventory requirements of federal law and with any additional rules the board issues.

**19-03.1-20.1. Report of any theft or loss.**

The registrant shall immediately, within one business day, notify the state board of pharmacy of any theft or significant loss of controlled substances. This report may be telephoned, faxed, or e-mailed to the state board of pharmacy. In addition, significant loss has been further defined to include a list of factors that are relevant in deciding whether a loss was significant. This list is as follows:

1. The actual quantity of controlled substances lost in relation to the type of business;
2. The specific controlled substances lost;
3. Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
4. A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known
5. Whether specific controlled substances are likely candidates for diversion; and
6. Local trends and other indicators of the diversion potential of the missing controlled substance.

**19-03.1-21. Order forms.**

Controlled substances in schedules I and II must be distributed by a registrant to another registrant only pursuant to an order form. Compliance with the provisions of federal law respecting order forms must be deemed compliance with this section.

**19-03.1-22. Prescriptions.**

1. Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, no controlled substance in schedule II may be dispensed without the written prescription of a practitioner. When the patient is a hospice patient or resides in a licensed long-term care facility and the prescription has been signed by the practitioner before faxing, the facsimile may serve as the original prescription without another signature. The prescription may not be filled more than six months after the date it was written.
2. In emergency situations, as defined by rule of the board, schedule II drugs may be dispensed upon oral prescription of a practitioner, reduced promptly to writing, and filed by the pharmacy. Prescriptions must be retained in conformity with the requirements of section 19-03.1-20. No prescription for a schedule II substance may be refilled.
3. Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a controlled substance included in schedule III or IV, which is a prescription drug as determined under this chapter or chapter 19-02.1, may not be dispensed without a written or oral prescription of a practitioner. The prescription may not be filled or refilled more than six months after the date thereof or be refilled more than five times, unless renewed by the practitioner. Any oral prescription for such drugs must be promptly reduced to writing by the pharmacist, intern, or technician on a new prescription blank. When the patient is a hospice patient or resides in a licensed long-term care facility and the prescription has been signed by the practitioner before faxing, the facsimile may serve as the original prescription without another signature.
4. Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, no controlled substance included in schedule V must be dispensed without the written or oral prescription of a practitioner. The prescription may not be filled or refilled more than six months after the date thereof or be refilled more than five times unless renewed by the practitioner. Any oral prescription for such compound, mixture, or preparation must be promptly reduced to writing by the pharmacist, intern, or technician on a new prescription blank. When the patient is a hospice patient or resides in a licensed long-term care facility and the prescription has been signed by the practitioner before faxing, the facsimile may serve as the original prescription without another signature.

**19-03.1-22.1. Volatile chemicals - Inhalation of vapors prohibited - Definitions - Penalty.**

An individual is guilty of a class B misdemeanor if that individual intentionally inhales the vapors of a volatile chemical in a manner designed to affect the individual's central nervous system; to create or induce a condition of intoxication, hallucination, or elation; or to distort, disturb, or change the individual's eyesight, thinking processes, balance, or coordination. This section does not apply to inhalations specifically prescribed for medical, dental, or optometric treatment purposes or to controlled substances described in this chapter. For the purposes of this section, "volatile chemical" includes the following chemicals or their isomers:

1. Acetone.
2. Aliphatic hydrocarbons.
3. Amyl nitrite.
4. Butane.
5. Butyl nitrite.
6. Carbon tetrachloride.
7. Chlorinated hydrocarbons.
8. Chlorofluorocarbons.
9. Chloroform.
10. Cyclohexane.
11. Diethyl ether.
12. Ethyl acetate.
13. Fluorocarbon.
14. Glycol ether inter solvent.
15. Glycol ether solvent.
16. Hexane.
17. Ketone solvent.
18. Methanol.
19. Methyl cellosolve acetate.
20. Methyl ethyl ketone.
21. Methyl isobutyl ketone.
22. Nitrous oxide.
23. Petroleum distillate.
24. Toluene.
25. Trichloroethane.
26. Trichloroethylene.
27. Xylol or xylene.

**19-03.1-22.2. Endangerment of child or vulnerable adult.**

1. For purposes of this section:
  - a. "Chemical substance" means a substance intended to be used as a precursor in the manufacture of a controlled substance or any other chemical intended to be used in the manufacture of a controlled substance. Intent under this subsection may be demonstrated by the substance's use, quantity, manner of storage, or proximity to other precursors or to manufacturing equipment.
  - b. "Child" means an individual who is under the age of eighteen years.
  - c. "Controlled substance" means the same as that term is defined in section 19-03.1-01, except the term does not include less than one-half ounce of marijuana.
  - d. "Drug paraphernalia" means the same as that term is defined in section 19-03.4-01.
  - e. "Prescription" means the same as that term is described in section 19-03.1-22.
  - f. "Vulnerable adult" means either a disabled adult or vulnerable elderly adult as those terms are defined in section 12.1-31-07.
2. Unless a greater penalty is otherwise provided by law, a person who knowingly or intentionally causes or permits a child or vulnerable adult to be exposed to, to ingest or inhale, or to have contact with a controlled substance, chemical substance, or drug paraphernalia as defined in subsection 1, is guilty of a class C felony.

3. Unless a greater penalty is otherwise provided by law, a person who violates subsection 2, and a child or vulnerable adult actually suffers bodily injury by exposure to, ingestion of, inhalation of, or contact with a controlled substance, chemical substance, or drug paraphernalia, is guilty of a class B felony unless the exposure, ingestion, inhalation, or contact results in the death of the child or vulnerable adult, in which case the person is guilty of a class A felony.
4. It is an affirmative defense to a violation of this section that the controlled substance was provided by lawful prescription for the child or vulnerable adult and that it was administered to the child or vulnerable adult in accordance with the prescription instructions provided with the controlled substance.

**19-03.1-22.3. Ingesting a controlled substance - Venue for violation - Penalty.**

A person who intentionally ingests, inhales, or otherwise takes into the body a controlled substance, unless the substance was obtained directly from a practitioner or pursuant to a valid prescription or order of a practitioner while acting in the course of the practitioner's professional practice, is guilty of a class A misdemeanor. The venue for a violation of this section exists in either the jurisdiction in which the controlled substance was ingested, inhaled, or otherwise taken into the body or the jurisdiction in which the controlled substance was detected in the body of the accused.

**19-03.1-22.4. Controlled substances dispensed by means of the internet.**

1. As used in this section:
  - a. "Covering practitioner" means, with respect to a patient, a practitioner who conducts a medical evaluation, other than an in-person medical evaluation, at the request of a practitioner who:
    - (1) Has conducted at least one in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine, within the previous twenty-four months; and
    - (2) Is temporarily unavailable to conduct the evaluation of the patient.
  - b. "Deliver, distribute, or dispense by means of the internet" refers, respectively, to delivery, distribution, or dispensing of a controlled substance that is caused or facilitated by means of the internet.
  - c. "In-person medical evaluation" means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.
  - d. "Internet" and "practice of telemedicine" have the meanings set forth in the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 [Pub. L. 110-425; 21 U.S.C. 802-803].
  - e. "Valid prescription" means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by a:
    - (1) Practitioner who has conducted at least one in-person medical evaluation of the patient; or
    - (2) Covering practitioner.
2. A controlled substance that is a prescription drug may not be delivered, distributed, or dispensed by means of the internet without a valid prescription, but nothing in this subsection may be construed to imply that one in-person medical evaluation by itself demonstrates that a prescription has been validly issued for a legitimate medical purpose within the usual course of professional practice.
3. This section applies to the delivery, distribution, and dispensing of a controlled substance by means of the internet from a location whether within or outside this state to a person or an address in this state.
4. Nothing in this section applies to the delivery, distribution, or dispensing of a controlled substance by a practitioner engaged in the practice of telemedicine in accordance with applicable federal and state laws.
5. Nothing in this section may be construed as authorizing, prohibiting, or limiting the use of electronic prescriptions for controlled substances.

**19-03.1-22.5. Controlled substance analog use - Venue for violation - Penalty.**

1. The use of controlled substance analog includes the ingestion, inhalation, absorption, or any other method of taking the controlled substance analog into the body. An individual who intentionally uses a controlled substance analog is guilty of a class C felony, unless the individual obtains the analog directly from a practitioner or pursuant to a valid prescription or order of a practitioner.
2. The venue for a violation under this section exists in the jurisdiction in which the substance was used or in which the substance was detected.



### **19-03.1-23. Prohibited acts A - Mandatory terms of imprisonment and fines - Unclassified offenses - Penalties.**

1. Except as authorized by this chapter, it is unlawful for any person to willfully, as defined in section 12.1-02-02, manufacture, deliver, or possess with intent to manufacture or deliver, a controlled substance, or to deliver, distribute, or dispense a controlled substance by means of the internet, but any person who violates section 12-46-24 or 12-47-21 may not be prosecuted under this subsection. Any person who violates this subsection with respect to:
  - a. A controlled substance classified in schedule I or II which is a narcotic drug, or methamphetamine, is guilty of a class A felony and must be sentenced:
    - (1) For a second offense, to imprisonment for at least five years.
    - (2) For a third or subsequent offense, to imprisonment for twenty years.
  - b. Any other controlled substance classified in schedule I, II, or III, or a controlled substance analog is guilty of a class B felony. Except for a person who manufactures, delivers, or possesses with the intent to manufacture or deliver marijuana, any person found guilty under this subdivision must be sentenced:
    - (1) For a second offense, to imprisonment for at least three years.
    - (2) For a third or subsequent offense, to imprisonment for ten years.
  - c. A substance classified in schedule IV, is guilty of a class C felony and must be sentenced:
    - (1) For a second offense, to imprisonment for at least six months.
    - (2) For a third offense, to imprisonment for at least one year.
    - (3) For a fourth or subsequent offense, to imprisonment for five years.
  - d. A substance classified in schedule V, is guilty of a class A misdemeanor.
2. Except as authorized by this chapter, it is unlawful for any person to willfully, as defined in section 12.1-02-02, create, deliver, distribute, or dispense a counterfeit substance by means of the internet or any other means, or possess with intent to deliver, a counterfeit substance by means of the internet or any other means, but any person who violates section 12-46-24 or 12-47-21 may not be prosecuted under this subsection. Any person who violates this subsection with respect to:
  - a. A counterfeit substance classified in schedule I or II which is a narcotic drug, is guilty of a class A felony.
  - b. Any other counterfeit substance classified in schedule I, II, or III, is guilty of a class B felony.
  - c. A counterfeit substance classified in schedule IV, is guilty of a class C felony.
  - d. A counterfeit substance classified in schedule V, is guilty of a class A misdemeanor.
3. For second or subsequent offenders, in addition to any other penalty imposed under this section, a person who violates this chapter, except a person who manufactures, delivers, or possesses with the intent to manufacture or deliver marijuana, is subject to, and the court shall impose, the following penalties to run consecutively to any other sentence imposed:
  - a. Any person, eighteen years of age or older, who violates this section by willfully manufacturing, delivering, or possessing with intent to manufacture or deliver a controlled substance in or on, or within one thousand feet [300.48 meters] of the real property comprising a public or private elementary or secondary school or a public career and technical education school is subject to an eight-year term of imprisonment.
  - b. If the defendant was at least twenty-one years of age at the time of the offense, and delivered a controlled substance to a person under the age of eighteen, the defendant must be sentenced to imprisonment for at least eight years. It is not a defense that the defendant did not know the age of a person protected under this subdivision.
4. A person at least eighteen years of age who solicits, induces, intimidates, employs, hires, or uses a person under eighteen years of age to aid or assist in the manufacture, delivery, or possession with intent to manufacture or deliver a controlled substance for the purpose of receiving consideration or payment for the manufacture or delivery of any controlled substance is guilty of a class B felony and must be sentenced:
  - a. For a second or subsequent offense, to imprisonment for at least five years.
  - b. It is not a defense to a violation of this subsection that the defendant did not know the age of a person protected under this subsection.

5. A violation of this chapter or a law of another state or the federal government which is equivalent to an offense under this chapter committed while the offender was an adult and which resulted in a plea or finding of guilt must be considered a prior offense under subsections 1, 3, and 4. The prior offense must be alleged in the complaint, information, or indictment. The plea or finding of guilt for the prior offense must have occurred before the date of the commission of the offense or offenses charged in the complaint, information, or indictment.
6. It is unlawful for a person to willfully, as defined in section 12.1-02-02:
  - a. Serve as an agent, intermediary, or other entity that causes the internet to be used to bring together a buyer and seller to engage in the delivery, distribution, or dispensing of a controlled substance in a manner not authorized by this chapter; or
  - b. Offer to fill or refill a prescription for a controlled substance based solely on a consumer's completion of an online medical questionnaire.
  - c. A person who violates this subsection is guilty of a class C felony.
7. It is unlawful for any person to willfully, as defined in section 12.1-02-02, possess a controlled substance or a controlled substance analog unless the substance was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of the practitioner's professional practice, or except as otherwise authorized by this chapter, but any person who violates section 12-46-24 or 12-47-21 may not be prosecuted under this subsection. Except as otherwise provided in this subsection, any person who violates this subsection is guilty of a class C felony. If, at the time of the offense the person is in or on, or within one thousand feet [300.48 meters] of the real property comprising a public or private elementary or secondary school or a public career and technical education school, the person is guilty of a class B felony, unless the offense involves one ounce [28.35 grams] or less of marijuana. Any person who violates this subsection regarding possession of one ounce [28.35 grams] or less of marijuana is guilty of a class B misdemeanor.
8. Except as provided by section 19-03.1-45, a court may order a person who violates this chapter or chapter 19-03.4 to undergo a drug addiction evaluation by a licensed addiction counselor. The evaluation must indicate the prospects for rehabilitation and whether addiction treatment is required. If ordered, the evaluation must be submitted to the court before imposing punishment for a felony violation or a misdemeanor violation.
9. If a person pleads guilty or is found guilty of a first offense regarding possession of one ounce [28.35 grams] or less of marijuana and a judgment of guilt is entered, a court, upon motion, shall seal the court record of that conviction if the person is not subsequently convicted within two years of a further violation of this chapter. Once sealed, the court record may not be opened even by order of the court.

