N.D. Admin. Code § 61-01-01-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-01. General Administration
Chapter 61-01-01. Organization of Board
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

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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.

General Authority: NDCC 28-32-02.1

Law Implemented: NDCC 28-32-02.1

NDAC 61-01-01-01, ND ADC 61-01-01-01

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-01-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-01. Pharmacy Permits
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.

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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.

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.

General Authority: NDCC 43-15-34

Law Implemented: NDCC 43-15-34

NDAC 61-02-01-01, ND ADC 61-02-01-01

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END OF DOCUMENT

N.D. Admin. Code § 61-02-01-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-01. Pharmacy Permits
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.

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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

NDAC 61-02-01-02, ND ADC 61-02-01-02

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END OF DOCUMENT

N.D. Admin. Code § 61-02-01-03

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-01. Pharmacy Permits
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.

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[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.

l. “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 ispropyl 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.

N.D. Admin. Code § 61-02-01-03

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 anteareas. 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.

N.D. Admin. Code § 61-02-01-03

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

NDAC 61-02-01-03, ND ADC 61-02-01-03

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-01-04

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-01. Pharmacy Permits
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

NDAC 61-02-01-04, ND ADC 61-02-01-04

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-01-05

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-01. Pharmacy Permits
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)

NDAC 61-02-01-05, ND ADC 61-02-01-05

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-01-06

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-01. Pharmacy Permits
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)

NDAC 61-02-01-06, ND ADC 61-02-01-06

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-01-07

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-01. Pharmacy Permits
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

NDAC 61-02-01-07, ND ADC 61-02-01-07

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-01-08

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-01. Pharmacy Permits
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)

NDAC 61-02-01-08, ND ADC 61-02-01-08

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-01-09

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-01. Pharmacy Permits
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)

NDAC 61-02-01-09, ND ADC 61-02-01-09

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-01-10

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-01. Pharmacy Permits
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)

NDAC 61-02-01-10, ND ADC 61-02-01-10

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-01-11

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-01. Pharmacy Permits
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)

NDAC 61-02-01-11, ND ADC 61-02-01-11

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-02-01-12

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-01. Pharmacy Permits
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

NDAC 61-02-01-12, ND ADC 61-02-01-12

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-01-13

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-01. Pharmacy Permits
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)

NDAC 61-02-01-13, ND ADC 61-02-01-13

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-01-14

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-01. Pharmacy Permits
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

NDAC 61-02-01-14, ND ADC 61-02-01-14

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-01-15

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-01. Pharmacy Permits
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.

N.D. Admin. Code § 61-02-01-15

General Authority: NDCC 43-15-10

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

NDAC 61-02-01-15, ND ADC 61-02-01-15

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-01-16

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-01. Pharmacy Permits
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

NDAC 61-02-01-16, ND ADC 61-02-01-16

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-01-17

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-01. Pharmacy Permits
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

NDAC 61-02-01-17, ND ADC 61-02-01-17

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-02-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-02. 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)

NDAC 61-02-02-01, ND ADC 61-02-02-01

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-03-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-03. 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)

NDAC 61-02-03-01, ND ADC 61-02-03-01

Current through Supplement 351 (January 2014).

N.D. Admin. Code § 61-02-03-01

END OF DOCUMENT

N.D. Admin. Code § 61-02-04-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-04. 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.

N.D. Admin. Code § 61-02-04-01

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

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

NDAC 61-02-04-01, ND ADC 61-02-04-01

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-05-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-05. 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)

NDAC 61-02-05-01, ND ADC 61-02-05-01

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-06-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-06. Computer Pharmacy Regulations

➡➡ 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)

NDAC 61-02-06-01, ND ADC 61-02-06-01

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-06-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
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 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)

N.D. Admin. Code § 61-02-06-02

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

NDAC 61-02-06-02, ND ADC 61-02-06-02

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-06-03

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-06. Computer Pharmacy Regulations
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)

NDAC 61-02-06-03, ND ADC 61-02-06-03

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-06-04

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-06. Computer Pharmacy Regulations
61-02-06-04. Written policy and procedures.

Written policy and procedures must be available at each computer location, detailing responsibilities of each pharmacist relative to the operation of the computer and its records.

History: Effective July 1, 1990.

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

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

NDAC 61-02-06-04, ND ADC 61-02-06-04

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code T. 61, Art. 61-02, Ch. 61-02-07, Repealed

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-07. Clerical Personnel

[Repealed effective October 1, 1993]

NDAC T. 61, Art. 61-02, Ch. 61-02-07, Repealed, ND ADC T. 61, Art. 61-02, Ch. 61-02-07, Repealed

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-07.1-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-07.1. Pharmacy Technician
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)

NDAC 61-02-07.1-01, ND ADC 61-02-07.1-01

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-07.1-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-07.1. Pharmacy Technician
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

NDAC 61-02-07.1-02, ND ADC 61-02-07.1-02

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-07.1-03

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
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 certfication:

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)

N.D. Admin. Code § 61-02-07.1-03

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

NDAC 61-02-07.1-03, ND ADC 61-02-07.1-03

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-07.1-04

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-07.1. Pharmacy Technician
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)

NDAC 61-02-07.1-04, ND ADC 61-02-07.1-04

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-07.1-05

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-07.1. Pharmacy Technician
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)

NDAC 61-02-07.1-05, ND ADC 61-02-07.1-05

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-07.1-06

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-07.1. Pharmacy Technician
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

NDAC 61-02-07.1-06, ND ADC 61-02-07.1-06

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-07.1-07

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-07.1. Pharmacy Technician
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.”.

