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
   ~~**E-mail address** - www.ndboph@btinet.net~~
   Telephone - 701-328-9535 **Fax** - 701-328-9536

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. October 1, 2019

General Authority: NDCC 28-32-02.1

Law Implemented: NDCC 28-32-02.1

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) Nonsterile simple. Should be conducted according to USP chapter 795.

         (b) 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.

Preparations should be compounded according to USP chapter 797 based on the appropriate risk level.

(c) Radiopharmaceuticals. See article 61-05.

(d) 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), hazardous drug compounding (USP 800), 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 must meet the facility, equipment, packaging, storage, and beyond-use date standards set in USP chapter 795. Policies and procedures should be developed to ensure compliance with those standards.

e. 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.

f. 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.

g. 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 follow the USP chapter 797 standards and use the following steps to minimize error and maximize the prescriber's intent:
   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 according to USP chapter 797, separate from nonsterile compounding areas, and restricted to qualified compounding personnel.
   e. Policies and procedures must be established in accordance with USP chapter 797 for personnel cleaning and garbing for protection and avoidance of containment.
   f. Clean and sanitize the compounding area and needed equipment according to USP chapter 797.
5. Facilities for sterile compounding should conform with USP chapter 797.
6. Equipment specific for sterile compounding should conform with USP chapter 797.
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. Compounding for office use.

a. It is acceptable to compound human drug products to be used by North Dakota practitioners in their office for administration to patients provided they are prepared by a facility licensed as an outsourcing facility in accordance to North Dakota Century Code section 43-15.3-13 or by a resident North Dakota pharmacy.
b. It is acceptable for any licensed pharmacy to compound veterinary drug products to be used by veterinarians in their office for administration to client's animals. These compounded office use products may be dispensed to clients for use in a single treatment episode, not to exceed a one hundred twenty-hour supply.
c. Sales to other pharmacies, veterinarians, clinics, or hospitals are manufacturing and are not allowed. It is the responsibility of the pharmacy and pharmacist involved in the compounding to ensure compliance with this section for the products they compound.

10. Compounding of 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 according to USP chapter 800. Appropriate personnel protective equipment shall be worn when compounding hazardous drugs according to USP chapter 800.
    b. Hazardous drugs shall be stored and prepared separately from other nonhazardous drugs in a manner to prevent contamination and personnel exposure according to USP chapter 800.
    c. Hazardous drugs shall be handled by the pharmacy according to USP chapter 800 ~~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 anteareas. If the CACI is used outside of a buffer area, the compounding area shall maintain a minimum negative pressure of 0.03 inch water column and have a minimum of twelve air changes per hour.~~
    f. All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs according to USP chapter 800. ~~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.~~

History: Amended effective August 1, 1983; April 1, 1988; October 1, 1999; December 1, 2003; April 1, 2012; April 1, 2017; October 1, 2019.

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

61-02-02-01. 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.~~ **Storage of Medications.** Systems at pharmacy location must ensure medications are stored within the manufacture recommended temperatures.
   a. Room temperature in the drug storage area should be monitored to ensure variations are limited
   b. When medications are stored in Refrigerator or Freezer, the pharmacy should utilize a continuous temperature monitoring device which reports excursions which may occur from accepted temperature levels. Units should exclusively be used for medications.
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; October 1, 2019.
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)

61-02-04-02 Handling of Hazardous Drugs. Pharmacy staff should follow practice and quality standards for handling hazardous drugs as outlined in USP Chapter 800.

1. Handling of hazardous drugs includes, but is not limited to, receipt, storage, compounding, dispensing, administration and disposal of sterile and nonsterile products and preparations.
2. Policies and procedures, incorporated into a manual required by chapter 61-02-01-18, should be developed to ensure compliance with USP Chapter 800.
3. The Pharmacist in charge or their appointee shall review the National Institute for Occupational Safety and Health (NIOSH) list of hazardous drugs according to standards set in USP Chapter 800 and have the required annual assessment of risk readily available for review at all times.

   History: Effective October 1, 2019.

   General Authority: NDCC 28-32-02, 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(14), 43-15-35(1), 43-15-36

   Law Implemented: NDCC 28-32-02, 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(14), 43-15-35(1), 43-15-36

CHAPTER 61-02-06
COMPUTER PHARMACY REGULATIONS

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 be able to produce a hard-copy daily summary of controlled substance transactions. Monthly summaries must be produced and filed with the biennial inventory or electronic system must allow tracking of adjustments and changes made to controlled substance transactions.
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; October 1, 2019.
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14)
Law Implemented: NDCC 43-15-10(9)(12)(14)
Law Implemented: NDCC 43-15-10(9)(12)(14)

CHAPTER 61-02-07.1
PHARMACY TECHNICIAN

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 (PTCB) and National Healthcareer Association (NHA) are ~~is an~~ approved certification ~~body~~ bodies.
   f. If a competency exam is developed by the National Association of Boards of Pharmacy to foster transfer of registration between states, this will be accepted in lieu of certification.

History: Effective October 1, 1993; amended effective October 1, 2012; October 1, 2019.
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~~ four (one pharmacist to ~~three~~ four 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 or interns.