**19-03.1-23.1. Increased penalties for aggravating factors in drug offenses.**

1. A person who violates section 19-03.1-23 is subject to the penalties provided in subsection 2 if:
  - a. The offense involved the manufacture, delivery, or possession, with intent to manufacture or deliver a controlled substance in or on, or within one thousand feet [300.48 meters] of, the real property comprising a child care or preschool facility, public or private elementary or secondary school, public career and technical education school, or a public or private college or university;
  - b. The defendant was at least sixteen years of age at the time of the offense and the offense involved the delivery of a controlled substance to a minor;
  - c. The offense involved:
    - (1) Fifty grams or more of a mixture or substance containing a detectable amount of heroin;
    - (2) Fifty grams or more of a mixture or substance containing a detectable amount of:
      - (a) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;
      - (b) Cocaine, its salts, optical and geometric isomers, and salts of isomers;
      - (c) Ecgonine, its derivatives, their salts, isomers, and salts of isomers; or
      - (d) Any compound, mixture, or preparation that contains any quantity of any of the substance referred to in subparagraphs a through c;
    - (3) Five grams or more of a mixture or substance described in paragraph 2 which contains cocaine base;

- (4) Ten grams or more of phencyclidine or one hundred grams or more of a mixture or substance containing a detectable amount of phencyclidine;
- (5) One gram, one hundred dosage units, or one-half liquid ounce or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide;
- (6) Forty grams or more of a mixture or substance containing a detectable amount of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide or ten grams or more of a mixture or substance containing a detectable amount of any analog of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide;
- (7) Fifty grams or more of a mixture or substance containing a detectable amount of methamphetamine;
- (8) Ten grams, one hundred dosage units, or one-half liquid ounce or more of a mixture or substance containing a detectable amount of 3,4-methylenedioxy-N-methylamphetamine, C<sub>11</sub>H<sub>15</sub>NO<sub>2</sub>;
- (9) One hundred dosage units or one-half liquid ounce of a mixture or substance containing a detectable amount of gamma-hydroxybutyrate or gamma-butyrolactone or 1,4 butanediol or any substance that is an analog of gamma-hydroxybutyrate;
- (10) One hundred dosage units or one-half liquid ounce of a mixture or substance containing a detectable amount of flunitrazepam; or
- (11) Five hundred grams or more of marijuana; or

d. The defendant had a firearm in the defendant's actual possession at the time of the offense.

2. The offense is:

- a. A class AA felony if the violation of section 19-03.1-23 is designated as a class A felony.
- b. A class A felony if the violation of section 19-03.1-23 is designated as a class B felony.
- c. A class B felony if the violation of section 19-03.1-23 is designated as a class C felony.
- d. A class C felony if the violation of section 19-03.1-23 is designated as a class A misdemeanor.

#### **19-03.1-23.2. Mandatory terms of imprisonment - Deferred or suspended sentence limited.**

Whenever a mandatory term of imprisonment is prescribed as a penalty for violation of this chapter, the court may not defer imposition of sentence, nor may the court suspend any part of a specified mandatory term, either at the time of or after the imposition of the sentence, unless the court first finds that the offense was the defendant's first violation of this chapter, chapter 19-03.2, or chapter 19-03.4 and that extenuating or mitigating circumstances exist which justify a suspension. The court shall announce the circumstances that justify a suspension in open court when sentence is imposed and recite these circumstances in the sentence or order suspending part of the sentence.

#### **19-03.1-23.3. Drug currency forfeiture.**

1. There is a presumption of forfeiture for money, coin, currency, and everything of value, furnished or intended to be furnished, in exchange for a controlled substance in violation of chapter 19-03.1 or imitation controlled substance in violation of chapter 19-03.2, if the state offers a reasonable basis to believe, based on the following circumstances, that there is a substantial connection between the property and an offense listed in chapter 19-03.1 or 19-03.2:
  - a. The property at issue is currency in excess of ten thousand dollars which, at the time of seizure, was being transported through an airport, on a highway, or at a port-of-entry, and the property was packaged or concealed in a highly unusual manner, the person transporting the property provided false information to any law enforcement officer who lawfully stopped the person for investigative purposes, the property was found in close proximity to a measurable quantity of any controlled substance, or the property was the subject of a positive alert by a properly trained dog;
  - b. The property at issue was acquired during a period of time when the person who acquired the property was engaged in an offense under chapter 19-03.1 or 19-03.2 or within a reasonable time after the period, and there is no likely source for the property other than that offense;

- c. The property at issue was, or was intended to be, transported, transmitted, or transferred to or from a major drug-transit country, a major illicit drug-producing country, or a major money-laundering country, and the transaction giving rise to the forfeiture:
    - (1) Occurred in part in a state or foreign country whose bank secrecy laws render this state unable to obtain records relating to the transaction; or
    - (2) Was conducted by, to, or through a corporation that does not conduct any ongoing and significant commercial or manufacturing business or any other form of commercial operation which was not engaged in any legitimate business activity; or
  - d. A person involved in the transaction giving rise to the forfeiture action has been convicted in a federal, state, or foreign jurisdiction of an offense equivalent to an offense under chapter 19-03.1 or 19-03.2 or a felony involving money laundering, or is a fugitive from prosecution for any of these offenses.
2. The presumption in this section does not preclude the use of other presumptions or the establishment of probable cause based on criteria other than those set forth in this section.

#### **19-03.1-23.4. Overdose prevention and immunity.**

An individual is immune from criminal prosecution under sections 19-03.1-22.1, 19-03.1-22.3, 19-03.1-22.5, subsection 7 of section 19-03.1-23, subsection 3 of section 19-03.2-03, and section 19-03.4-03 if that individual contacted law enforcement or emergency medical services and reported that the individual was or that another individual was in need of emergency medical assistance due to a drug overdose. To receive immunity under this section, the individual receiving immunity must have remained on the scene until assistance arrived, cooperated with emergency medical services and law enforcement personnel in the medical treatment of the reported drug overdosed individual, and the overdosed individual must have been in need of emergency medical services. The maximum number of individuals that may be immune for any one occurrence is three individuals. Immunity from prosecution under this section is not applicable for a violation under section 19-03.1-23.1.

#### **19-03.1-24. Prohibited acts B - Penalties.**

- 1. It is unlawful for any person:
  - a. Who is subject to the provisions of sections 19-03.1-15 through 19-03.1-22 to distribute or dispense a controlled substance in violation of section 19-03.1-22;
  - b. Who is a registrant, to manufacture a controlled substance not authorized by their registration, or to distribute or dispense a controlled substance not authorized by their registration to another registrant or other authorized person;
  - c. To refuse or fail to make, keep, or furnish any record, notification, order form, statement, invoice, or information required under this chapter;
  - d. To refuse an entry into any premises for any inspection authorized by this chapter; or
  - e. Knowingly to keep or maintain any store, shop, warehouse, dwelling, building, vehicle, boat, aircraft, or other structure or place, which is resorted to by persons using controlled substances in violation of this chapter for the purpose of using these substances, or which is used for keeping or selling them in violation of this chapter.
- 2. Any person who violates this section is guilty of a class C felony.

#### **19-03.1-25. Prohibited acts C - Penalties.**

- 1. It is unlawful for any person:
  - a. To distribute as a registrant a controlled substance classified in schedule I or II, except pursuant to an order form as required by section 19-03.1-21;
  - b. To use in the course of the manufacture or distribution of a controlled substance a registration number which is fictitious, revoked, suspended, or issued to another person;
  - c. To acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge;
  - d. To furnish false or fraudulent material information in, or omit any material information from, any application, report, or other document required to be kept or filed under this chapter, or any record required to be kept by this chapter; or

- e. To make, distribute, or possess any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render the drug a counterfeit substance.

2. Any person who violates this section is guilty of a class C felony.

**19-03.1-26. Disposing of needles and paraphernalia - Penalty.**

Any registrant who shall use, administer, or dispense or cause to be used, administered, or dispensed any drug or controlled substance in a manner requiring the use of any type of syringe, needle, eyedropper, or other similar paraphernalia shall destroy and dispose of said syringe, needle, eyedropper, or other similar paraphernalia in a manner that will prevent its reuse by any person other than the registrant. The board may adopt rules pursuant to chapter 28-32 setting out the specific manner in which the provisions of this section must be carried out. Any registrant who violates the provisions of this section is guilty of a class A misdemeanor.

**19-03.1-27. Penalties under other laws.**

Any penalty imposed for violation of this chapter is in addition to, and not in lieu of, any civil or administrative penalty or sanction otherwise authorized by law.

**19-03.1-28. Bar to prosecution.**

If a violation of this chapter is a violation of a federal law or the law of another state, a conviction or acquittal under federal law or the law of another state for the same act is a bar to prosecution in this state.

**19-03.1-29. Distribution to persons under age eighteen.**

[Repealed by S.L. 1975 ch.106 § 673.]

**19-03.1-30. Conditional discharge for possession as first offense.**

[Repealed by S.L. 2005, ch. 196, § 4.]

**19-03.1-31. Second or subsequent offenses.**

[Repealed by S.L. 1975, ch. 106, § 673.]

**19-03.1-32. Powers of enforcement personnel - Search warrants.**

1. Any officer of the bureau of criminal investigation designated by the attorney general of this state may:
  - a. Carry firearms in the performance of official duties.
  - b. Execute and serve search warrants, arrest warrants, administrative inspection warrants, subpoenas, and summonses issued under the authority of this state.
  - c. Make arrests without warrant for any offense under this chapter committed in the officer's presence, or if the officer has probable cause to believe that the person to be arrested has committed or is committing a violation of this chapter which may constitute a felony.
  - d. Make seizures of property pursuant to this chapter.
  - e. Perform other law enforcement duties as the attorney general designates.
2. A search warrant relating to offenses involving controlled substances may be issued and executed at any time of the day or night, if the judge or magistrate issuing the warrant so specifies in the warrant.
3. Any officer authorized to execute a search warrant, without notice of the officer's authority and purpose, may break open an outer or inner door or window of a building, or any part of the building, or anything therein, if the judge or magistrate issuing the warrant has probable cause to believe that if such notice were to be given the property sought in the case may be easily and quickly destroyed or disposed of, or that danger to the life or limb of the officer or another may result, and has included in the warrant a direction that the officer executing it is not required to give such notice. Any officers acting under such warrant, as soon as practicable after entering the premises, shall identify themselves and state the purpose of entering the premises and the authority for doing so.

**19-03.1-33. Administrative inspections and warrants.**

1. Issuance and execution of administrative inspection warrants must be as follows:
  - a. A district judge within a district judge's jurisdiction, and upon proper oath or affirmation showing probable cause, may issue warrants for the purpose of conducting administrative inspections authorized by this chapter or rules hereunder and seizures of property appropriate to the inspections. For purposes of the issuance of administrative inspection warrants, probable cause exists upon showing a valid public interest in the effective enforcement of this chapter or rules thereunder, sufficient to justify administrative inspection of the area, premises, building, or conveyance in the circumstances specified in the application for the warrant.
  - b. A warrant may issue only upon an affidavit of a designated officer or employee having knowledge of the facts alleged, sworn to before the judge or magistrate and establishing the grounds for issuing the warrant. If the judge or magistrate is satisfied that grounds for the application exist or that there is probable cause to believe they exist, the judge or magistrate shall issue a warrant identifying the area, premises, building, or conveyance to be inspected, the purpose of the inspection, and, if appropriate, the type of property to be inspected, if any. The warrant must:
    - (1) State the grounds for its issuance and the name of each person whose affidavit has been taken in support thereof;
    - (2) Be directed to a person authorized to execute it;
    - (3) Command the person to whom it is directed to inspect the area, premises, building, or conveyance identified for the purpose specified and, if appropriate, direct the seizure of the property specified;
    - (4) Identify the item or types of property to be seized, if any; and
    - (5) Direct that it be served during normal business hours and designate the judge or magistrate to whom it shall be returned.
  - c. A warrant issued pursuant to this section must be executed and returned within ten days of its date unless, upon a showing of a need for additional time, the court orders otherwise. If property is seized pursuant to a warrant, a copy must be given to the person from whom or from whose premises the property is taken, together with a receipt for the property taken. The return of the warrant must be made promptly, accompanied by a written inventory of any property taken. The inventory must be made in the presence of the person executing the warrant and of the person from whose possession or premises the property was taken, if present, or in the presence of at least one credible person other than the person executing the warrant. A copy of the inventory must be delivered to the person from whom or from whose premises the property was taken and to the applicant for the warrant.
  - d. The judge or magistrate who has issued a warrant shall attach thereto a copy of the return and all papers returnable in connection therewith and file them with the clerk of the district court for the county in which the inspection was made.
2. The board may make administrative inspections of controlled premises in accordance with the following provisions:
  - a. For purposes of this section only, "controlled premises" means:
    - (1) Places where persons registered or exempted from registration requirements under this chapter are required to keep records; and
    - (2) Places, including factories, warehouses, establishments, and conveyances in which persons registered or exempted from registration requirements under this chapter are permitted to hold, manufacture, compound, process, sell, deliver, or otherwise dispose of any controlled substance.
  - b. When authorized by an administrative inspection warrant issued pursuant to subsection 1, an officer or employee designated by the board, upon presenting the warrant and appropriate credentials to the owner, operator, or agent in charge, may enter controlled premises for the purpose of conducting an administrative inspection.
  - c. When authorized by an administrative inspection warrant, an officer or employee designated by the board may:
    - (1) Inspect and copy records required by this chapter to be kept;

- (2) Inspect, within reasonable limits and in a reasonable manner, controlled premises and all pertinent equipment, finished and unfinished material, containers and labeling found therein, and, except as provided in subdivision e, all other things therein, including records, files, papers, processes, controls, and facilities bearing on violation of this chapter; and
- (3) Inventory any stock of any controlled substance therein and obtain samples thereof.
- d. This section does not prevent the inspection without a warrant of books and records pursuant to an administrative subpoena issued in accordance with section 28-32-33, nor does it prevent entries and administrative inspections, including seizures of property, without a warrant:
  - (1) If the owner, operator, or agent in charge of the controlled premises consents;
  - (2) In situations presenting imminent danger to health or safety;
  - (3) In situations involving inspection of conveyances if there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant;
  - (4) In any other exceptional emergency circumstances in which time or opportunity to apply for a warrant is lacking; or
  - (5) In all other situations in which a warrant is not constitutionally required.
- e. An inspection authorized by this section may not extend to financial data, sales data, other than shipment data, or pricing data unless the owner, operator, or agent in charge of the controlled premises consents in writing.

#### **19-03.1-34. Injunctions.**

- 1. The district courts of this state shall have jurisdiction to restrain or enjoin violations of this chapter.
- 2. The defendant may demand trial by jury for an alleged violation of an injunction or restraining order under this section.

#### **19-03.1-35. Cooperative arrangements and confidentiality.**

- 1. The board shall cooperate with federal and other state agencies in discharging its responsibilities concerning traffic in controlled substances and in suppressing the abuse of controlled substances. To this end, it may:
  - a. Arrange for exchange of information among governmental officials concerning the use and abuse of controlled substances.
  - b. Coordinate and cooperate in training programs concerning controlled substance law enforcement at local and state levels.
  - c. Cooperate with the bureau by establishing a centralized unit to accept, catalog, file, and collect statistics, including records of drug-dependent persons and other controlled substance law offenders within the state, and make the information available for federal, state, and local law enforcement purposes. It may not furnish the name or identity of a patient or research subject whose identity could not be obtained under subsection 3.
  - d. Conduct programs of eradication aimed at destroying wild or illicit growth of plant species from which controlled substances may be extracted.
- 2. Results, information, and evidence received from the bureau relating to regulatory functions of this chapter, including results of inspections conducted by it, may be relied and acted upon by the board in the exercise of its regulatory functions under this chapter.
- 3. A practitioner engaged in medical practice or research is not required or compelled to furnish the name or identity of a patient or research subject to the board nor may the practitioner be compelled in any state or local civil, criminal, administrative, legislative, or other proceedings to furnish the name or identity of an individual that the practitioner is obligated to keep confidential.