N.D. Admin. Code § 61-02-07.1-07

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

NDAC 61-02-07.1-07, ND ADC 61-02-07.1-07

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END OF DOCUMENT

N.D. Admin. Code § 61-02-07.1-08

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-07.1. Pharmacy Technician
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)

NDAC 61-02-07.1-08, ND ADC 61-02-07.1-08

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-07.1-09

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-07.1. Pharmacy Technician
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)

NDAC 61-02-07.1-09, ND ADC 61-02-07.1-09

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-07.1-10

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-07.1. Pharmacy Technician
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.

N.D. Admin. Code § 61-02-07.1-10

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

Law Implemented: NDCC 28-32-03

NDAC 61-02-07.1-10, ND ADC 61-02-07.1-10

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-07.1-11

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-07.1. Pharmacy Technician
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

NDAC 61-02-07.1-11, ND ADC 61-02-07.1-11

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-07.1-12

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-07.1. Pharmacy Technician
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.

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.

N.D. Admin. Code § 61-02-07.1-12

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.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-03

NDAC 61-02-07.1-12, ND ADC 61-02-07.1-12

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-07.1-13

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-07.1. Pharmacy Technician
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)

NDAC 61-02-07.1-13, ND ADC 61-02-07.1-13

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-08-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-08. Telepharmacy Rules
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

NDAC 61-02-08-01, ND ADC 61-02-08-01

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-02-08-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-08. Telepharmacy Rules
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

NDAC 61-02-08-02, ND ADC 61-02-08-02

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-08-03

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-08. Telepharmacy Rules
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.

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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 permitholder 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

NDAC 61-02-08-03, ND ADC 61-02-08-03

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-08-04

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-08. Telepharmacy Rules
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.

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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

NDAC 61-02-08-04, ND ADC 61-02-08-04

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-02-08-05

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-08. Telepharmacy Rules
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

NDAC 61-02-08-05, ND ADC 61-02-08-05

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-08-06

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-08. Telepharmacy Rules
61-02-08-06. Expiration.

Repealed effective July 1, 2005.

NDAC 61-02-08-06, ND ADC 61-02-08-06

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-08-07

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-08. Telepharmacy Rules
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)

N.D. Admin. Code § 61-02-08-07

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

NDAC 61-02-08-07, ND ADC 61-02-08-07

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-02-08-08

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-08. Telepharmacy Rules
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

NDAC 61-02-08-08, ND ADC 61-02-08-08

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-02-08-09

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-02. Pharmacies
Chapter 61-02-08. Telepharmacy Rules
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

NDAC 61-02-08-09, ND ADC 61-02-08-09

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-03-01-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
Chapter 61-03-01. Licensure of Pharmacists
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

NDAC 61-03-01-01, ND ADC 61-03-01-01

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-03-01-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
Chapter 61-03-01. Licensure of Pharmacists
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

NDAC 61-03-01-02, ND ADC 61-03-01-02

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-03-01-03

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
Chapter 61-03-01. Licensure of Pharmacists
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

NDAC 61-03-01-03, ND ADC 61-03-01-03

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-03-01-04

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
Chapter 61-03-01. Licensure of Pharmacists
61-03-01-04. Licensure without examination.

An applicant seeking licensure by 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. A statement from the secretary under seal of the board of pharmacy from which the applicant is a licentiate, showing date of examination, qualification, detailed ratings, and general average, must be submitted.

General Authority: NDCC 43-15-22

Law Implemented: NDCC 43-15-22

NDAC 61-03-01-04, ND ADC 61-03-01-04

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-03-01-05

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
Chapter 61-03-01. Licensure of Pharmacists
61-03-01-05. Cancellation of certificates.

Repealed effective January 1, 2006.

NDAC 61-03-01-05, ND ADC 61-03-01-05

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-03-01-06

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
Chapter 61-03-01. Licensure of Pharmacists
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

NDAC 61-03-01-06, ND ADC 61-03-01-06

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-03-01-07

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
Chapter 61-03-01. Licensure of Pharmacists
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

NDAC 61-03-01-07, ND ADC 61-03-01-07

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-03-01-08

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
Chapter 61-03-01. Licensure of Pharmacists
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)

NDAC 61-03-01-08, ND ADC 61-03-01-08

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-03-01-09

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
Chapter 61-03-01. Licensure of Pharmacists
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

NDAC 61-03-01-09, ND ADC 61-03-01-09

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-03-01-10

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
Chapter 61-03-01. Licensure of Pharmacists
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

NDAC 61-03-01-10, ND ADC 61-03-01-10

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-03-02-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
Chapter 61-03-02. Consulting Pharmacist Regulations for Long-Term Care Facilities (Skilled, Intermediate, and Basic Care)

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)

NDAC 61-03-02-01, ND ADC 61-03-02-01

N.D. Admin. Code § 61-03-02-01

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-03-02-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
Chapter 61-03-02. Consulting Pharmacist Regulations for Long-Term Care Facilities (Skilled, Intermediate, and Basic Care)

➡➡ 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)

NDAC 61-03-02-02, ND ADC 61-03-02-02

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-03-02-03

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
Chapter 61-03-02. Consulting Pharmacist Regulations for Long-Term Care Facilities (Skilled, Intermediate, and Basic Care)

➡➡ 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.