History: Effective October 1, 1993; amended effective January 1, 2005; October 1, 2019.
General Authority: NDCC 28-32-02, 43-15-10(12)(14)
Law Implemented: NDCC 28-32-03, 43-15-10(12)(14)
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; October 1, 2019.
General Authority: NDCC 28-32-02, 43-15-10(12)(14)(19)
Law Implemented: NDCC 28-32-03

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

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 nursing facility according to policies and procedures set by the consultant pharmacist. Destruction must render the medication

non retrievable. Destruction must be witnessed and documented on a log by a combination of at least two licensed staff members or pharmacists

c. ~~Controlled drugs shall be destroyed at the specific institution.~~ Noncontrolled drugs may be destroyed at the institution according to policies and procedures set by the consultant pharmacist 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; October 1, 2019.
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 61-03-03.1
INTERNSHIP

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 graduated from high school and successfully completed no less than one academic year of full-time college or university enrollment directed towards the pre-pharmacy requirements with a consistently declared intent to seek admission to an accredited doctor of pharmacy program and has satisfied the state board of pharmacy that the candidate is of good moral character or as required when a student has been unconditionally 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; amended effective October 1, 2019.
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

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; October 1, 2019.
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~~

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 allowed to destroy ~~prohibited from destruction of~~ controlled substances as defined in subsection 4 of North Dakota Century Code section 19-03.1-01. Destruction of a pharmacy's controlled substance inventory must be done consistent with standards set by the Drug Enforcement Administration (DEA) and must be documented on a DEA form 41. The DEA form 41 should be kept at the pharmacy with controlled substance records and must be made available to the state Board upon request. Destruction of controlled substances is permitted ~~and shall be limited to~~ to be completed by the executive ~~secretary~~ director 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; amended effective October 1, 2019.
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 61-08-01
REQUIREMENTS FOR OUT-OF-STATE PHARMACIES

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 publicly held, shall have undergone a state and federal fingerprint-based criminal background check ~~as specified~~ upon request 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~~ twenty four 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~~ inspected 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; October 1, 2019.

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 upon request. ~~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; amended effective October 1, 2019.

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

CHAPTER 61-12-01
PRESCRIPTION DRUG MONITORING PROGRAM

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.
3. The board may allow access to controlled substance records to delegates certified by an authorized individual listed in 19-03.5-03. It is the responsibility of the authorized individual to manage the delegates accessing the repository under their authority.
4. The board shall allow access to controlled substance records to authorized individuals listed in NDCC 19-03.5-03 for a period of 3 years.

History: Effective December 1, 2006; amended effective October 1, 2019.
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~~ NARxCARE 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; amended effective October 1, 2019.
General Authority: NDCC 19-03.5, 19-03.5-09, 43-15-10(12)
Law Implemented: NDCC 19-03.5

CHAPTER 61-13-01
CONTROLLED SUBSTANCES SCHEDULES

Section

61-13-01-03. Scheduling. Substances may be added to this section upon a rule change process in accordance with NDCC 19-03.1-02.

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-3morpholinyl)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.~~

- ~~(a) (1-Pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone - Other names: UR-144.~~
- ~~(b) (1-(5-fluoropentyl)indol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone - Other names: XLR-11.~~
- ~~(c) (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:~~

- ~~(a) 1-[(N-methylpiperidin-2-yl)methyl]-3-(adamant-1- oyl) indole - Other names: AM-1248.~~
- ~~(b) N-Adamantyl-1-pentyl-1H-indole-3-carboxamide Other names: JWH-018 adamantyl carboxamide.~~
- ~~(c) N-Adamantyl-1-fluoropentylindole-3-carboxamide Other names: STS-135.~~
- ~~(d) N-Adamantyl-1-pentyl-1H-Indazole-3-carboxamide Other names: AKB 48.~~
- ~~(e) 1-Pentyl-3-(1-adamantoyl)indole - Other names: AB-001 and JWH-018 adamantyl analog.~~
- ~~(f) 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.

(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, trifluoromethyl, alkoxy, or alkylthio groups, or

(b) By substitution at the 2-position by any alkyl groups, or

(c) By substitution at the 2-amino nitrogen atom with alkyl, dialkyl, benzyl, hydroxybenzyl, or methoxybenzyl groups.

(2) Examples include:

(a) 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (also known as 2C-Cor2,5-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 2C-T-2 or 2,5-Dimethoxy-4-ethylthiophenethylamine).

(i) 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl] ethanamine (also known as C-T-4 2,5-Dimethoxy-4-isopropylthiophenethylamine). or

(j) 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-diallytryptamine (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-Methylenedioxypyrovalerone (MDPV).
c. Substituted cathinones. Any compound, material, mixture, preparation, or other product, unless listed in another schedule or an approved FDA drug (e.g., buproprion, 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-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 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) (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.~~

History: Effective February 26, 2010; amended effective December 3, 2012; October 1, 2019.
General Authority: NDCC 19-03.1-02, 19-03.1-05
Law Implemented: NDCC 19-03.1-02