#### **19-03.1-36. Forfeitures.**

- 1. The following are subject to forfeiture:
  - a. All controlled substances which have been manufactured, distributed, dispensed, or acquired in violation of this chapter.
  - b. All imitation controlled substances as defined by sections 19-03.2-01 and 19-03.2-02.
  - c. All raw materials, products, and equipment of any kind which are used, or intended for use, in manufacturing, compounding, processing, delivering, importing, or exporting any controlled substance in violation of this chapter.

- d. All property which is used, or intended for use, as a container for property described in subdivision a, b, or c.
  - e. All conveyances, including aircraft, vehicles, or vessels, which are used, or intended for use, to transport, or in any manner to facilitate the transportation, for the purpose of sale or receipt of property described in subdivision a, b, or c, but:
    - (1) No conveyance used by any person as a common carrier in the transaction of business as a common carrier is subject to forfeiture under this section unless it appears that the owner or other person in charge of the conveyance is a consenting party or privy to a violation of this chapter.
    - (2) No conveyance is subject to forfeiture under this section by reason of any act or omission established by the owner thereof to have been committed or omitted without the owner's knowledge or consent.
    - (3) A conveyance is not subject to forfeiture for a violation of subsection 7 of section 19-03.1-23 or subsection 3 of section 19-03.2-03.
    - (4) A forfeiture of a conveyance encumbered by a bona fide security interest is subject to the interest of the secured party if the secured party neither had knowledge of nor consented to the act or omission.
  - f. All books, records, and research products and materials, including formulas, microfilm, tapes, and data which are used, or intended for use, in violation of this chapter.
  - g. All drug paraphernalia as defined in chapter 19-03.4.
  - h. All money, coin, currency, and everything of value furnished, or intended to be furnished, in exchange for a controlled substance in violation of this chapter or an imitation controlled substance in violation of chapter 19-03.2, and all real and personal property, assets, profits, income, proceeds, or an interest therein, acquired or derived from the unlawful purchase, attempted purchase, delivery, attempted delivery, manufacturing, or attempted manufacturing of any controlled substance or imitation controlled substance.
2. Property subject to forfeiture under this chapter, except conveyances, may be seized by the board upon process issued by any district court having jurisdiction over the property. A conveyance subject to forfeiture under this chapter may be seized by a state, county, or city law enforcement agency upon process issued by any district court having jurisdiction over the conveyance. Seizure without process may be made if:
    - a. The seizure is incident to an arrest or a search under a search warrant or an inspection under an administrative inspection warrant.
    - b. The property subject to seizure has been the subject of a prior judgment in favor of the state in a criminal injunction or forfeiture proceedings based upon this chapter.
    - c. The board or a law enforcement agency has probable cause to believe that the property is directly or indirectly dangerous to health or safety.
    - d. The board or a law enforcement agency has probable cause to believe that the property was used or is intended to be used in violation of this chapter.
  3. In the event of seizure pursuant to subsection 2, proceedings under subsection 4 must be instituted promptly.
  4. Property taken or detained under this section is not subject to replevin, but is deemed to be in custody of the board or a law enforcement agency subject only to the orders and decrees of the district court having jurisdiction over the forfeiture proceedings as set out in subsection 2. When property is seized under this chapter, the board or a law enforcement agency may:
    - a. Place the property under seal.
    - b. Remove the property to a place designated by it.
    - c. Require the attorney general to take custody of the property and remove it to an appropriate location for disposition in accordance with law.



5. When property is forfeited under this chapter, the board or a law enforcement agency may:
  - a. Retain it for official use or transfer the custody or ownership of any forfeited property to any federal, state, or local agency. The board shall ensure the equitable transfer of any forfeited property to the appropriate federal, state, or local law enforcement agency so as to reflect generally the contribution of that agency participating directly in any of the acts that led to the seizure or forfeiture of the property. A decision to transfer the property is not subject to review.
  - b. Sell that which is not required to be destroyed by law and which is not harmful to the public. The proceeds must be used for payment of all proper expenses of the proceedings for forfeiture and sale, including expenses of seizure, maintenance of custody, advertising, and court costs, with any remaining proceeds to be deposited, subject to section 54-12-14, in the appropriate state, county, or city general fund. When two or more law enforcement agencies are involved in seizing a conveyance, the remaining proceeds may be divided proportionately.
  - c. Require the attorney general to take custody of property and remove it for disposition in accordance with law.
  - d. Forward it to the bureau for disposition.
  - e. Use the property, including controlled substances, imitation controlled substances, and plants forfeited under subsections 6 and 7, in enforcement of this chapter. However, in a case involving the delivery of a forfeited controlled substance by a law enforcement officer or a person acting as an agent of a law enforcement officer, no prosecution or conviction for simple possession of a controlled substance under subsection 6 of section 19-03.1-23 may be based upon the forfeited controlled substances supplied by the law enforcement officer or the officer's agent.
6. Controlled substances as defined in this chapter and imitation controlled substances as defined in chapter 19-03.2 that are possessed, transferred, sold, or offered for sale in violation of this chapter and drug paraphernalia as defined in chapter 19-03.4 are contraband and must be seized and summarily forfeited to the state. Controlled substances as defined in this chapter and imitation controlled substances as defined in chapter 19-03.2, which are seized or come into the possession of the state and drug paraphernalia as defined in chapter 19-03.4, the owners of which are unknown, are contraband and must be summarily forfeited to the state.
7. Species of plants from which controlled substances in schedules I and II may be derived which have been planted or cultivated in violation of this chapter, or of which the owners or cultivators are unknown, or which are wild growths, may be seized and summarily forfeited to the state.
8. The failure, upon demand by the board, or its authorized agent, of the person in occupancy or in control of land or premises upon which the species of plants are growing or being stored to produce an appropriate registration, or proof that the person is the holder thereof, constitutes authority for the seizure and forfeiture of the plants.

#### **19-03.1-36.1. Manner of forfeiture.**

Property subject to forfeiture under this chapter, other than property that may be summarily forfeited, may be forfeited by order of a district court only after:

1. A written consent to forfeiture executed by the owner of the property and all persons with a legal interest in the property to be forfeited has been filed with the court; or
2. Commencement of forfeiture proceedings.

#### **19-03.1-36.2. Forfeiture proceeding as civil action - Standard of proof.**

Forfeiture proceedings are civil actions against the property to be forfeited and the standard of proof is a preponderance of the evidence.

#### **19-03.1-36.3. Summons and complaint for forfeiture of property - Contents of complaint - Notice.**

When property described in subsection 1 of section 19-03.1-36 is to be forfeited, other than property described in subsection 6 of section 19-03.1-36, and in the absence of a written consent to forfeiture, forfeiture proceedings must be commenced by the filing of a summons and complaint for forfeiture of the property in the district court of the county in which the property was seized, is being held, or is located. In the case of real property, the summons and complaint must be filed in the county in which the real property, or some part of the real property, is located. The proceedings must be brought in the name of the state. The complaint must describe the property, state its location, state its present custodian, state the name of each

owner if known, state the name of each party with a legal interest in the property if known or of legal record, allege the essential elements of the violation that is claimed to exist, and must conclude with a prayer to enforce the forfeiture. Notice of the forfeiture proceedings must be given to each known owner and known person with a legal interest in the property to be forfeited by serving a copy of the summons and complaint in accordance with the North Dakota Rules of Civil Procedure. The procedure governing the proceedings, except as otherwise provided in this chapter, is the same as that prescribed for civil proceedings.

**19-03.1-36.4. Answer by claimant of property - Time for filing.**

Within twenty days after the service of the summons and complaint for forfeiture, the owner of the property to be forfeited and any other person with a legal interest in the property may file an answer claiming an interest in that property and claiming that person's interest is not subject to forfeiture under this chapter.

**19-03.1-36.5. Disposition of property if no answer filed.**

If at the end of twenty days after the summons and complaint have been served there is no answer filed with the court against the complaint for forfeiture, the court shall order the forfeiture and disposition of the property as prayed for in the complaint.

**19-03.1-36.6. Hearing on contested forfeiture - Order releasing or forfeiting property.**

If an answer is filed within the time limits in this chapter, the forfeiture proceedings must be set for hearing before the court. At the hearing, the state shall establish probable cause for instituting the forfeiture action following which any owner or person with a legal interest in the property to be forfeited who has filed an answer to the complaint has the burden of proving that the property to be forfeited is not subject to forfeiture under this chapter. If the court finds that the property is not subject to forfeiture under this chapter, the court shall order the property released to the owner or other person with a legal interest in the property as that person's right, title, or interest appears. The court shall order the property forfeited if it determines that such property or an interest therein is subject to forfeiture.

**19-03.1-36.7. Legal interest in property.**

A person alleging a bona fide legal interest in property to be forfeited must establish by a preponderance of the evidence that such legal interest existed at the time of seizure or taking of custody of the property. In the case of a claimed bona fide security interest in the property, the person claiming such interest must establish by a preponderance of the evidence that the security interest in the property to be forfeited existed or was of public record at the time of seizure or taking of custody of the property.

**19-03.1-37. Burden of proof - Liabilities.**

1. It is not necessary for the state to negate any exemption or exception in this chapter in any complaint, information, indictment, or other pleading or in any trial, hearing, or other proceeding under this chapter. The burden of proof of any exemption or exception is upon the person claiming it.
2. In the absence of proof that a person is the duly authorized holder of an appropriate registration or order form issued under this chapter, the person is presumed not to be the holder of the registration or form. The burden of proof is upon the person to rebut the presumption.
3. No liability is imposed by this chapter upon any authorized state, county, or municipal officer engaged in the lawful performance of the officer's duties.
4. In all prosecutions under this chapter, chapter 19-03.2, or chapter 19-03.4 involving the analysis of a substance or sample thereof, a certified copy of the analytical report signed by the director of the state crime laboratory or the director's designee, or electronically posted by the director of the state crime laboratory or the director's designee on the crime laboratory information management system and certified by a law enforcement officer or individual who has authorized access to the crime laboratory information management system through the criminal justice data information sharing system, must be accepted as prima facie evidence of the results of the analytical findings.
5. Superseded by N.D.R.Ev., Rule 707.
6. In all cases of conspiracy to violate chapter 19-03.1, 19-03.2, or 19-03.4, the state is not required to prove or establish that a conspirator knew the other person to the agreement intended to deliver or possess with intent to deliver a controlled substance, an imitation controlled substance, or drug paraphernalia to a third person.

**19-03.1-38. Judicial review.**

All final determinations, findings, and conclusions of the board under this chapter are final and conclusive decisions of the matters involved. Any person aggrieved by the decision may obtain review of the decision in the district court. Findings of fact by the board, if supported by substantial evidence, are conclusive.

**19-03.1-39. Education and research.**

1. The board shall carry out educational programs designed to prevent and deter misuse of controlled substances. In connection with these programs it may:
  - a. Promote better recognition of the problems of misuse and abuse of controlled substances within the regulated industry and among interested groups and organizations.
  - b. Assist the regulated industry and interested groups and organizations in contributing to the reduction of misuse and abuse of controlled substances.
  - c. Consult with interested groups and organizations to aid them in solving administrative and organizational problems.
  - d. Evaluate procedures, projects, techniques, and controls conducted or proposed as part of educational programs on misuse and abuse of controlled substances.
  - e. Disseminate the results of research on misuse and abuse of controlled substances to promote a better public understanding of what problems exist and what can be done to combat them.
  - f. Assist in the education and training of state and local law enforcement officials in their efforts to control misuse and abuse of controlled substances.
2. The board shall encourage research on misuse and abuse of controlled substances. In connection with the research, and in furtherance of the enforcement of this chapter, it may:
  - a. Establish methods to assess accurately the effects of controlled substances and identify and characterize those with potential for abuse.
  - b. Make studies and undertake programs of research to:
    - (1) Develop new or improved approaches, techniques, systems, equipment, and devices to strengthen the enforcement of this chapter.
    - (2) Determine patterns of misuse and abuse of controlled substances and the social effects thereof.
    - (3) Improve methods for preventing, predicting, understanding, and dealing with the misuse and abuse of controlled substances.
  - c. Enter contracts with public agencies, institutions of higher education, and private organizations or individuals for the purpose of conducting research, demonstrations, or special projects which bear directly on misuse and abuse of controlled substances.
3. The board may enter into contracts for educational and research activities without performance bonds and without regard to statutory provisions affecting such contracts.
4. The board may authorize persons engaged in research on the use and effects of controlled substances to withhold the names and other identifying characteristics of individuals who are the subjects of the research. Persons who obtain this authorization are not compelled in any civil, criminal, administrative, legislative, or other proceeding to identify the individuals who are the subjects of research for which the authorization was obtained.
5. The board may authorize the possession and distribution of controlled substances by persons engaged in research. Persons who obtain this authorization are exempt from state prosecution for possession and distribution of controlled substances to the extent of the authorization.

**19-03.1-40. Pending proceedings.**

[Repealed by S.L. 1985, ch. 262, § 27.]

**19-03.1-41. Continuation of rules.**

Any orders and rules promulgated under any law affected by this chapter in effect on July 1, 1971, and not in conflict with it continue in effect until modified, superseded, or repealed.

**19-03.1-42. Uniformity of interpretation.**

[Repealed by S.L. 1983, ch. 82, § 154.]

**19-03.1-43.Short title.**

This chapter may be cited as the Uniform Controlled Substances Act.

**19-03.1-44.Comprehensive status and trends report.**

On or before July first of each even-numbered year, the attorney general, or designee of the attorney general, shall report the current status and trends of unlawful drug use and abuse and drug control and enforcement efforts in this state. This report must be made to an interim legislative committee and must include the following information:

1. The superintendent of public instruction shall provide the results of the most recent survey of the state's young people regarding drug usage. This survey must include information regarding the accessibility of gateway and other illicit drugs, the prevalence of gateway and other illicit drugs in schools or on school property, and the types and frequency of gateway and other illicit drugs used by young people.
2. The state crime laboratory shall provide a report that includes the type of each controlled substance tested and the number of times tests were run for each controlled substance.
3. The department of human services shall provide a current status of the number of people who were treated in the state. The report must include information about the variety of drugs, legal and illegal, for which people were treated.
4. The department of corrections and rehabilitation shall provide the current status of the number of people incarcerated or on probation in the state correctional system for violation of title 19. This report must specify the average length of sentence including probation, average length of incarceration ordered by a court to be served, and average actual time incarcerated for drug offenders sentenced to the custody of the department. The report also must identify the number of people referred to treatment and treated as a condition of sentencing, probation, or parole.
5. The attorney general shall provide the current status of the number of arrests for violation of title 19 and the current enforcement efforts to combat unlawful drug trafficking and usage.