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.

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)

NDAC 61-03-02-03, ND ADC 61-03-02-03

N.D. Admin. Code § 61-03-02-03

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-03-02-04

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
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 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.

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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)

NDAC 61-03-02-04, ND ADC 61-03-02-04

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code T. 61, Art. 61-03, Ch. 61-03-03, Repealed

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
Chapter 61-03-03. Preceptor/Intern - Internship/Externship/Clerkship

[Repealed effective October 1, 1999]

NDAC T. 61, Art. 61-03, Ch. 61-03-03, Repealed, ND ADC T. 61, Art. 61-03, Ch. 61-03-03, Repealed

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-03-03.1-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
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 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.

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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

NDAC 61-03-03.1-01, ND ADC 61-03-03.1-01

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-03-03.1-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
Chapter 61-03-03.1. Internship
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

NDAC 61-03-03.1-02, ND ADC 61-03-03.1-02

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-03-03.1-03

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
Chapter 61-03-03.1. Internship
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

NDAC 61-03-03.1-03, ND ADC 61-03-03.1-03

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-03-03.1-04

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
Chapter 61-03-03.1. Internship
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

NDAC 61-03-03.1-04, ND ADC 61-03-03.1-04

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-03-03.1-05

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
Chapter 61-03-03.1. Internship
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

NDAC 61-03-03.1-05, ND ADC 61-03-03.1-05

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-03-03.1-06

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
Chapter 61-03-03.1. Internship
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

NDAC 61-03-03.1-06, ND ADC 61-03-03.1-06

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-03-03.1-07

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
Chapter 61-03-03.1. Internship
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

NDAC 61-03-03.1-07, ND ADC 61-03-03.1-07

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-03-04-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
Chapter 61-03-04. 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

NDAC 61-03-04-01, ND ADC 61-03-04-01

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-03-04-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
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.

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

N.D. Admin. Code § 61-03-04-02

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

NDAC 61-03-04-02, ND ADC 61-03-04-02

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END OF DOCUMENT

N.D. Admin. Code § 61-03-04-03

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
Chapter 61-03-04. Continuing Pharmaceutical Education
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

NDAC 61-03-04-03, ND ADC 61-03-04-03

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-03-04-04

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-03. Pharmacists
Chapter 61-03-04. Continuing Pharmaceutical Education
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

N.D. Admin. Code § 61-03-04-04

NDAC 61-03-04-04, ND ADC 61-03-04-04

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-04-01-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-01. 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 rerent 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

NDAC 61-04-01-01, ND ADC 61-04-01-01

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-04-02-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-02. 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, 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.

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)

NDAC 61-04-02-01, ND ADC 61-04-02-01

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-04-03-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-03. 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)

NDAC 61-04-03-01, ND ADC 61-04-03-01

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-04-03.1-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
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)

NDAC 61-04-03.1-01, ND ADC 61-04-03.1-01

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-04-04-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-04. 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 of 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

N.D. Admin. Code § 61-04-04-01

the rules of the state board of pharmacy.

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.

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

Law Implemented: NDCC 28-32-02

NDAC 61-04-04-01, ND ADC 61-04-04-01

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-04-05-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-05. Electronic 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)

NDAC 61-04-05-01, ND ADC 61-04-05-01

Current through Supplement 351 (January 2014).

N.D. Admin. Code § 61-04-05-01

END OF DOCUMENT

N.D. Admin. Code § 61-04-05-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-05. Electronic Transmission of Prescriptions
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.

N.D. Admin. Code § 61-04-05-02

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

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

NDAC 61-04-05-02, ND ADC 61-04-05-02

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-04-05-03

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-05. Electronic Transmission of Prescriptions
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)

NDAC 61-04-05-03, ND ADC 61-04-05-03

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-04-05.1-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-05.1. Prescription Transfer Requirements
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

NDAC 61-04-05.1-01, ND ADC 61-04-05.1-01

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-04-05.1-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-05.1. Prescription Transfer Requirements
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

NDAC 61-04-05.1-02, ND ADC 61-04-05.1-02

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-04-05.1-03

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-05.1. Prescription Transfer Requirements
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

N.D. Admin. Code § 61-04-05.1-03

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

NDAC 61-04-05.1-03, ND ADC 61-04-05.1-03

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-04-05.1-04

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-05.1. Prescription Transfer Requirements
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

N.D. Admin. Code § 61-04-05.1-04

NDAC 61-04-05.1-04, ND ADC 61-04-05.1-04

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-04-06-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-06. Prescription Label Requirements
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.

N.D. Admin. Code § 61-04-06-01

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

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

NDAC 61-04-06-01, ND ADC 61-04-06-01

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-04-06-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-06. Prescription Label Requirements
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)

N.D. Admin. Code § 61-04-06-02

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

NDAC 61-04-06-02, ND ADC 61-04-06-02

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-04-06-03

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-06. Prescription Label Requirements
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.

N.D. Admin. Code § 61-04-06-03

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

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

NDAC 61-04-06-03, ND ADC 61-04-06-03

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-04-07-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-07. 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.

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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

NDAC 61-04-07-01, ND ADC 61-04-07-01

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-04-08-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-08. Limited Prescriptive Practices
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

NDAC 61-04-08-01, ND ADC 61-04-08-01

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-04-08-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-08. Limited Prescriptive Practices
61-04-08-02. Definitions.

For purposes of this chapter:

1. “Collaborative agreement” means the written document signed by a physician 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 physician 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 physician shall make any diagnosis required.

4. “Medical record” means a written record of clinical care developed and maintained by a patient's physician 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. “Pharmacist in an institutional setting” means a pharmacist who:

a. Has a written agreement to provide daily or regular pharmaceutical services within a hospital, physician clinic, skilled nursing facility, swing-bed facility, or long-term care facility; and

b. Is physically present in the facility when exercising prescriptive practices under the terms of a collaborative agreement.

7. “Supervision” means the active role taken by the physician to oversee the pharmacist throughout the provision

N.D. Admin. Code § 61-04-08-02

of drug therapy to patients under the terms of a collaborative agreement.

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

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

NDAC 61-04-08-02, ND ADC 61-04-08-02

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N.D. Admin. Code § 61-04-08-03

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-08. Limited Prescriptive Practices
61-04-08-03. Eligibility and approval.

1. A physician 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 in an institutional setting on a limited basis.

2. A physician may have a collaborative agreement with no more than three eligible pharmacists unless the physician's licensing board specifies otherwise based on individual circumstances. A pharmacist may have a collaborative agreement with one or more physicians, the number of which may be limited by the board based on individual circumstances.

3. The collaborative agreement serves as a formal arrangement between an individual pharmacist and an individual collaborative supervising physician and is operative only within the institutional setting identified on the collaborative agreement form.

4. Each individual collaborative agreement must be reviewed by the board of medical examiners and the board of pharmacy, and will not become effective until both boards grant approval and notify the parties. Each agreement must be reviewed at least every two years or when modifications are proposed by the parties, and must receive continued approval from both boards in order to remain in effect.

5. A collaborative agreement may be terminated by either board 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 either board.

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.

N.D. Admin. Code § 61-04-08-03

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

NDAC 61-04-08-03, ND ADC 61-04-08-03

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N.D. Admin. Code § 61-04-08-04

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-08. Limited Prescriptive Practices
61-04-08-04. Procedures.

A physician who has signed an approved collaborative agreement with a pharmacist shall remain responsible for the care of the patient following initial diagnosis and assessment, and for the supervision of the pharmacist as prescriptive authority is exercised. The physician 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.

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

NDAC 61-04-08-04, ND ADC 61-04-08-04

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N.D. Admin. Code § 61-04-08-05

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-08. Limited Prescriptive Practices
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 physician. A pharmacist may initiate drug therapy only if the pharmacist has obtained a doctor of science, doctor of philosophy in clinical pharmacy, master of science, or doctor of pharmacy degree, has been certified a fellow by the board of pharmaceutical specialties, or has completed an accredited pharmacy fellowship or residency, and has been authorized to do so within the collaborative agreement. Verification of these credentials must be provided by the pharmacist. The pharmacist must provide immediate notification to the physician when the pharmacist initiates drug therapy.

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

NDAC 61-04-08-05, ND ADC 61-04-08-05

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N.D. Admin. Code § 61-04-08-06

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-08. Limited Prescriptive Practices
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 physician. 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 physician when the pharmacist modifies drug therapy.

2. The physician 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 physician within the facility setting. The pharmacist, unless physician or facility policy 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.

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

NDAC 61-04-08-06, ND ADC 61-04-08-06

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N.D. Admin. Code § 61-04-08-06

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N.D. Admin. Code § 61-04-08-07

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-08. Limited Prescriptive Practices
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 medical examiners and board of pharmacy. Upon request, either 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 the facility within which the 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.

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

NDAC 61-04-08-07, ND ADC 61-04-08-07

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N.D. Admin. Code §§ T. 61, Art. 61-04, Ch. 61-04-08, App

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter **61**-04-08. Limited Prescriptive Practices
Appendix Collaborative Agreement Form
Appendix Collaborative Agreement Form

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

_____
Institution

_____
Pharmacist Name

_____
Physician Name

_____
Address

_____
Address

_____
Telephone License Number

_____
Telephone 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.)

N.D. Admin. Code §§ T. 61, Art. 61-04, Ch. 61-04-08, App

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.