**19-03.1-45. Drug abuse assessment and treatment - Presentence investigation - Certified drug abuse treatment programs.**

1. If a person has pled guilty or has been found guilty of a felony violation of subsection 7 of section 19-03.1-23, if that person has not previously pled guilty or been found guilty of any offense involving the use, possession, manufacture, or delivery of a controlled substance or of any other felony offense of this or another state or the federal government, the court shall impose a period of probation up to the length authorized under section 12.1-32-06.1 with a suspended execution of a sentence of imprisonment, a sentence to probation, or an order deferring imposition of sentence.
2. Upon a plea or finding of guilt of a person subject to subsection 1, the court shall order a presentence investigation to be conducted by the department. The presentence investigation must include a drug and alcohol evaluation conducted by a licensed addiction counselor.
3. If the licensed addiction counselor recommends treatment, the court shall require the person to participate in an addiction program licensed by the department of human services as a condition of the probation. The court shall commit the person to treatment through a licensed addiction program until determined suitable for discharge by the court. The term of treatment may not exceed eighteen months and may include an aftercare plan. During the commitment and while subject to probation, the department shall supervise the person.
4. If the person fails to participate in, or has a pattern of intentional conduct that demonstrates the person's refusal to comply with or participate in the treatment program, as established by judicial finding, the person is subject to revocation of the probation. Notwithstanding subsection 2 of section 12.1-32-02, the amount of time participating in the treatment program under this section is not "time spent in custody" and will not be a credit against any sentence to term of imprisonment.
5. In this section:
  - a. "Department" means the department of corrections and rehabilitation; and
  - b. "Licensed addiction counselor" is a person licensed pursuant to section 43-45-05.1.

**19-03.1-46. Bail - Additional conditions of release.**

A court shall impose as a condition of release or bail that an individual who has been arrested upon a felony violation of this chapter or chapter 19-03.4 not use a controlled substance without a valid prescription from a licensed medical practitioner and that the individual submit to a medical examination or other reasonable random testing for the purpose of determining the person's use of a controlled substance. The court shall order the frequency of the random testing and the location at which random testing must occur. The court shall provide notice to the selected provider of the required examination or testing. The provider shall notify the court if the individual fails to appear for the examination or testing. The testing must be at the individual's own cost. Submission of an individual to a medical examination or other reasonable random testing as a condition for release is not required if the court makes a specific finding on the record that:

1. The individual has not been arrested for a felony offense relating to the use, possession, manufacture, or delivery of methamphetamine;
2. The individual will appear as required by the court and will comply with all conditions of release without submission to an examination or testing; and
3. Not imposing examination or testing as a condition of release will pose no danger to the individual or to the community.

**CHAPTER 19-03.2  
IMITATION CONTROLLED SUBSTANCES**

**19-03.2-01. Definitions.**

1. "Controlled substance" means a substance as defined in section 19-03.1-01.
2. "Distribute" means the actual, constructive, or attempted transfer, delivery, or dispensing to another of an imitation controlled substance.
3. "Imitation controlled substance" means a substance that is not a controlled substance, but which by appearance, including color, shape, size, markings, or packaging, or by representations made, would lead a reasonable person to believe that the substance is a controlled substance.
4. "Manufacture" means producing, preparing, compounding, processing, encapsulating, packaging, repackaging, labeling, or relabeling of an imitation controlled substance.

**19-03.2-02. Determination of imitation controlled substance.**

When the appearance of the dosage unit is not reasonably sufficient to establish that the substance is an "imitation controlled substance" as in the case of a powder or a liquid substance, the court or authority concerned should consider, in addition to all other logically relevant factors, all of the following factors as related to "representations made" in determining whether the substance is an "imitation controlled substance":

1. Statements made by an owner or by anyone else in control of the substance concerning the nature of the substance or its use or effect.
2. Statements made to the recipient that the substance may be resold for inordinate profit.
3. Whether the substance is packaged in a manner normally used for illicit controlled substances.
4. Evasive tactics or actions utilized by the owner or person in control of the substance to avoid detection by law enforcement authorities.
5. Prior convictions, if any, of an owner, or anyone in control of the object, under state or federal law related to controlled substances, imitation controlled substances, or fraud.
6. The proximity of the substances to controlled substances.

**19-03.2-03. Prohibited acts - Penalties - Exception.**

1. It is a class C felony for any person to manufacture, distribute, or possess with intent to distribute, an imitation controlled substance.
2. It is a class C felony for a person to place in any newspaper, magazine, handbill, or other publication, or to post or distribute in any public place, any advertisement or solicitation with reasonable knowledge that the purpose of the advertisement or solicitation is to promote the distribution of imitation controlled substances.
3. It is a class B misdemeanor for a person to use, or to possess with intent to use, an imitation controlled substance.
4. It is not a defense that the defendant believed the substance actually to be a controlled substance.

5. No civil or criminal liability may be imposed by virtue of this chapter on any person registered under chapter 19-03.1 who manufactures, distributes, or possesses an imitation controlled substance for use as a placebo by a registered practitioner in the course of professional practice or research.

### **CHAPTER 19-03.3**

### **CONTROLLED SUBSTANCES FOR CARE AND TREATMENT**

#### **19-03.3-01. Definitions.**

As used in this chapter, unless the context otherwise requires:

1. "Board" means the North Dakota board of medicine.
2. "Pain" means acute pain and chronic pain. Acute pain is the normal, predicted physiological response to a noxious chemical or thermal or mechanical stimulus and typically is associated with invasive procedures, trauma, or disease, and is generally time-limited. Chronic pain is a state that persists beyond the usual course of an acute disease or healing of an injury or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.
3. "Physician" means a physician licensed by the board.

#### **19-03.3-02. Prescription or administration of drugs by physician.**

Notwithstanding any other provision of law, a physician may prescribe or administer controlled substances to a patient in the course of the physician's treatment of the patient for pain. A physician shall keep records of purchases and disposals of controlled substances prescribed or administered under this section. The records must include the date of purchase, the date of sale or administration by the physician, the name and address of the patient, and the reason for the prescribing or the administering of the substances to the patient.

#### **19-03.3-03. Restriction by hospital or health care facility of prescribed drug use prohibited.**

No hospital or health care facility may forbid or restrict the use of controlled substances when prescribed or administered by a physician having staff privileges at that hospital or health care facility for a patient diagnosed and treated by a physician for pain.

#### **19-03.3-04. Disciplinary action for prescribing or administering drug treatment prohibited.**

The board may not discipline a physician for prescribing or administering controlled substances in the course of treatment of a patient for pain under this chapter.

#### **19-03.3-05. Application.**

This chapter does not apply to a person being treated by a physician for chemical dependency because of the person's use of controlled substances not related to treatment for pain. This chapter does not authorize a physician to prescribe or administer any drug legally classified as a controlled substance or as an addictive or dangerous drug for other than medically accepted therapeutic purposes. A person to whom controlled substances are prescribed or administered for pain is not exempt from section 39-08-01 or 39-20-04.1.

#### **19-03.3-06. Cancellation, revocation, or suspension of physician's license.**

This chapter does not limit the authority of the board to cancel, revoke, or suspend the license of any physician who:

1. Prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in the manner the drug or treatment is administered or prescribed.
2. Fails to keep complete and accurate records of purchases and disposals of controlled substances listed in chapter 19-03.1.
3. Writes false or fictitious prescriptions for controlled substances scheduled in chapter 19-03.1.

### **CHAPTER 19-03.4**

### **DRUG PARAPHERNALIA**

#### **19-03.4-01. Definition - Drug paraphernalia.**

In this chapter, unless the context otherwise requires, "drug paraphernalia" means all equipment, products, and materials of any kind which are used, intended for use, or designed for use in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing,

preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance in violation of chapter 19-03.1. The term includes:

1. Kits used, intended for use, or designed for use in planting, propagating, cultivating, growing, or harvesting of any species of plant which is a controlled substance or from which a controlled substance can be derived.
2. Kits used, intended for use, or designed for use in manufacturing, compounding, converting, producing, processing, or preparing controlled substances.
3. Isomerization devices used, intended for use, or designed for use in increasing the potency of any species of plant which is a controlled substance.
4. Testing equipment used, intended for use, or designed for use in identifying or in analyzing the strength, effectiveness, or purity of controlled substances.
5. Scales and balances used, intended for use, or designed for use in weighing or measuring controlled substances.
6. Diluents and adulterants, including quinine hydrochloride, mannitol, dextrose, and lactose, used, intended for use, or designed for use in cutting controlled substances.
7. Separation gins and sifters used, intended for use, or designed for use in removing twigs and seeds from, or in otherwise cleaning or refining, marijuana.
8. Blenders, bowls, containers, spoons, grinders, and mixing devices used, intended for use, or designed for use in compounding, manufacturing, producing, processing, or preparing controlled substances.
9. Capsules, balloons, envelopes, and other containers used, intended for use, or designed for use in packaging small quantities of controlled substances.
10. Containers and other objects used, intended for use, or designed for use in storing or concealing controlled substances or products or materials used or intended for use in manufacturing, producing, processing, or preparing controlled substances.
11. Hypodermic syringes, needles, and other objects used, intended for use, or designed for use in parenterally injecting controlled substances into the human body.
12. Objects used, intended for use, or designed for use in ingesting, inhaling, or otherwise introducing marijuana, cocaine, hashish, or hashish oil into the human body, including:
  - a. Metal, wooden, acrylic, glass, stone, plastic, or ceramic pipes with or without screens, permanent screens, hashish heads, or punctured metal bowls.
  - b. Water pipes.
  - c. Carburetion tubes and devices.
  - d. Smoking and carburetion masks.
  - e. Objects, sometimes commonly referred to as roach clips, used to hold burning material, for example, a marijuana cigarette, that has become too small or too short to be held in the hand.
  - f. Miniature cocaine spoons and cocaine vials.
  - g. Chamber pipes.
  - h. Carburetor pipes.
  - i. Electric pipes.
  - j. Air-driven pipes.
  - k. Chillums.
  - l. Bongs.
  - m. Ice pipes or chillers.
13. Ingredients or components to be used or intended or designed to be used in manufacturing, producing, processing, preparing, testing, or analyzing a controlled substance, whether or not otherwise lawfully obtained, including anhydrous ammonia, nonprescription medications, methamphetamine precursor drugs, or lawfully dispensed controlled substances.

#### **19-03.4-02. Drug paraphernalia - Guidelines.**

In determining whether an object is drug paraphernalia, a court or other authority shall consider, in addition to all other logically relevant factors:

1. Statements by an owner or by anyone in control of the object concerning its use.

2. Prior convictions, if any, of an owner, or of anyone in control of the object, under any state or federal law relating to any controlled substance.
3. The proximity of the object, in time and space, to a direct violation of chapter 19-03.1.
4. The proximity of the object to controlled substances.
5. The existence of any residue of controlled substances on the object.
6. Direct or circumstantial evidence of the intent of an owner, or of any person in control of the object, to deliver the object to another person whom the owner or person in control of the object knows, or should reasonably know, intends to use the object to facilitate a violation of chapter 19-03.1. The innocence of an owner, or of any person in control of the object, as to a direct violation of chapter 19-03.1 may not prevent a finding that the object is intended or designed for use as drug paraphernalia.
7. Instructions, oral or written, provided with the object concerning the object's use.
8. Descriptive materials accompanying the object which explain or depict the object's use.
9. National and local advertising concerning the object's use.
10. The manner in which the object is displayed for sale.
11. Whether the owner, or anyone in control of the object, is a legitimate supplier of like or related items to the community, for example, a licensed distributor or dealer of tobacco products.
12. Direct or circumstantial evidence of the ratio of sales of the object or objects to the total sales of the business enterprise.
13. The existence and scope of legitimate uses for the object in the community.
14. Expert testimony concerning the object's use.
15. The actual or constructive possession by the owner or by a person in control of the object or the presence in a vehicle or structure where the object is located of written instructions, directions, or recipes to be used, or intended or designed to be used, in manufacturing, producing, processing, preparing, testing, or analyzing a controlled substance.

#### **19-03.4-03. Unlawful possession of drug paraphernalia - Penalty.**

1. A person may not use or possess with intent to use drug paraphernalia to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, or conceal a controlled substance in violation of chapter 19-03.1. Any person violating this subsection is guilty of a class C felony if the drug paraphernalia is used, or possessed with intent to be used, to manufacture, compound, convert, produce, process, prepare, test, or analyze a controlled substance, other than marijuana, classified in schedule I, II, or III of chapter 19-03.1.
2. A person may not use or possess with the intent to use drug paraphernalia to inject, ingest, inhale, or otherwise induce into the human body a controlled substance, other than marijuana, classified in schedule I, II, or III of chapter 19-03.1. A person violating this subsection is guilty of a class A misdemeanor. If a person previously has been convicted of an offense under this title, other than an offense related to marijuana, or an equivalent offense from another court in the United States, a violation of this subsection is a class C felony.
3. A person may not use or possess with intent to use drug paraphernalia to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, or conceal marijuana in violation of chapter 19-03.1. A person violating this subsection is guilty of a class A misdemeanor.
4. A person may not use or possess with the intent to use drug paraphernalia to ingest, inhale, or otherwise introduce into the human body marijuana in violation of chapter 19-03.1. A person violating this subsection is guilty of a class B misdemeanor.

#### **19-03.4-04. Unlawful manufacture or delivery of drug paraphernalia - Penalty.**

A person may not deliver, possess with intent to deliver, or manufacture with intent to deliver, drug paraphernalia, if that person knows or should reasonably know that the drug paraphernalia will be used to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inject, ingest, inhale, or otherwise introduce into the human body a controlled substance in violation of chapter 19-03.1. Any person violating this section is guilty of a class C felony if the drug paraphernalia will be used to manufacture, compound, convert, produce, process, prepare, test, inject, ingest, inhale, or analyze a controlled substance, other than marijuana,



classified in schedule I, II, or III of chapter 19-03.1. Otherwise, a violation of this section is a class A misdemeanor.

**19-03.4-05. Unlawful delivery of drug paraphernalia to a minor - Penalty.**

A person eighteen years of age or over may not deliver drug paraphernalia, in violation of this chapter, to a person under eighteen years of age who is at least three years the deliverer's junior. Any person violating this section is guilty of a class C felony.

**19-03.4-06. Unlawful advertisement of drug paraphernalia - Penalty.**

A person may not place an advertisement in any newspaper, magazine, handbill, or other publication if that person knows or should reasonably know that the purpose of the advertisement, in whole or in part, is to promote the sale of objects designed or intended for use as drug paraphernalia. Any person violating this section is guilty of a class A misdemeanor.

**19-03.4-07. Prima facie proof of intent.**

Possession of more than twenty-four grams of a methamphetamine precursor drug or combination of methamphetamine precursor drugs calculated in terms of ephedrine HCl and pseudoephedrine HCl is prima facie evidence of intent to violate sections 19-03.4-03 and 19-03.4-04. This section does not apply to a practitioner as defined in section 19-03.1-01 or to a product possessed in the course of a legitimate and lawful business.

**19-03.4-08. Retail or over-the-counter sale of scheduled listed chemical products - Penalty.**

1. The retail sale of scheduled listed chemical products is limited to:
  - a. Sales in packages containing not more than a total of two grams of one or more scheduled listed chemical products, calculated in terms of ephedrine base, pseudoephedrine base, and phenylpropanolamine base; and
  - b. Sales in blister packs, each blister containing not more than two dosage units, or when the use of blister packs is technically infeasible, sales in unit dose packets or pouches.
2. A person may not:
  - a. Deliver in a single over-the-counter sale more than two packages of a scheduled listed chemical product or a combination of scheduled listed chemical products; or
  - b. Without regard to the number of over-the-counter sales, deliver more than a daily amount of three and six-tenths grams of scheduled listed chemical products, calculated in terms of ephedrine base, pseudoephedrine base, and phenylpropanolamine base, to a purchaser.
3. When offering scheduled listed chemical products for sale, the person shall place the products behind a counter or other barrier, or in a locked cabinet, where purchasers do not have direct access to the products before the sale is made.
4. When offering scheduled listed chemical products for retail sale, a person shall require, obtain, and make a written record of the identification of the person purchasing the scheduled listed chemical product, the identification being a document issued by a government agency as described in subdivisions a and b of subsection 6, and shall deliver the product directly into the custody of the purchaser.
  - a. The person shall maintain a written list of sales that identifies the product by name, the quantity sold, the names and addresses of the purchasers, the dates and times of the sales, a unique identification number relating to the electronic record submitted into the electronic recordkeeping system described in subsection 13, and a notice to a purchaser that the making of false statements or misrepresentations may subject the purchaser to federal and state criminal penalties. The purchaser shall sign the written list of sales and enter the purchaser's name, address, and the date and time of the sale. The person making the sale shall determine that the name entered by the purchaser corresponds with the name on the identification provided by the purchaser and that the date and time of the purchase is correct. The person making the sale shall enter the name of the product and the quantity sold on the list.
  - b. Before completing the transaction, the person making the sale shall submit all the information from the written record into the electronic recordkeeping system described in subsection 13.

- c. The person shall maintain the record of identification required by this section for three years, after which the record must be destroyed. The person may not use or maintain the record for any private or commercial purpose or disclose the record to any person, except as required by law. The person shall disclose the record, upon request, to a law enforcement agency for a law enforcement purpose. A person who in good faith releases the information in the record of identification to federal, state, or local law enforcement authorities is immune from civil liability for such release unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.
5. A person may not deliver in an over-the-counter sale a scheduled listed chemical product to a person under the age of eighteen years.
6. It is a prima facie case of a violation of subsection 5 if the person making the sale did not require and obtain proof of age from the purchaser. "Proof of age" means a document issued by a governmental agency which:
  - a. Contains a description of the person or a photograph of the person, or both, and gives the person's date of birth; and
  - b. Includes a passport, military identification card, or driver's license.
7. It is an affirmative defense to a violation of subsection 5 if:
  - a. The person making the sale required and obtained proof of age from the purchaser;
  - b. The purchaser falsely represented the purchaser's proof of age by use of a false, forged, or altered document;
  - c. The appearance of the purchaser was such that an ordinary and prudent person would believe the purchaser to be at least eighteen years of age; and
  - d. The sale was made in good faith and in reliance upon the appearance and representation of proof of age of the purchaser.
8. This section does not apply to a product that the state board of pharmacy, upon application of a manufacturer, exempts from this section because the product has been formulated in such a way as to effectively prevent the conversion of the active ingredient into methamphetamine, or its salts or precursors.
9. A person may not:
  - a. Make a false statement or misrepresentation in the written list of sale that is prepared and maintained as required by subsection 4; or
  - b. Purchase more than nine grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base in scheduled listed chemical products in a thirty-day period.
10. A person who willfully violates subsection 1 or 9 is guilty of a class A misdemeanor. A person who willfully violates subsection 2, 3, 4, or 5 is guilty of an infraction.
11. A person who is the owner, operator, or manager of the retail outlet or who is the supervisor of the employee or agent committing a violation of this section of the outlet where scheduled listed chemical products are available for sale is not subject to the penalties of this section if the person:
  - a. Did not have prior knowledge of, participate in, or direct the employee or agent to commit, the violation of this section; and
  - b. Certifies to the attorney general that the employee or agent, at the time of initial employment and each calendar year thereafter, participated in a training program approved by the attorney general providing the employee or agent with information regarding the state and federal regulations governing the sale, possession, and packaging of such products. The approval of the training program by the attorney general is not subject to chapter 28-32.
12. A political subdivision, including a home rule city or county, may not enact any ordinance relating to the sale by a retail distributor of over-the-counter products containing ephedrine, pseudoephedrine, or phenylpropanolamine. Any existing ordinance is void.
  - a. The bureau of criminal investigation shall provide retailers of listed chemical products access to a real-time electronic recordkeeping system to enter into the record system any transaction required to be recorded by subsection 4.
  - b. The real-time electronic recordkeeping system must be maintained in a central repository as defined in subsection 1 of section 19-03.5-01, and must have the capability to calculate state and federal ephedrine base, pseudoephedrine base, and phenylpropanolamine base purchase limitations.

- c. The electronic recordkeeping system must include a record of all the information in the written record, the unique identification number, and certification that a signature has been obtained.
- d. The information entered into the electronic recordkeeping system is subject to subdivision d of subsection 4.
- e. If feasible, the prescription drug monitoring system utilized under chapter 19-03.5 may be used as the electronic recordkeeping system. The bureau of criminal investigation may contract with a private vendor to implement this subsection. A contractor shall comply with the confidentiality requirements of this chapter and is subject to sanctions for violation of confidentiality requirements, including termination of the contract.
- f. The bureau of criminal investigation may not charge a retailer a fee for the establishment of, maintenance of, or access to, the electronic recordkeeping system.

## **CHAPTER 19-03.5**

### **PRESCRIPTION DRUG MONITORING PROGRAM**

#### **19-03.5-01. Definitions.**

- 1. "Board" means the state board of pharmacy.
- 2. "Central repository" means a place where electronic data related to the prescribing and dispensing of controlled substances is collected.
- 3. "Controlled substance" means a drug, substance, or immediate precursor defined in section 19-03.1-01 and nonscheduled substances containing tramadol or carisoprodol.
- 4. "De-identified information" means health information that is not individually identifiable information because an expert has made that determination under title 45, Code of Federal Regulations, section 164.514 or direct identifiers and specified demographic information have been removed in accordance with the requirements of that section.
- 5. "Dispense" means to deliver a controlled substance to an ultimate user by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for delivery.
- 6. "Dispenser" means an individual who delivers a controlled substance to the ultimate user but does not include a licensed hospital pharmacy that provides a controlled substance for the purpose of inpatient hospital care or a licensed health care practitioner or other authorized individual in those instances when the practitioner administers a controlled substance to a patient.
- 7. "Individually identifiable health information" has the meaning set forth in title 45, Code of Federal Regulations, section 160.103.
- 8. "Patient" means an individual or the owner of an animal who is the ultimate user of a controlled substance for whom a prescription is issued or for whom a controlled substance is dispensed.
- 9. "Prescriber" 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.
- 10. "Program" means the prescription drug monitoring program implemented under this chapter.

#### **19-03.5-02. Requirements for prescription drug monitoring program.**

- 1. The board shall establish and maintain a program for the monitoring of prescribing and dispensing of all controlled substances.
- 2. Each dispenser shall submit to the board by electronic means information regarding each prescription dispensed for a controlled substance. The board shall establish and update rules to direct dispensers on the version of the American Society for Automation in Pharmacy Rules-Based Standard Implementation Guide for Prescription Monitoring Programs in which the dispensing history must be submitted to the central repository.
- 3. Each dispenser shall submit the information in accordance with transmission methods and frequency established by the board.
- 4. The board may issue an extension of time to a dispenser that is unable to submit prescription information by electronic means.

**19-03.5-03. Access to prescription information.**

1. Information submitted to the central repository is confidential and may not be disclosed except as provided in this section.
2. The board shall maintain procedures to ensure that the privacy, confidentiality, and security of patient information collected, recorded, transmitted, and maintained is not disclosed except as provided in this section.
3. Unless disclosure is prohibited by law, the board may provide data in the central repository to:
  - a. A prescriber for the purpose of providing medical care to a patient, a dispenser for the purpose of filling a prescription or providing pharmaceutical care for a patient, a prescriber or dispenser inquiring about the prescriber's or dispenser's own prescribing activity, or a prescriber or dispenser in order to further the purposes of the program;
  - b. An individual who requests the prescription information of the individual or the individual's minor child;
  - c. State boards and regulatory agencies that are responsible for the licensing of individuals authorized to prescribe or dispense controlled substances if the board or regulatory agency is seeking information from the central repository that is relevant to an investigation of an individual who holds a license issued by that board or regulatory agency;
  - d. Local, state, and federal law enforcement or prosecutorial officials engaged in the enforcement of laws relating to controlled substances who seek information for the purpose of an investigation or prosecution of the drug-related activity or probation compliance of an individual;
  - e. The department of human services for purposes regarding the utilization of controlled substances by a medicaid recipient or establishment and enforcement of child support and medical support;
  - f. Workforce safety and insurance for purposes regarding the utilization of controlled substances by a claimant;
  - g. Judicial authorities under grand jury subpoena or court order or equivalent judicial process for investigation of criminal violations of controlled substances laws;
  - h. Public or private entities for statistical, research, or educational purposes after the information is de-identified with respect to any prescriber, dispenser, or patient who received a prescription for a controlled substance;
  - i. A peer review committee which means any committee of a health care organization, composed of health care providers, employees, administrators, consultants, agents, or members of the health care organization's governing body, which conducts professional peer review as defined in chapter 23-34; or
  - j. A licensed addiction counselor for the purpose of providing services for a licensed treatment program in this state.
4. The board shall maintain a record of each person who requests information from the central repository. The board may use the records to document and report statistics and outcomes. The board may provide records of the requests for information to:
  - a. A board or regulatory agency responsible for the licensing of individuals authorized to prescribe or dispense controlled substances that is engaged in an investigation of the individual who submitted the request for information from the central repository; and
  - b. Local, state, and federal law enforcement or prosecutorial officials engaged in the enforcement of laws relating to controlled substances for the purpose of an active investigation of an individual who requested information from the central repository.

**19-03.5-04. Authority to contract.**

The board is authorized to contract with another agency of this state or with a private vendor to facilitate the effective operation of the prescription drug monitoring program. Any contractor is bound to comply with the provisions regarding confidentiality of prescription drug information in this chapter and is subject to termination or sanction or both for unlawful acts.

**19-03.5-05. Immunity.**

Nothing in this chapter requires a prescriber or dispenser to obtain information about a patient from the central repository prior to prescribing or dispensing a controlled substance. A prescriber, dispenser, or other health care practitioner may not be held liable in damages to any person in any civil action on the basis that the prescriber, dispenser, or other health care practitioner did or did not seek to obtain information from the central repository. Unless there is shown a lack of good faith, the board, any other state agency, a prescriber, dispenser, or any other individual in proper possession of information provided under this chapter may not be subject to any civil liability by reason of:

1. The furnishing of information under the conditions provided in this chapter;
2. The receipt and use of, or reliance on, such information;
3. The fact that any such information was not furnished; or
4. The fact that such information was factually incorrect or was released by the board to the wrong person or entity.

**19-03.5-06. Data review and referral - Corrections.**

1. The board shall review the information received by the central repository to determine if there is reason to believe:
  - a. A prescriber or dispenser may have engaged in an activity that may be a basis for disciplinary action by the board or regulatory agency responsible for the licensing of the prescriber or dispenser; or
  - b. A patient may have misused, abused, or diverted a controlled substance.
  - c. If the board determines that there is reason to believe that any of the acts described in subdivision a may have occurred, the board may notify the appropriate law enforcement agency or the board or regulatory agency responsible for the licensing of the prescriber or dispenser. The advisory council described in section 19-03.5-07 shall recommend guidelines to the board for reviewing data and making determinations with respect to the referral of patients, prescribers, or dispensers to law enforcement or appropriate regulatory authorities.
2. A patient, dispenser, or prescriber may request that erroneous information contained in the central repository be corrected or deleted. The board shall review the request to determine if the information is erroneous with respect to the patient, prescriber, or dispenser. The board shall correct any erroneous information the board discovers due to the request for review by a patient, prescriber, or dispenser.
3. The board shall adopt a procedure to allow information contained in the central repository to be shared with officials in other states acting for the purpose of controlled substance monitoring and for requesting and receiving similar controlled substance monitoring information from other states.

**19-03.5-07. Advisory council.**

1. An advisory council is established to advise and make recommendations to the board regarding how to best use the program to improve patient care and foster the goal of reducing misuse, abuse, and diversion of controlled substances; to encourage cooperation and coordination among state, local, and federal agencies and other states to reduce the misuse, abuse, and diversion of controlled substances; and to provide advice and recommendations to the board regarding any other matters as requested by the board. The advisory council may have access to central repository information to fulfill its duties.
2. The advisory council must consist of:
  - a. One dispenser selected by the board;
  - b. One physician selected by the North Dakota medical association;
  - c. One prescriber selected by the board of nursing;
  - d. A designee of the attorney general;
  - e. A designee of the department of human services;
  - f. One prescriber selected by the North Dakota board of medicine;
  - g. One prescriber selected by the North Dakota nurses association; and
  - h. Any other prescriber or dispenser determined by the board to be necessary to meet a mandate of, or avoid a delay in implementing, an appropriations measure. The number of additional members selected by the board must be limited to the number necessary to meet the mandate or avoid the delay of an appropriation.

3. The advisory council shall make recommendations to the board regarding:
  - a. Safeguards for the release of information to individuals who have access to the information contained in the central repository;
  - b. The confidentiality of program information and the integrity of the patient's relationship with the patient's health care provider;
  - c. Advancing the purposes of the program, including enhancement of the quality of health care delivery in this state; and
  - d. The continued benefits of maintaining the program in relationship to the cost and other burdens to the state.
4. The board may provide reimbursement of expenses and per diem to members of the advisory council within the limits provided in state law.

#### **19-03.5-08. Extraterritorial application.**

The board may provide data in the central repository to a practitioner or controlled substances monitoring system in another state, if the disclosure to a practitioner or the prescription drug monitoring program located in this state is authorized by this chapter.