_____		_____	
Pharmacist Signature	Date	Physician Signature	Date
_____		_____	
State Board of Pharmacy	Approval Date	Board of Medical Examiners	Approval Date

NDAC T. 61, Art. 61-04, Ch. 61-04-08, App, ND ADC T. 61, Art. 61-04, Ch. 61-04-08, App

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-04-09-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-09. Warning Notice
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

NDAC 61-04-09-01, ND ADC 61-04-09-01

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-04-09-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-09. Warning Notice
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

NDAC 61-04-09-02, ND ADC 61-04-09-02

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-04-09-03

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-09. Warning Notice
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

NDAC 61-04-09-03, ND ADC 61-04-09-03

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-04-09-04

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-09. Warning Notice
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

NDAC 61-04-09-04, ND ADC 61-04-09-04

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-04-09-05

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-09. Warning Notice
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

NDAC 61-04-09-05, ND ADC 61-04-09-05

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-04-09-06

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-09. Warning Notice
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

NDAC 61-04-09-06, ND ADC 61-04-09-06

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-04-10-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-10. Clia Waived Laboratory Tests
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 proficiency testing 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.

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

Law Implemented: NDCC 43-15-25.3

NDAC 61-04-10-01, ND ADC 61-04-10-01

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-04-10-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-10. Clia Waived Laboratory Tests
➡➡ 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 that section:

1. Successfully complete a board-approved course of study that incorporates principles of general laboratory procedures to include, at a minimum:

a. Infection control;

b. OSHA requirements;

c. Proper technique to collect laboratory specimens;

d. Recognized screening and monitoring values; and

e. Quality control.

2. Recertify every three years by portfolio review or reeducation.

3. Successfully complete training for each specific instrument used to perform CLIA waived laboratory tests.

History: Effective December 1, 1999.

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

Law Implemented: NDCC 43-15-25.3

N.D. Admin. Code § 61-04-10-02

NDAC 61-04-10-02, ND ADC 61-04-10-02

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-04-10-03

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-10. Clia Waived Laboratory Tests
61-04-10-03. Minimum quality standards required.

Pharmacists performing CLIA waived laboratory tests must meet the following standards:

1. Develop and maintain a procedural manual that includes the following areas:

a. Quality control;

b. Infection control;

c. Hazardous waste disposal;

d. Recordkeeping; and

e. Test result reporting.

2. Maintain participation in a nationally recognized proficiency program approved by the board.

History: Effective December 1, 1999.

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

Law Implemented: NDCC 43-15-25.3

NDAC 61-04-10-03, ND ADC 61-04-10-03

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-04-10-04

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-10. Clia Waived Laboratory Tests
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 facility where the tests are performed has a proper CLIA certificate.

History: Effective December 1, 1999.

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

Law Implemented: NDCC 43-15-25.3

NDAC 61-04-10-04, ND ADC 61-04-10-04

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-04-10-05

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-10. Clia Waived Laboratory Tests
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. The notification must specify the types of tests which are to be performed.

History: Effective December 1, 1999.

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

Law Implemented: NDCC 43-15-25.3

NDAC 61-04-10-05, ND ADC 61-04-10-05

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-04-11-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-11. Administration of Medications and Immunizations
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

NDAC 61-04-11-01, ND ADC 61-04-11-01

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-04-11-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-11. Administration of Medications and Immunizations
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;

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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

NDAC 61-04-11-02, ND ADC 61-04-11-02

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-04-11-03

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-11. Administration of Medications and Immunizations
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

NDAC 61-04-11-03, ND ADC 61-04-11-03

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-04-11-04

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-11. Administration of Medications and Immunizations
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

NDAC 61-04-11-04, ND ADC 61-04-11-04

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-04-11-05

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-11. Administration of Medications and Immunizations
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

NDAC 61-04-11-05, ND ADC 61-04-11-05

N.D. Admin. Code § 61-04-11-05

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-04-11-06

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-11. Administration of Medications and Immunizations
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

N.D. Admin. Code § 61-04-11-06

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

NDAC 61-04-11-06, ND ADC 61-04-11-06

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-04-11-07

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-11. Administration of Medications and Immunizations
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

NDAC 61-04-11-07, ND ADC 61-04-11-07

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-04-11-08

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-04. Professional Practice
Chapter 61-04-11. Administration of Medications and Immunizations
61-04-11-08. Policy and procedural manual.

The pharmacy shall maintain a current policy and procedural manual related to the administration of medications by injection.

History: Effective May 1, 2002.

General Authority: NDCC 43-15-10

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

NDAC 61-04-11-08, ND ADC 61-04-11-08

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-05-01-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-05. Radiopharmaceutical Services
Chapter 61-05-01. Radiopharmaceutical Services
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

NDAC 61-05-01-01, ND ADC 61-05-01-01

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-05-01-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-05. Radiopharmaceutical Services
Chapter 61-05-01. Radiopharmaceutical Services
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

NDAC 61-05-01-02, ND ADC 61-05-01-02

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N.D. Admin. Code § 61-05-01-03

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-05. Radiopharmaceutical Services
Chapter 61-05-01. Radiopharmaceutical Services
➡➡ 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.

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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

NDAC 61-05-01-03, ND ADC 61-05-01-03

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N.D. Admin. Code § 61-05-01-04

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-05. Radiopharmaceutical Services
Chapter 61-05-01. Radiopharmaceutical Services
➡➡ 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 readioactivity.