#### **19-03.5-09. Authority to adopt rules - Rules adopted by professional licensing boards.**

1. The state board of pharmacy may adopt rules that set forth the procedures and methods for implementing the prescription drug monitoring program under this chapter.
2. Each professional licensing board that is responsible for the licensing of individuals authorized to prescribe or dispense controlled substances for human consumption shall adopt rules under chapter 28-32 to require licensed individuals under that board's jurisdiction who prescribe or dispense controlled substances to humans to utilize the prescription drug monitoring program. In drafting rules required under this subsection, each professional licensing board shall consult with the state board of pharmacy, the other boards required to adopt rules under this subsection, and the advisory council in order to maximize the uniformity among the rules for each profession. All or any of the professional licensing boards subject to the rulemaking requirement of this subsection may conduct a joint rulemaking proceeding under chapter 28-32 to implement rules required by this subsection.

#### **19-03.5-10. Reporting unlawful acts and penalties.**

1. The board may report to a dispenser's licensing board any dispenser who knowingly fails to submit prescription drug monitoring information to the board as required by this chapter or by administrative rule or who knowingly submits incorrect prescription information to the board.
2. A person, including a vendor that uses or discloses prescription drug monitoring information in violation of this chapter is subject to the penalty provided in section 12.1-13-01.

### **CHAPTER 19-03.6 PHARMACY RECORDS AUDITS**

#### **19-03.6-01. Definitions.**

For the purposes of this chapter:

1. "Entity" means a managed care company, an insurance company, a third-party payer, a pharmacy benefits manager, or any other organization that represents an insurance company, a third-party payer, or a pharmacy benefits manager.
2. "Insurance company" includes any corporation, association, benefit society, exchange, partnership, or individual engaged as principal in the business of insurance.
3. "Managed care company" is an entity that handles both health care and health care financing.
4. "Pharmacy benefits manager" means a person that performs pharmacy benefits management and includes any other person acting for such person under a contractual or employment relationship in the performance of pharmacy benefits management for a managed care company, nonprofit hospital or medical service organization, insurance company, third-party payer, or health program administered by a state agency.

5. "Plan sponsor" means the employer in the case of an employee benefit plan established or maintained by a single employer, or the employee organization in the case of a plan established or maintained by an employee organization, an association, joint board of trustees, committee, or other similar group that establishes or maintains the plan.
6. "Third-party payer" means an organization other than the patient or health care provider involved in the financing of personal health services.

#### **19-03.6-02. Pharmacy benefits manager audit - Rules.**

1. An entity conducting an audit of a pharmacy shall:
  - a. If conducting an onsite audit, give the pharmacy a written notice at least fourteen business days before conducting an initial audit.
  - b. If the audit involves clinical or professional judgment, ensure the audit is conducted by or in consultation with a pharmacist licensed in any state and employed by or contracted with the pharmacy benefits manager.
  - c. Limit the audit to no more than twenty-four months from the date that the claim was submitted to or adjudicated by the entity. A claim may not be reviewed that is older than twenty-four months from the date of the audit, unless a longer period is permitted under federal law.
  - d. Refrain from conducting the audit during the first five business days of the month unless otherwise consented to by the pharmacy.
  - e. Refrain from entering the pharmacy area where patient-specific information is available and remain out of sight and hearing range of the pharmacy customers. The pharmacy shall designate an area for auditors to conduct their business.
  - f. Allow the pharmacy to use the records, including a medication administration record, of a hospital, physician, or other authorized practitioner to validate the pharmacy record and delivery.
  - g. Allow the pharmacy to use any legal prescription, including medication administration records, electronic documents, or documented telephone calls from the prescriber or the prescriber's agents, to validate claims in connection with prescriptions and refills or changes in prescriptions.
2. An audit may not allow a recoupment to be assessed for items on the face of a prescription not required by rules adopted by the state board of pharmacy with respect to patient hard copy prescription forms for controlled and uncontrolled drugs.
3. A finding of overpayment or underpayment may be based only on the actual overpayment or underpayment and not on a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs. A calculation of an overpayment may not include dispensing fees, unless a prescription was not dispensed or the prescriber denied authorization. In the case of an error that has no financial harm to the patient or plan, the pharmacy benefits manager may not assess any chargeback. The entity conducting the audit may not use extrapolation in calculating the recoupment or penalties for audits. Any recoupment may not be deducted against future remittances and must be invoiced to the pharmacy for payment. An entity performing an audit may not receive payment based on a percentage of the amount recovered. Interest may not accrue during the audit period, which begins with the notice of audit and ends with the final audit report.
4. A clerical or recordkeeping error may not be considered fraud, but may be subject to recoupment. A person is not subject to any criminal penalty for a clerical or recordkeeping error without proof of intent to commit fraud.
5. The parameters of an audit must comply with consumer-oriented parameters based on manufacturer listings or recommendations for the following:
  - a. The day supply for eye drops must be calculated so that the consumer pays only one 30-day copayment if the bottle of eye drops is intended by the manufacturer to be a thirty-day supply.
  - b. The day supply for insulin must be calculated so that the highest dose prescribed is used to determine the day supply and consumer copayment.
  - c. The day supply for a topical product must be determined by the judgment of the pharmacist based upon the treated area.

6. Unless an alternate price is published in a provider contract and signed by both parties, the usual and customary price charged by a pharmacy for compounded medications is considered to be the reimbursable cost.
7. An entity conducting an audit shall utilize the same standards and parameters in auditing a pharmacy the entity uses with other similarly situated pharmacies.
8. An entity conducting an audit shall establish a written appeals process.

**19-03.6-03. Audit reports - Disclosure - Distribution of recouped funds - Review of auditor.**

1. A preliminary audit report must be delivered to the pharmacy within one hundred twenty days after the conclusion of the audit.
2. A pharmacy must be allowed at least sixty days following receipt of the preliminary audit to provide documentation to address any discrepancy found in the audit.
3. A final audit report must be delivered to the pharmacy within ninety days after receipt of the preliminary audit report or final appeal, whichever is later.
4. No chargeback, recoupment, or other penalty may be assessed until the appeal process has been exhausted and the final report issued.
5. An entity shall remit any money due to a pharmacy or pharmacist as a result of an underpayment of a claim within thirty days after the appeals process has been exhausted and the final audit report has been issued.
6. An auditing entity shall provide a copy of the final report to the plan sponsor for which claims were included in the audit. Any funds recouped must be returned to the plan sponsor.

**19-03.6-04. Applicability.**

1. This chapter applies to claims adjudicated after July 31, 2011.
2. This chapter does not apply to any audit, review, or investigation that is initiated based upon alleged fraud, willful misrepresentation, or abuse, including:
  - a. Insurance fraud as defined in chapter 26.1-02.1.
  - b. Billing for services not furnished or supplies not provided.
  - c. Billing that appears to be a deliberate application for duplicate payment for the same services or supplies, billing both the beneficiary and the pharmacy benefits manager or payer for the same service.
  - d. Altering claim forms, electronic claim records, or medical documentation to obtain a higher payment amount.
  - e. Soliciting, offering, or receiving a kickback or bribe.
  - f. Participating in any scheme that involves collusion between a provider and a beneficiary or between a supplier and a provider which results in higher costs or charges to the entity.
  - g. Misrepresenting a date or description of services furnished or the identity of the beneficiary or the individual who furnished the services.
  - h. Billing for a prescription without a prescription on file in a situation in which an over-the-counter item is dispensed.
  - i. Dispensing a prescription using an out-of-date drug.
  - j. Billing with an incorrect national drug code or billing for a brand name when a generic drug is dispensed.
  - k. Failing to credit the payer for a medication or a portion of a prescription that was not obtained by the payer within fourteen days unless extenuating circumstances exist.
  - l. Billing the payer a higher price than the usual and customary charge of the pharmacy to the general public.
  - m. Billing for a product without proof that the purchaser purchased the product.
3. Any case of suspected fraud or violation of law must be reported by an auditor to the licensing board.
4. This chapter does not apply to state medicaid programs.

**19-03.6-05. Penalty.**

Any person violating this chapter is guilty of a class B misdemeanor.



## CHAPTER 19-04

### POISONS AND DELETERIOUS PREPARATIONS

#### **19-04-01. Selling certain enumerated poisons regulated - Penalty.**

Every person who, at retail, without receiving a physician's prescription specifying that such prescription shall contain a poison and giving the name thereof, sells, furnishes, gives away, or delivers to another:

1. Arsenic or any preparation thereof, corrosive sublimate, white precipitate, red precipitate, biniodide of mercury, cyanide of potassium, hydrocyanic acid, strychnia, or any other poison or vegetable alkaloid, or the salts thereof, or essential oil of bitter almonds; or
2. Aconite, belladonna, colchicum, conium, formaldehyde, nux vomica, henbane, savin, ergot, cotton root, cantharides, creosote, digitalis, or the pharmaceutical preparations of any of them, croton oil, chloroform, sulfate of zinc, mineral acids, carbolic acid, or oxalic acid, without affixing to the bottle, box, vessel, or package containing the same, the name of the contents, the word "poison", and the person's name and place of business, is guilty of a class A misdemeanor. Any storekeeper, however, may sell in original, unbroken packages, fungicides and insecticides, including formaldehyde and Paris green, generally used for agricultural purposes which have been designated as such by the state board of pharmacy.

#### **19-04-02. Chloral hydrate not to be sold without prescription.**

[Repealed by S.L. 1975, ch. 106, § 673.]

#### **19-04-03. Records to be kept of poisons dispensed - Examination of records - Penalty.**

Every person who sells at retail, furnishes, gives away, or delivers to another any of the articles or preparations mentioned in section 19-04-01 or any drug, chemical, or preparation which, according to the standard works on medicine or materia medica, is liable, in quantities of sixty grains [388.80 centigrams] or less, to destroy adult human life, and who:

1. Fails or neglects, before delivering the same, to enter or cause to be entered in a book kept for that purpose, the date of sale, the name and address of the person to whom the article or preparation is delivered or sold, the name, quantity, and quality of the article or preparation delivered or sold, and the name of the dispenser; or
2. Fails, neglects, or refuses, during business hours, to exhibit such book, and every part thereof, for inspection, and to permit the same to be inspected, upon demand, by any physician, coroner, peace officer, or magistrate of the county, is guilty of a class A misdemeanor.

#### **19-04-04. Distribution of certain drugs and preparations prohibited - Penalty.**

No person, for the purpose of advertising or inviting or suggesting the use of any such article, may leave, throw, or deposit upon the doorstep or premises of another, or within the dwelling, barn, or other building owned or occupied by another, without a special personal request, samples or any quantities of any of the following preparations:

1. Patent or proprietary medicines; or
2. Any preparation, pill, tablet, powder, capsule, cosmetic, disinfectant, antiseptic, drug, medicine, or condiment that contains poison or any ingredient that is deleterious to health, or that contains an ingredient the name of which has to be printed upon the label or to be disclosed otherwise under any law of this state or of the United States. Any person who violates any provision of this section is guilty of a class B misdemeanor.

#### **19-04-05. Definitions of terms used in preceding section.**

The terms "drug", "medicine", "patent or proprietary medicine", "pill", "tablet", "powder", "capsule", "cosmetic", "disinfectant", "antiseptic", or "condiment" as used in section 19-04-04 include all remedies for internal, external, or technical use, either in package or bulk, simple, mixed, or compound.

#### **19-04-06. Preparations a nuisance - May be destroyed.**

The samples of goods described in section 19-04-04 must be deemed a nuisance and a danger and menace to the safety of children, members of the household, or livestock. If such samples are not removed upon notice by a member of the household, or if they are left behind purposely and not removed within twenty-four hours without notice, such samples may be removed, destroyed, or annihilated and disposed of by any member of the household and no accounting will have to be rendered, and an action demanding such accounting may not be maintained in any court. A defense for a violation of section 19-04-04 may not be sustained unless a receipt or a request for the goods, dated and signed by the householder, is produced as evidence.

#### **19-04-07. Penalty.**

[Repealed by S.L. 1975, ch. 106, § 673.]

#### **19-04-08. Distribution of anabolic steroids prohibited - Exception - Penalty.**

A person who distributes or possesses with the intent to distribute an anabolic steroid for any use in humans other than the treatment of disease under the prescription of a physician is guilty of a class B felony.

#### **19-04-09. Distribution of substance or device to defraud urine test prohibited - Penalty.**

A person is guilty of a class A misdemeanor if that person willfully manufactures, advertises, sells, or distributes any substance or device that is intended to defraud a urine test designed to detect the presence of a chemical substance or a controlled substance.

### **CHAPTER 26.1-27.1 PHARMACY BENEFITS MANAGEMENT**

#### **26.1-27.1-01. Definitions.**

In this chapter, unless the context otherwise requires:

1. "Covered entity" means a nonprofit hospital or a medical service corporation; a health insurer; a health benefit plan; a health maintenance organization; a health program administered by the state in the capacity of provider of health coverage; or an employer, a labor union, or other entity organized in the state which provides health coverage to covered individuals who are employed or reside in the state. The term does not include a self-funded plan that is exempt from state regulation pursuant to the Employee Retirement Income Security Act of 1974 [Pub. L. 93-406; 88 Stat. 829; 29 U.S.C. 1001 et seq.]; a plan issued for coverage for federal employees; or a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, medicare supplement, disability income, long-term care, or other limited-benefit health insurance policy or contract.
2. "Covered individual" means a member, a participant, an enrollee, a contractholder, a policyholder, or a beneficiary of a covered entity who is provided health coverage by the covered entity. The term includes a dependent or other individual provided health coverage through a policy, contract, or plan for a covered individual.
3. "De-identified information" means information from which the name, address, telephone number, and other variables have been removed in accordance with requirements of title 45, Code of Federal Regulations, part 164, section 512, subsections (a) or (b).
4. "Generic drug" means a drug that is chemically equivalent to a brand name drug for which the patent has expired.
5. "Labeler" means a person that has been assigned a labeler code by the federal food and drug administration under title 21, Code of Federal Regulations, part 207, section 20, and that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale.
6. "Payment received by the pharmacy benefits manager" means the aggregate amount of the following types of payments:
  - a. A rebate collected by the pharmacy benefits manager which is allocated to a covered entity;
  - b. An administrative fee collected from the manufacturer in consideration of an administrative service provided by the pharmacy benefits manager to the manufacturer;

- c. A pharmacy network fee; and
  - d. Any other fee or amount collected by the pharmacy benefits manager from a manufacturer or labeler for a drug switch program, formulary management program, mail service pharmacy, educational support, data sales related to a covered individual, or any other administrative function.
7. "Pharmacy benefits management" means the procurement of prescription drugs at a negotiated rate for dispensation within this state to covered individuals; the administration or management of prescription drug benefits provided by a covered entity for the benefit of covered individuals; or the providing of any of the following services with regard to the administration of the following pharmacy benefits:
    - a. Claims processing, retail network management, and payment of claims to a pharmacy for prescription drugs dispensed to a covered individual;
    - b. Clinical formulary development and management services; or
    - c. Rebate contracting and administration.
  8. "Pharmacy benefits manager" means a person that performs pharmacy benefits management. The term includes a person acting for a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management for a covered entity. The term does not include a public self-funded pool or a private single-employer self-funded plan that provides benefits or services directly to its beneficiaries. The term does not include a health carrier licensed under title 26.1 if the health carrier is providing pharmacy benefits management to its insureds.
  9. "Rebate" means a retrospective reimbursement of a monetary amount by a manufacturer under a manufacturer's discount program with a pharmacy benefits manager for drugs dispensed to a covered individual.
  10. "Utilization information" means de-identified information regarding the quantity of drug prescriptions dispensed to members of a health plan during a specified time period.