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 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

NDAC 61-05-01-04, ND ADC 61-05-01-04

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-05-01-05

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-05. Radiopharmaceutical Services
Chapter 61-05-01. Radiopharmaceutical Services
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

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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

NDAC 61-05-01-05, ND ADC 61-05-01-05

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-05-01-06

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-05. Radiopharmaceutical Services
Chapter 61-05-01. Radiopharmaceutical Services
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.

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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

NDAC 61-05-01-06, ND ADC 61-05-01-06

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-06-01-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-06. Home Health Care Pharmacy Services
Chapter 61-06-01. Home Health Care Pharmacy Services
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)

NDAC 61-06-01-01, ND ADC 61-06-01-01

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-06-01-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-06. Home Health Care Pharmacy Services
Chapter 61-06-01. Home Health Care Pharmacy Services
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)

NDAC 61-06-01-02, ND ADC 61-06-01-02

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-06-01-03

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-06. Home Health Care Pharmacy Services
Chapter 61-06-01. Home Health Care Pharmacy Services
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)

NDAC 61-06-01-03, ND ADC 61-06-01-03

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N.D. Admin. Code § 61-06-01-04

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-06. Home Health Care Pharmacy Services
Chapter 61-06-01. Home Health Care Pharmacy Services
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.**

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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)

NDAC 61-06-01-04, ND ADC 61-06-01-04

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N.D. Admin. Code § 61-06-01-05

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-06. Home Health Care Pharmacy Services
Chapter 61-06-01. Home Health Care Pharmacy Services
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 primary, 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 and maintained at each pharmacy providing home health care pharmacy services and be available for inspection. The policy and procedure manual must set forth in detail the objectives and operational guidelines of the pharmacy. The manual must be reviewed and revised on an annual basis. A copy must be provided the board of pharmacy when applying for a permit or engaging in this specialized area of practice.

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:

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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.

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

NDAC 61-06-01-05, ND ADC 61-06-01-05

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END OF DOCUMENT

N.D. Admin. Code § 61-06-01-06

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-06. Home Health Care Pharmacy Services
Chapter 61-06-01. Home Health Care Pharmacy Services
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)

NDAC 61-06-01-06, ND ADC 61-06-01-06

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N.D. Admin. Code § 61-06-01-07

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-06. Home Health Care Pharmacy Services
Chapter 61-06-01. Home Health Care Pharmacy Services
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)

NDAC 61-06-01-07, ND ADC 61-06-01-07

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N.D. Admin. Code § 61-06-01-08

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-06. Home Health Care Pharmacy Services
Chapter 61-06-01. Home Health Care Pharmacy Services
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)

NDAC 61-06-01-08, ND ADC 61-06-01-08

N.D. Admin. Code § 61-06-01-08

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N.D. Admin. Code § 61-07-01-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-07. Hospital Pharmacy
Chapter 61-07-01. Hospital Pharmacy
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)

NDAC 61-07-01-01, ND ADC 61-07-01-01

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END OF DOCUMENT

N.D. Admin. Code § 61-07-01-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-07. Hospital Pharmacy
Chapter 61-07-01. Hospital Pharmacy
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)

NDAC 61-07-01-02, ND ADC 61-07-01-02

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N.D. Admin. Code § 61-07-01-03

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-07. Hospital Pharmacy
Chapter 61-07-01. Hospital Pharmacy
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)

NDAC 61-07-01-03, ND ADC 61-07-01-03

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-07-01-04

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-07. Hospital Pharmacy
Chapter 61-07-01. Hospital Pharmacy
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)

N.D. Admin. Code § 61-07-01-04

NDAC 61-07-01-04, ND ADC 61-07-01-04

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N.D. Admin. Code § 61-07-01-05

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-07. Hospital Pharmacy
Chapter 61-07-01. Hospital Pharmacy
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)

NDAC 61-07-01-05, ND ADC 61-07-01-05

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N.D. Admin. Code § 61-07-01-06

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-07. Hospital Pharmacy
Chapter 61-07-01. Hospital Pharmacy
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)

N.D. Admin. Code § 61-07-01-06

NDAC 61-07-01-06, ND ADC 61-07-01-06

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N.D. Admin. Code § 61-07-01-07

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-07. Hospital Pharmacy
Chapter 61-07-01. Hospital Pharmacy
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. Fullest 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)

NDAC 61-07-01-07, ND ADC 61-07-01-07

Current through Supplement 351 (January 2014).

N.D. Admin. Code § 61-07-01-07

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N.D. Admin. Code § 61-07-01-08

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-07. Hospital Pharmacy
Chapter 61-07-01. Hospital Pharmacy
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)

NDAC 61-07-01-08, ND ADC 61-07-01-08

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END OF DOCUMENT

N.D. Admin. Code § 61-07-01-09

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-07. Hospital Pharmacy
Chapter 61-07-01. Hospital Pharmacy
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)

NDAC 61-07-01-09, ND ADC 61-07-01-09

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END OF DOCUMENT

N.D. Admin. Code § 61-07-01-10

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-07. Hospital Pharmacy
Chapter 61-07-01. Hospital Pharmacy
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 consulation 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)

N.D. Admin. Code § 61-07-01-10

NDAC 61-07-01-10, ND ADC 61-07-01-10

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N.D. Admin. Code § 61-07-01-11

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-07. Hospital Pharmacy
Chapter 61-07-01. Hospital Pharmacy
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, inprocess 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)