**26.1-27.1-02. Licensing.**

A person may not perform or act as a pharmacy benefits manager in this state unless that person holds a certificate of registration as an administrator under chapter 26.1-27.

**26.1-27.1-03. Disclosure requirements.**

1. A pharmacy benefits manager shall disclose to the commissioner any ownership interest of any kind with:
  - a. Any insurance company responsible for providing benefits directly or through reinsurance to any plan for which the pharmacy benefits manager provides services.
  - b. Any parent company, subsidiary, or other organization that is related to the provision of pharmacy services, the provision of other prescription drug or device services, or a pharmaceutical manufacturer.
2. A pharmacy benefits manager shall notify the commissioner in writing within five business days of any material change in the pharmacy benefits manager's ownership.

**26.1-27.1-04. Prohibited practices.**

1. A pharmacy benefits manager shall comply with chapter 19-02.1 regarding the substitution of one prescription drug for another.
2. A pharmacy benefits manager may not require a pharmacist or pharmacy to participate in one contract in order to participate in another contract. The pharmacy benefits manager may not exclude an otherwise qualified pharmacist or pharmacy from participation in a particular network if the pharmacist or pharmacy accepts the terms, conditions, and reimbursement rates of the pharmacy benefits manager's contract.

**26.1-27.1-05. Contents of pharmacy benefits management agreement - Requirements.**

1. A pharmacy benefits manager shall offer to a covered entity options for the covered entity to contract for services that must include:
  - a. A transaction fee without a sharing of a payment received by the pharmacy benefits manager;

- b. A combination of a transaction fee and a sharing of a payment received by the pharmacy benefits manager; or
  - c. A transaction fee based on the covered entity receiving all the benefits of a payment received by the pharmacy benefits manager.
2. The agreement between the pharmacy benefits manager and the covered entity must include a provision allowing the covered entity to have audited the pharmacy benefits manager's books, accounts, and records, including de-identified utilization information, as necessary to confirm that the benefit of a payment received by the pharmacy benefits manager is being shared as required by the contract.

**26.1-27.1-06. Examination of insurer-covered entity.**

- 1. During an examination of a covered entity as provided for in chapter 26.1-03, 26.1-17, or 26.1-18.1, the commissioner shall examine any contract between the covered entity and a pharmacy benefits manager and any related record to determine if the payment received by the pharmacy benefits manager which the covered entity received from the pharmacy benefits manager has been applied toward reducing the covered entity's rates or has been distributed to covered individuals.
- 2. To facilitate the examination, the covered entity shall disclose annually to the commissioner the benefits of the payment received by the pharmacy benefits manager received under any contract with a pharmacy benefits manager and shall describe the manner in which the payment received by the pharmacy benefits manager is applied toward reducing rates or is distributed to covered individuals.
- 3. Any information disclosed to the commissioner under this section is considered a trade secret under chapter 47-25.1.

**26.1-27.1-07. Rulemaking authority.**

The commissioner shall adopt rules as necessary before implementation of this chapter.

**26.1-36-12.2. Freedom of choice for pharmacy services.**

- 1. No third-party payer, including a health care insurer as defined in section 26.1-47-01, providing pharmacy services and prescription drugs to any beneficiary may:
  - a. Prevent a beneficiary from selecting the pharmacy or pharmacist of the beneficiary's choice to provide pharmaceutical goods and services, provided that pharmacist or pharmacy is licensed in this state;
  - b. Impose upon any beneficiary selecting a participating or contracting provider a copayment, fee, or other condition not equally imposed upon all beneficiaries in the plan selecting a participating or contracting provider; or
  - c. Deny any pharmacy or pharmacist the right to participate as a preferred provider under chapter 26.1-47 or as a contracting provider for any policy or plan, provided the pharmacist or pharmacy is licensed in this state, and accepts the terms of the third-party payer's contract.
- 2. Notwithstanding the provisions of subsection 1, the department of human services may exclude, from participation in the medical assistance program administered under chapter 50-24.1 and title XIX of the Social Security Act [Pub. L. 89-97; 79 Stat. 343; 42 U.S.C. 1396 et seq.], as amended, any provider of pharmacy services who does not agree to comply with state and federal requirements governing the program, or who, after so agreeing, fails to comply with those requirements.
- 3. Any provision in a health insurance policy in this state which violates the provisions in subsection 1 is void.
- 4. Any person who violates this section is guilty of a class A misdemeanor and each violation is a separate offense. The commissioner may levy an administrative penalty not to exceed ten thousand dollars for a violation of this section.
- 5. The insurance commissioner shall enforce the provisions of this section.

## CHAPTER 9-16 ELECTRONIC TRANSACTIONS

### 9-16-01. Definitions.

In this chapter:

1. "Agreement" means the bargain of the parties in fact, as found in the parties' language or inferred from other circumstances and from rules and procedures given the effect of agreements under laws otherwise applicable to a particular transaction.
2. "Automated transaction" means a transaction conducted or performed, in whole or in part, by electronic means or electronic records, in which the acts or records of one or both parties are not reviewed by an individual in the ordinary course in forming a contract, performing under an existing contract, or fulfilling an obligation required by the transaction.
3. "Computer program" means a set of statements or instructions to be used directly or indirectly in an information processing system in order to bring about a certain result.
4. "Contract" means the total legal obligation resulting from the parties' agreement as affected by this chapter and other applicable law.
5. "Electronic" means relating to technology having electrical, digital, magnetic, wireless, optical, electromagnetic, or similar capabilities.
6. "Electronic agent" means a computer program or an electronic or other automated means used independently to initiate an action or respond to electronic records or performances, in whole or in part, without review or action by an individual.
7. "Electronic record" means a record created, generated, sent, communicated, received, or stored by electronic means.
8. "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.
9. "Governmental agency" means an executive, legislative, or judicial agency, department, board, commission, authority, institution, or instrumentality of the state.
10. "Information" means data, text, images, sounds, codes, computer programs, software, databases, or the like.
11. "Information processing system" means an electronic system for creating, generating, sending, receiving, storing, displaying, or processing information.
12. "Record" means information that is inscribed on a tangible medium or which is stored in an electronic or other medium and is retrievable in perceivable form.
13. "Security procedure" means a procedure employed for the purpose of verifying that an electronic signature, record, or performance is that of a specific person or for detecting changes or errors in the information in an electronic record. The term includes a procedure that requires the use of algorithms or other codes, identifying words or numbers, encryption, or callback or other acknowledgment procedures.
14. "State" means a state of the United States, the District of Columbia, Puerto Rico, the United States Virgin Islands, or any territory or insular possession subject to the jurisdiction of the United States. The term includes an Indian tribe or band, or Alaskan native village, which is recognized by federal law or formally acknowledged by a state.
15. "Transaction" means an action or set of actions occurring between two or more persons relating to the conduct of business, commercial, or governmental affairs.

### 9-16-02. Scope.

1. Except as otherwise provided in subsection 2, this chapter applies to electronic records and electronic signatures relating to a transaction.
2. This chapter does not apply to a transaction to the extent the transaction is governed by:
  - a. A law governing the creation and execution of wills, codicils, or testamentary trusts;
  - b. The Uniform Commercial Code other than section 41-01-20 and chapters 41-02 and 41-02.1; and
  - c. Chapters 41-03, 41-04, 41-04.1, 41-05, 41-07, 41-08, or 41-09.

3. This chapter applies to an electronic record or electronic signature otherwise excluded from the application of this chapter under subsection 2 to the extent it is governed by a law other than those specified in subsection 2.
4. A transaction subject to this chapter is also subject to other applicable substantive law.

#### **9-16-03. Prospective application.**

This chapter applies to any electronic record or electronic signature created, generated, sent, communicated, received, or stored after July 31, 2001.

#### **9-16-04 Use of electronic records and electronic signatures - Variation by agreement.**

1. This chapter does not require a record or signature to be created, generated, sent, communicated, received, stored, or otherwise processed or used by electronic means or in electronic form.
2. This chapter applies only to transactions between parties each of which has agreed to conduct transactions by electronic means. Whether the parties agree to conduct transactions by electronic means is determined from the context and surrounding circumstances, including the parties' conduct.
3. If a party agrees to conduct a transaction by electronic means, this chapter does not prohibit the party from refusing to conduct other transactions by electronic means. This subsection may not be varied by agreement.
4. Except as otherwise provided in this chapter, the effect of any of this chapter's provisions may be varied by agreement. The presence in certain provisions of this chapter of the words "unless otherwise agreed", or words of similar import, does not imply that the effect of other provisions may not be varied by agreement.
5. Whether an electronic record or electronic signature has legal consequences is determined by this chapter and other applicable law.

#### **9-16-05. Construction and application.**

This chapter must be construed and applied:

1. To facilitate electronic transactions consistent with other applicable law;
2. To be consistent with reasonable practices concerning electronic transactions and with the continued expansion of those practices; and
3. To effectuate its general purpose to make uniform the law with respect to the subject of this chapter among states enacting it.

#### **9-16-06. Legal recognition of electronic records, electronic signatures, and electronic contracts.**

1. A record or signature may not be denied legal effect or enforceability solely because the record or signature is in electronic form.
2. A contract may not be denied legal effect or enforceability solely because an electronic record was used in the contract's formation.
3. If a law requires a record to be in writing, an electronic record satisfies the law.
4. If a law requires a signature, an electronic signature satisfies the law.

#### **9-16-07. Provision of information in writing - Presentation of records.**

1. If parties have agreed to conduct transactions by electronic means and a law requires a person to provide, send, or deliver information in writing to another person, the requirement is satisfied if the information is provided, sent, or delivered, as the case may be, in an electronic record capable of retention by the recipient at the time of receipt. An electronic record is not capable of retention by the recipient if the sender or the sender's information processing system inhibits the ability of the recipient to print or store the electronic record.
2. If a law other than this chapter requires a record to be posted or displayed in a certain manner, to be sent, communicated, or transmitted by a specified method, or to contain information that is formatted in a certain manner, the following rules apply:
  - a. The record must be posted or displayed in the manner specified in the other law.
  - b. Except as otherwise provided in subdivision b of subsection 4, the record must be sent, communicated, or transmitted by the method specified in the other law.
  - c. The record must contain the information formatted in the manner specified in the other law.

3. If a sender inhibits the ability of a recipient to store or print an electronic record, the electronic record is not enforceable against the recipient.
4. The requirements of this section may not be varied by agreement, but:
  - a. To the extent a law other than this chapter requires information to be provided, sent, or delivered in writing but permits that requirement to be varied by agreement, the requirement under subsection 1 that the information be in the form of an electronic record capable of retention may also be varied by agreement; and
  - b. A requirement under a law other than this chapter to send, communicate, or transmit a record by United States mail first-class postage prepaid may be varied by agreement to the extent permitted by the other law.

**9-16-08. Attribution and effect of electronic record and electronic signature.**

1. An electronic record or electronic signature is attributable to a person if it was the act of the person. The act of the person may be shown in any manner, including a showing of the efficacy of any security procedure applied to determine the person to which the electronic record or electronic signature was attributable.
2. The effect of an electronic record or electronic signature attributed to a person under subsection 1 is determined from the context and surrounding circumstances at the time of the record's or signature's creation, execution, or adoption, including the parties' agreement, if any, and otherwise as provided by law.

**9-16-09. Effect of change or error.**

If a change or error in an electronic record occurs in a transmission between parties to a transaction, the following rules apply:

1. If the parties have agreed to use a security procedure to detect changes or errors and one party has conformed to the procedure, but the other party has not, and the nonconforming party would have detected the change or error had that party also conformed, the conforming party may avoid the effect of the changed or erroneous electronic record.
2. In an automated transaction involving an individual, the individual may avoid the effect of an electronic record that resulted from an error made by the individual in dealing with the electronic agent of another person if the electronic agent did not provide an opportunity for the prevention or correction of the error and, at the time the individual learns of the error, the individual:
  - a. Promptly notifies the other person of the error and that the individual did not intend to be bound by the electronic record received by the other person;
  - b. Takes reasonable steps, including steps that conform to the other person's reasonable instructions, to return to the other person or, if instructed by the other person, to destroy the consideration received, if any, as a result of the erroneous electronic record; and
  - c. Has not used or received any benefit or value from the consideration, if any, received from the other person.
3. If neither subsection 1 nor subsection 2 applies, the change or error has the effect provided by other law, including the law of mistake, and the parties' contract, if any.
4. Subsections 2 and 3 may not be varied by agreement.

**9-16-10. Notarization and acknowledgment.**

If a law requires a signature or record to be notarized, acknowledged, verified, or made under oath, the requirement is satisfied if the electronic signature of the person authorized to perform those acts, together with all other information required to be included by other applicable law, is attached to or logically associated with the signature or record.

**9-16-11. Retention of electronic records - Originals.**

1. If a law requires that a record be retained, the requirement is satisfied by retaining an electronic record of the information in the record which:
  - a. Accurately reflects the information set forth in the record after it was first generated in its final form as an electronic record or otherwise; and
  - b. Remains accessible for later reference.

2. A requirement to retain a record in accordance with subsection 1 does not apply to any information the sole purpose of which is to enable the record to be sent, communicated, or received.
3. A person may satisfy subsection 1 by using the services of another person if the requirements of that subsection are satisfied.
4. If a law requires a record to be presented or retained in the record's original form, or provides consequences if the record is not presented or retained in the record's original form, that law is satisfied by an electronic record retained in accordance with subsection 1.
5. If a law requires retention of a check, that requirement is satisfied by retention of an electronic record of the information on the front and back of the check in accordance with subsection 1.
6. A record retained as an electronic record in accordance with subsection 1 satisfies a law requiring a person to retain a record for evidentiary, audit, or like purposes, unless a law enacted after July 31, 2001, specifically prohibits the use of an electronic record for the specified purpose.
7. This section does not preclude a governmental agency of this state from specifying additional requirements for the retention of a record subject to the agency's jurisdiction.

#### **9-16-12. Admissibility in evidence.**

In a proceeding, evidence of a record or signature may not be excluded solely because it is in electronic form.

#### **9-16-13. Automated transactions.**

In an automated transaction, the following rules apply:

1. A contract may be formed by the interaction of electronic agents of the parties, even if no individual was aware of or reviewed the electronic agents' actions or the resulting terms and agreements.
2. A contract may be formed by the interaction of an electronic agent and an individual, acting on the individual's own behalf or for another person, including by an interaction in which the individual performs actions that the individual is free to refuse to perform and which the individual knows or has reason to know will cause the electronic agent to complete the transaction or performance.
3. The terms of the contract are determined by the substantive law applicable to the contract.