NDAC 61-07-01-11, ND ADC 61-07-01-11

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-07-01-12

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-07. Hospital Pharmacy
Chapter 61-07-01. Hospital Pharmacy
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)

NDAC 61-07-01-12, ND ADC 61-07-01-12

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-07-01-13

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-07. Hospital Pharmacy
Chapter 61-07-01. Hospital Pharmacy
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)

NDAC 61-07-01-13, ND ADC 61-07-01-13

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-07-01-14

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-07. Hospital Pharmacy
Chapter 61-07-01. Hospital Pharmacy
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)

NDAC 61-07-01-14, ND ADC 61-07-01-14

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-08-01-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-08. Out-Of-State Pharmacies
Chapter 61-08-01. Requirements for Out-Of-State Pharmacies
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

NDAC 61-08-01-01, ND ADC 61-08-01-01

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END OF DOCUMENT

N.D. Admin. Code § 61-08-01-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-08. Out-Of-State Pharmacies
Chapter 61-08-01. Requirements for Out-Of-State Pharmacies
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

NDAC 61-08-01-02, ND ADC 61-08-01-02

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N.D. Admin. Code § 61-08-01-03

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-08. Out-Of-State Pharmacies
Chapter 61-08-01. Requirements for Out-Of-State Pharmacies
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

NDAC 61-08-01-03, ND ADC 61-08-01-03

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-08-01-04

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-08. Out-Of-State Pharmacies
Chapter 61-08-01. Requirements for Out-Of-State Pharmacies
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

NDAC 61-08-01-04, ND ADC 61-08-01-04

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-08-01-05

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-08. Out-Of-State Pharmacies
Chapter 61-08-01. Requirements for Out-Of-State Pharmacies
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

NDAC 61-08-01-05, ND ADC 61-08-01-05

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N.D. Admin. Code § 61-08-01-06

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-08. Out-Of-State Pharmacies
Chapter 61-08-01. Requirements for Out-Of-State Pharmacies
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

NDAC 61-08-01-06, ND ADC 61-08-01-06

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N.D. Admin. Code § 61-08-01-07

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-08. Out-Of-State Pharmacies
Chapter 61-08-01. Requirements for Out-Of-State Pharmacies
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

NDAC 61-08-01-07, ND ADC 61-08-01-07

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N.D. Admin. Code § 61-08-01-08

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-08. Out-Of-State Pharmacies
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.

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

NDAC 61-08-01-08, ND ADC 61-08-01-08

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END OF DOCUMENT

N.D. Admin. Code § 61-08-01-09

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-08. Out-Of-State Pharmacies
Chapter 61-08-01. Requirements for Out-Of-State Pharmacies
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 comer 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

NDAC 61-08-01-09, ND ADC 61-08-01-09

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END OF DOCUMENT

N.D. Admin. Code § 61-08-01-10

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-08. Out-Of-State Pharmacies
Chapter 61-08-01. Requirements for Out-Of-State Pharmacies
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

NDAC 61-08-01-10, ND ADC 61-08-01-10

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N.D. Admin. Code § 61-08-01-11

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-08. Out-Of-State Pharmacies
Chapter 61-08-01. Requirements for Out-Of-State Pharmacies
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

NDAC 61-08-01-11, ND ADC 61-08-01-11

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N.D. Admin. Code § 61-08-01-12

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-08. Out-Of-State Pharmacies
Chapter 61-08-01. Requirements for Out-Of-State Pharmacies
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

NDAC 61-08-01-12, ND ADC 61-08-01-12

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-08-01-13

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-08. Out-Of-State Pharmacies
Chapter 61-08-01. Requirements for Out-Of-State Pharmacies
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

NDAC 61-08-01-13, ND ADC 61-08-01-13

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-09-01-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-09. Prescription Drug Inventory of Ambulance Services
Chapter 61-09-01. Prescription Drug Inventory of Ambulance Services
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. 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.

7. 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.

8. Lost, stolen, or misused prescription drugs must be reported to the ambulance service's medical director or the pharmacy where they were obtained.

9. 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.

10. 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.

11. 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)

NDAC 61-09-01-01, ND ADC 61-09-01-01

Current through Supplement 351 (January 2014).

N.D. Admin. Code § 61-09-01-01

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N.D. Admin. Code § 61-09-01-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-09. Prescription Drug Inventory of Ambulance Services
Chapter 61-09-01. Prescription Drug Inventory of Ambulance Services
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)

NDAC 61-09-01-02, ND ADC 61-09-01-02

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-09-02-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-09. Prescription Drug Inventory of Ambulance Services
Chapter 61-09-02. Prescription Drug Inventory 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

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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

NDAC 61-09-02-01, ND ADC 61-09-02-01

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-09-02-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-09. Prescription Drug Inventory of Ambulance Services
Chapter 61-09-02. Prescription Drug Inventory of Nursing Supply Kits
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

NDAC 61-09-02-02, ND ADC 61-09-02-02

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-10-01-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-10. Wholesale Drug Distributors
Chapter 61-10-01. Wholesale Drug Distributors
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

NDAC 61-10-01-01, ND ADC 61-10-01-01

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-10-01-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-10. Wholesale Drug Distributors
Chapter 61-10-01. Wholesale Drug Distributors
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)

NDAC 61-10-01-02, ND ADC 61-10-01-02

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-10-01-03

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-10. Wholesale Drug Distributors
Chapter 61-10-01. Wholesale Drug Distributors
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

NDAC 61-10-01-03, ND ADC 61-10-01-03

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-10-01-04

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-10. Wholesale Drug Distributors
Chapter 61-10-01. Wholesale Drug Distributors
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

NDAC 61-10-01-04, ND ADC 61-10-01-04

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-10-01-05

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-10. Wholesale Drug Distributors
Chapter 61-10-01. Wholesale Drug Distributors
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.

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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

NDAC 61-10-01-05, ND ADC 61-10-01-05

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N.D. Admin. Code § 61-10-01-06

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-10. Wholesale Drug Distributors
Chapter 61-10-01. Wholesale Drug Distributors
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.

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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

NDAC 61-10-01-06, ND ADC 61-10-01-06

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-10-01-07

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-10. Wholesale Drug Distributors
Chapter 61-10-01. Wholesale Drug Distributors
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

NDAC 61-10-01-07, ND ADC 61-10-01-07

Current through Supplement 351 (January 2014).

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N.D. Admin. Code § 61-10-01-08

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-10. Wholesale Drug Distributors
Chapter 61-10-01. Wholesale Drug Distributors
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

NDAC 61-10-01-08, ND ADC 61-10-01-08

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N.D. Admin. Code § 61-10-01-09

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-10. Wholesale Drug Distributors
Chapter 61-10-01. Wholesale Drug Distributors
➡➡ 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

NDAC 61-10-01-09, ND ADC 61-10-01-09

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N.D. Admin. Code § 61-11-01-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-11. Fees
Chapter 61-11-01. 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 ($90 is paid to the North Dakota State University college of pharmacy for student programs)	100.00
	b. Internship licensure - Pre-pharmacy students	10.00
5.	Manufacturer-distributor-warehouse-reverse distributer	
	Wholesale drug license	
		200.00
	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 ($17.50 is forwarded to the northland association of pharmacy technicians (NAPT))	35.00
	Penalty for late renewal	10.00
11.	Pharmacy technician-in-training (per year) (two years allowed to complete a program)	10.00
12.	License verifications (self-addressed return envelope)	25.00

History: Effective January 1, 2006; amended effective October 1, 2010; July 1, 2011.

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

NDAC 61-11-01-01, ND ADC 61-11-01-01

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-12-01-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-12. Prescription Drug Monitoring Program
Chapter 61-12-01. Prescription Drug Monitoring Program
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

NDAC 61-12-01-01, ND ADC 61-12-01-01

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-12-01-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-12. Prescription Drug Monitoring Program
Chapter 61-12-01. Prescription Drug Monitoring Program
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 August 31, 2005, version 003, release 000.

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.

General Authority: NDCC 19-03.5

Law Implemented: NDCC 19-03.5

NDAC 61-12-01-02, ND ADC 61-12-01-02

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-12-01-03

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-12. Prescription Drug Monitoring Program
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.

History: Effective December 1, 2006.

General Authority: NDCC 19-03.5

Law Implemented: NDCC 19-03.5

NDAC 61-12-01-03, ND ADC 61-12-01-03

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-13-01-01

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-13. Controlled Substances
Chapter 61-13-01. Controlled Substances Schedules
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

NDAC 61-13-01-01, ND ADC 61-13-01-01

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-13-01-02

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-13. Controlled Substances
Chapter 61-13-01. Controlled Substances Schedules
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

NDAC 61-13-01-02, ND ADC 61-13-01-02

Current through Supplement 351 (January 2014).

END OF DOCUMENT

N.D. Admin. Code § 61-13-01-03

North Dakota Administrative Code Currentness
Title **61**. State Board of Pharmacy
Article **61**-13. Controlled Substances
Chapter 61-13-01. Controlled Substances Schedules
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, cycloalkyl methyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1 -(N-methyl-2-pyrrolidinyl)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-3-morpholinyl)methyl, (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, 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-ylmeth-anone - 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-(1-Naphthalenylmethylene)-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 compund 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, (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.

(a) (1-Pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)meth-anone - 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 names: AKB 48.

(e) 1-Penty1-3-(1-adamantoyl)indole - Other names: AB-001 and JWH-018 adamantyl analog.

(f) Naphthalen-1-yl-(4-pentyloxynaphthalen-1-yl) 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, tetra hydrofuran, 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-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-lodo-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-Nor 2, 5-Dimethoxy-4-nitrophenethylamine).

(g) 2-(2,5-Dimethoxy-4-(n)-propylphenyl) ethanamine (also known 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-(lsopropylthio)-2,5-dimethoxyphenyl (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-[(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; 251-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. 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-diallytryptamine (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-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, 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 1, 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) 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).

d. Fluoroamphetamine.

e. Fluoromethamphetamine.

History: Effective February 26, 2010; amended effective December 3, 2012.

General Authority: NDCC 19-03.1-02, 19-03.1-05

N.D. Admin. Code § 61-13-01-03

Law Implemented: NDCC 19-03.1-02

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