#### **9-16-14. Time and place of sending and receipt.**

1. Unless otherwise agreed between the sender and the recipient, an electronic record is sent when the record:
  - a. Is addressed properly or otherwise directed properly to an information processing system that the recipient has designated or uses for the purpose of receiving electronic records or information of the type sent and from which the recipient is able to retrieve the electronic record;
  - b. Is in a form capable of being processed by that system; and
  - c. Enters an information processing system outside the control of the sender or of a person that sent the electronic record on behalf of the sender or enters a region of the information processing system designated or used by the recipient which is under the control of the recipient.
2. Unless otherwise agreed between a sender and the recipient, an electronic record is received when:
  - a. The record enters an information processing system that the recipient has designated or uses for the purpose of receiving electronic records or information of the type sent and from which the recipient is able to retrieve the electronic record; and
  - b. The record is in a form capable of being processed by that system.
3. Subsection 2 applies even if the place the information processing system is located is different from the place the electronic record is deemed to be received under subsection 4.
4. Unless otherwise expressly provided in the electronic record or agreed between the sender and the recipient, an electronic record is deemed to be sent from the sender's place of business and to be received at the recipient's place of business. For purposes of this subsection:
  - a. If the sender or recipient has more than one place of business, the place of business of that person is the place having the closest relationship to the underlying transaction.
  - b. If the sender or the recipient does not have a place of business, the place of business is the sender's or recipient's residence, as the case may be.
5. An electronic record is received under subsection 2 even if no individual is aware of the record's receipt.



6. Receipt of an electronic acknowledgment from an information processing system described in subsection 2 establishes that a record was received but, by itself, does not establish that the content sent corresponds to the content received.
7. If a person is aware that an electronic record purportedly sent under subsection 1, or purportedly received under subsection 2, was not actually sent or received, the legal effect of the sending or receipt is determined by other applicable law. Except to the extent permitted by the other law, this subsection may not be varied by agreement.

#### **9-16-15. Transferable records.**

1. In this section, "transferable record" means an electronic record that:
  - a. Would be a note under chapter 41-03 or a document under chapter 41-07 if the electronic record were in writing; and
  - b. The issuer of the electronic record expressly has agreed is a transferable record.
2. A person has control of a transferable record if a system employed for evidencing the transfer of interests in the transferable record reliably establishes that person as the person to which the transferable record was issued or transferred.
3. A system satisfies subsection 2, and a person is deemed to have control of a transferable record, if the transferable record is created, stored, and assigned in such a manner that:
  - a. A single authoritative copy of the transferable record exists which is unique, identifiable, and, except as otherwise provided in subdivisions d, e, and f, unalterable;
  - b. The authoritative copy identifies the person asserting control as:
    - (1) The person to which the transferable record was issued; or
    - (2) If the authoritative copy indicates that the transferable record has been transferred, the person to which the transferable record was most recently transferred;
  - c. The authoritative copy is communicated to and maintained by the person asserting control or its designated custodian;
  - d. Copies or revisions that add or change an identified assignee of the authoritative copy can be made only with the consent of the person asserting control;
  - e. Each copy of the authoritative copy and any copy of a copy is readily identifiable as a copy that is not the authoritative copy; and
  - f. Any revision of the authoritative copy is readily identifiable as authorized or unauthorized.
4. Except as otherwise agreed, a person having control of a transferable record is the holder, as defined in section 41-01-09, of the transferable record and has the same rights and defenses as a holder of an equivalent record or writing under title 41, including, if the applicable statutory requirements under subsection 1 of section 41-03-28, section 41-07-30, or section 41-09-29 are satisfied, the rights and defenses of a holder in due course, a holder to which a negotiable document of title has been duly negotiated, or a purchaser, respectively. Delivery, possession, and endorsement are not required to obtain or exercise any of the rights under this subsection.
5. Except as otherwise agreed, an obligor under a transferable record has the same rights and defenses as an equivalent obligor under equivalent records or writings under title 41.
6. If requested by a person against which enforcement is sought, the person seeking to enforce the transferable record shall provide reasonable proof that the person is in control of the transferable record. Proof may include access to the authoritative copy of the transferable record and related business records sufficient to review the terms of the transferable record and to establish the identity of the person having control of the transferable record.

#### **9-16-16. Creation and retention of electronic records and conversion of written records by governmental agencies.**

The state records administrator shall provide guidelines to determine whether, and the extent to which, a governmental agency will create and retain electronic records and convert written records to electronic records.

**9-16-17. Acceptance and distribution of electronic records by governmental agencies.**

1. Except as otherwise provided in subsection 6 of section 9-16-11, the state records administrator shall provide guidelines to determine whether, and the extent to which, a governmental agency will send and accept electronic records and electronic signatures to and from other persons.
2. To the extent that a governmental agency uses electronic records and electronic signatures under subsection 1, the state records administrator, giving due consideration to security, may specify:
  - a. The manner in which the electronic records must be sent, communicated, received, and stored and the systems established for those purposes;
  - b. If electronic records must be signed by electronic means, the type of electronic signature required, the manner and format in which the electronic signature must be affixed to the electronic record, and the identity of, or criteria that must be met by, any third party used by a person filing a document to facilitate the process;
  - c. Control processes and procedures as appropriate to ensure adequate preservation, disposition, integrity, security, confidentiality, and auditability of electronic records; and
  - d. Any other required attributes for electronic records which are specified for corresponding nonelectronic records or reasonably necessary under the circumstances.
3. Except as otherwise provided in subsection 6 of section 9-16-11, this chapter does not require a governmental agency of this state to use or permit the use of electronic records or electronic signatures.

**9-16-18. Interoperability.**

The state records administrator shall encourage and promote consistency and interoperability with similar requirements adopted by other governmental agencies of this and other states and the federal government and nongovernmental persons interacting with governmental agencies of this state. If appropriate, those standards may specify differing levels of standards from which governmental agencies of this state may choose in implementing the most appropriate standard for a particular application.

**ARTICLE 33-37****EPINEPHRINE ADMINISTRATION**

## Chapter

## 33-37-01 Epinephrine Administration

**CHAPTER 33-37-01****EPINEPHRINE ADMINISTRATION**

## Section

## 33-37-01-01 Persons Eligible to Administer Epinephrine

## 33-37-01-02 Training Requirements

## 33-37-01-03 Administration Devices

**33-37-01-01. Persons eligible to administer epinephrine.** A person whose employment creates a reasonable expectation to care for the health and safety of others may administer epinephrine to persons suffering from an anaphylactic reaction. A person who is deemed to have a reasonable expectation to care for the health and safety of others includes a teacher, camp counselor, day care operator, and security person. Prehospital emergency medical services personnel must meet the requirements specified in chapter 33-36-01.

**History:** Effective December 1, 1996.

**General Authority:** NDCC 23-01-05.2

**Law Implemented:** NDCC 23-01-05.2

**33-37-01-02. Training requirements.** A person authorized to administer epinephrine under this chapter shall complete training by a physician licensed by the North Dakota state board of medical examiners or the physician's designee. The physician shall determine the training content, criteria for satisfactory completion, and frequency. The physician shall maintain a record of the training which identifies the individuals trained, the training content, and the date of the training. The physician shall make training records available to the state department of health upon request.

**History:** Effective December 1, 1996.

**General Authority:** NDCC 23-01-05.2

**Law Implemented:** NDCC 23-01-05.2

**33-37-01-03. Administration devices.** A person authorized to administer epinephrine shall utilize a single use disposable device that automatically injects a premeasured dose. The device may be obtained by a trained person from a pharmacy upon the request of a licensed physician. The device must be stored and maintained where trained staff are present.

**History:** Effective December 1, 1996.

**General Authority:** NDCC 23-01-05.2

**Law Implemented:** NDCC 23-01-05.2

## **CHAPTER 51-30**

### **NOTICE OF SECURITY BREACH FOR PERSONAL INFORMATION**

#### **51-30-01. Definitions.**

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

1. "Breach of the security system" means unauthorized acquisition of computerized data when access to personal information has not been secured by encryption or by any other method or technology that renders the electronic files, media, or databases unreadable or unusable. Good-faith acquisition of personal information by an employee or agent of the person is not a breach of the security of the system, if the personal information is not used or subject to further unauthorized disclosure.
2. "Health insurance information" means an individual's health insurance policy number or subscriber identification number and any unique identifier used by a health insurer to identify the individual.
3. "Medical information" means any information regarding an individual's medical history, mental or physical condition, or medical treatment or diagnosis by a health care professional.
4. a. "Personal information" means an individual's first name or first initial and last name in combination with any of the following data elements, when the name and the data elements are not encrypted:
  - (1) The individual's social security number;
  - (2) The operator's license number assigned to an individual by the department of transportation under section 39-06-14;
  - (3) A nondriver color photo identification card number assigned to the individual by the department of transportation under section 39-06-03.1;
  - (4) The individual's financial institution account number, credit card number, or debit card number in combination with any required security code, access code, or password that would permit access to an individual's financial accounts;
  - (5) The individual's date of birth;
  - (6) The maiden name of the individual's mother;
  - (7) Medical information;
  - (8) Health insurance information;
  - (9) An identification number assigned to the individual by the individual's employer in combination with any required security code, access code, or password; or
  - (10) The individual's digitized or other electronic signature.
- b. "Personal information" does not include publicly available information that is lawfully made available to the general public from federal, state, or local government records.

#### **51-30-02. Notice to attorney general and consumers.**

Any person that owns or licenses computerized data that includes personal information, shall disclose any breach of the security system following discovery or notification of the breach in the security of the data to any resident of the state whose unencrypted personal information was, or is reasonably believed to have been, acquired by an unauthorized person. In addition, any person that experiences a breach of the security system as provided in this section shall disclose to the attorney general by mail or email any breach of the security system which exceeds two hundred fifty individuals. The disclosure must be made in the most expedient time possible and without unreasonable delay, consistent with the legitimate needs of law enforcement, as provided in section 51-30-04, or any measures necessary to determine the scope of the breach and to restore the integrity of the data system.

**51-30-03. Notice to owner or licensee of personal information.**

Any person that maintains computerized data that includes personal information that the person does not own shall notify the owner or licensee of the information of the breach of the security of the data immediately following the discovery, if the personal information was, or is reasonably believed to have been, acquired by an unauthorized person.

**51-30-04. Delayed notice.**

The notification required by this chapter may be delayed if a law enforcement agency determines that the notification will impede a criminal investigation. The notification required by this chapter must be made after the law enforcement agency determines that the notification will not compromise the investigation.

**51-30-05. Method of notice.**

Notice under this chapter may be provided by one of the following methods:

1. Written notice;
2. Electronic notice, if the notice provided is consistent with the provisions regarding electronic records and signatures set forth in section 7001 of title 15 of the United States Code; or
3. Substitute notice, if the person demonstrates that the cost of providing notice would exceed two hundred fifty thousand dollars, or that the affected class of subject persons to be notified exceeds five hundred thousand, or the person does not have sufficient contact information. Substitute notice consists of the following:
  - a. E-mail notice when the person has an e-mail address for the subject persons;
  - b. Conspicuous posting of the notice on the person's website page, if the person maintains one; and
  - c. Notification to major statewide media.

**51-30-06. Alternate compliance.**

Notwithstanding section 51-30-05, a person that maintains its own notification procedures as part of an information security policy for the treatment of personal information and is otherwise consistent with the timing requirements of this chapter is deemed to be in compliance with the notification requirements of this chapter if the person notifies subject individuals in accordance with its policies in the event of a breach of security of the system. A financial institution, trust company, or credit union that is subject to, examined for, and in compliance with the federal interagency guidance on response programs for unauthorized access to customer information and customer notice is in compliance with this chapter. A covered entity, business associate, or subcontractor subject to breach notification requirements under title 45, Code of Federal Regulations, subpart D, part 164, is considered to be in compliance with this chapter.

**51-30-07. Enforcement - Powers - Remedies - Penalties.**

The attorney general may enforce this chapter. The attorney general, in enforcing this chapter, has all the powers provided in chapter 51-15 and may seek all the remedies in chapter 51-15. A violation of this chapter is deemed a violation of chapter 51-15. The remedies, duties, prohibitions, and penalties of this chapter are not exclusive and are in addition to all other causes of action, remedies, and penalties under chapter 51-15, or otherwise provided by law.

## **CHAPTER 12.1-32**

### **PENALTIES AND SENTENCING**

**12.1-32-01. Classification of offenses - Penalties.**

Offenses are divided into seven classes, which are denominated and subject to maximum penalties, as follows:

1. Class AA felony, for which a maximum penalty of life imprisonment without parole may be imposed. The court must designate whether the life imprisonment sentence imposed is with or without an opportunity for parole. Notwithstanding the provisions of section 12-59-05, a person found guilty of a class AA felony and who receives a sentence of life imprisonment with parole, shall not be eligible to have that person's sentence considered by the parole board for thirty years, less sentence reduction earned for good conduct, after that person's admission to the penitentiary.
2. Class A felony, for which a maximum penalty of twenty years' imprisonment, a fine of twenty thousand dollars, or both, may be imposed.

3. Class B felony, for which a maximum penalty of ten years' imprisonment, a fine of twenty thousand dollars, or both, may be imposed.
4. Class C felony, for which a maximum penalty of five years' imprisonment, a fine of ten thousand dollars, or both, may be imposed.
5. Class A misdemeanor, for which a maximum penalty of one year's imprisonment, a fine of three thousand dollars, or both, may be imposed.
6. Class B misdemeanor, for which a maximum penalty of thirty days' imprisonment, a fine of one thousand five hundred dollars, or both, may be imposed.
7. Infraction, for which a maximum fine of one thousand dollars may be imposed. Any person convicted of an infraction who has, within one year prior to commission of the infraction of which the person was convicted, been previously convicted of an offense classified as an infraction may be sentenced as though convicted of a class B misdemeanor. If the prosecution contends that the infraction is punishable as a class B misdemeanor, the complaint shall specify that the offense is a misdemeanor.

This section shall not be construed to forbid sentencing under section 12.1-32-09, relating to extended sentences.

#### **12.1-32-01.1. Organizational fines.**

Any organization, as defined in section 12.1-03-04, shall, upon conviction, be subject to a maximum fine in accordance with the following classification:

1. For a class A felony, a maximum fine of one hundred thousand dollars.
2. For a class B felony, a maximum fine of seventy thousand dollars.
3. For a class C felony, a maximum fine of fifty thousand dollars.
4. For a class A misdemeanor, a maximum fine of thirty thousand dollars.
5. For a class B misdemeanor, a maximum fine of twenty thousand dollars.

Nothing in this section shall be construed as preventing the imposition of the sanction provided for in section 12.1-32-03, nor as preventing the prosecution of agents of the organization under section 12.1-03-03.