CHAPTER 61-02-01 **Final Copy**
PHARMACY PERMITS

~~61-02-01-18 Continuous Quality Improvement~~

~~61-02-01-18-01 Definitions: In this chapter, unless the context or subject matter otherwise requires:~~

1. ~~"Actively Reports" means reporting all dispensing errors and analysis of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error.~~

2. ~~"Analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors.~~

3. ~~"Dispensing error" means one or more of the following discovered after the final verification by the pharmacist:~~

    a. ~~Variation from the prescriber's prescription drug order, including, but not limited to:~~

        i. ~~Incorrect drug;~~

        ii. ~~Incorrect drug strength;~~

iii. Incorrect dosage form;

iv. Incorrect patient; or

v. Inadequate or incorrect packaging, labeling, or directions.

b. Failure to exercise professional judgment in identifying and managing:

i. Therapeutic duplication;

ii. Drug-disease contraindications, if known;

iii. Drug-drug interactions, if known;

iv. Incorrect drug dosage or duration of drug treatment; interactions;

v. A clinically significant, avoidable delay in therapy; or

vi. Any other significant, actual or potential problem with a patient's drug therapy.

c. Delivery of a drug to the incorrect patient.

d. Variation in bulk repackaging or filling of automated devices, including, but not limited to:

i. Incorrect drug;

ii. Incorrect drug strength;

iii. Incorrect dosage form; or

iv. nadequate or incorrect packaging or labeling.

4. "Incident" A patient safety event that reached the patient, whether or not the patient was harmed.

5. "Near Miss" A patient safety event that did not or could not have reached the patient.

6. "Patient safety organization" means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) and is credentialed by the Agency for Healthcare Research and Quality.

7. "Unsafe Condition" Any circumstance that increases the probability of a patient safety event.

61-02-01-18-02 Continuous Quality Improvement Program

1. Each pharmacy permittee shall establish a Continuous Quality Improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing incidents, near misses, and unsafe conditions.

2. A pharmacy permittee meets the requirements if they meet the following:

    a. Maintains and complies with the policies and procedures as noted in (4);

    b. The pharmacy reports incidents, near misses and unsafe events through either:

        i. a contracted Patient Safety Organization (PSO) that is listed as an Agency for Health Research and Quality (AHRQ) on www.ahrq.com whose primary mission is pharmacy continuous quality improvement; or.

        ii. an internal program to the pharmacy which is acceptable to the Board where proper documentation and evaluation can be completed

3. At a minimum, a CQI Program shall include provisions to:

    a. Designate an individual or individuals responsible for implementing, maintaining, and monitoring the CQI Program, which is managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form;

    b. Initiate documentation of incidents, near misses, and unsafe conditions as soon as possible, but no more than seven days, after determining their occurrence;

4. Policies and Procedures in compliance with 61-02-01-19 and must include.

    a. Train all pharmacy personnel in relevant phases of the CQI program;

    b. Identify and document reportable incidents and near misses and unsafe events;

    c. Minimize the impact of incidents and near misses and unsafe events on patients;

d. Analyze data collected to assess the causes and any contributing factors relating to incidents and near misses and unsafe events;

e. Use the findings to formulate an appropriate response and to develop pharmacy systems and workflow processes designed to prevent and reduce incidents and near misses and unsafe events; and

f. Periodically, but at least quarterly, meet with appropriate pharmacy personnel to review findings and inform personnel of changes that have been made to pharmacy policies, procedures, systems, or processes as a result of CQI program findings.

5. Quality Self-Audit

a. Each Pharmacy shall conduct a Quality Self-Audit at least quarterly to determine whether the occurrence of incidents, near misses, and unsafe conditions has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI Program in the future. Each pharmacy shall conduct a Quality Self-Audit upon change of Pharmacist-in-Charge to familiarize that Person with the Pharmacy's CQI Program.

6. Protection from Discovery

a. Records that are generated as a component of a pharmacy's ongoing quality assurance program and that are maintained for that program are peer review documents and are not subject to subpoena or discovery in an arbitration or civil proceeding.

b. Records that are generated as a component of a pharmacy's ongoing quality assurance program and that are maintained for that program are confidential and shall not be released, distributed or communicated in any manner, except as provided by these rule or the permitee's policies and procedures. Recognizing the importance of sharing information with staff , experts, consultants, and others is necessary in reducing medication errors, information used as a part of the permitee's quality program in any manner shall not compromise the confidentiality and privilege of such information.

c. This subsection does not prohibit a patient from accessing the patient's prescription records or affect the discoverability of any records that are not generated solely as a component of a pharmacy's ongoing quality assurance program and maintained solely for that program.

7. The Board's regulatory oversight activities regarding a pharmacy's CQI program are limited to inspection of the pharmacy's CQI policies and procedures and enforcing the pharmacy's compliance with those policies and procedures.

8. ~~An analysis or summary of findings, produced within six months of submission, shall be evidence of compliance with the records and data collection provisions. A permittee shall not be required to produce data, charts, error reports or findings collected and used in compiling an analysis summary.~~

9. ~~Not withstanding paragraphs (6) and (8), If pharmacy is reporting to a Patient Safety Organization whose primary mission is continuous quality improvement all data and records are privileged and confidential as provided in the 2005 Patient Safety and Quality Improvement Act of 2005 and implementing regulations.~~

61-02-01-19 Policy and Procedure Manual Required

1. Each Pharmacy must have a written or electronic and easily accessible policy and procedure manual to address all aspects of the pharmacies operations. The policy and procedure manual must be available for inspection. The policy and procedure manual must set forth in detail the objectives and operational guidelines of the pharmacy. The policy and procedure manual must be reviewed and revised or reaffirmed on an annual basis
    a. Inspection Procedures including
        i. Location of Controlled substance records including
            1. Location of current biennial inventory
            2. Wholesale records of receipt and sale of controlled substances
            3. DEA 222 forms, both paper and electronic, executed or not.
            4. Information for running reports from the pharmacy computer system relative to dispensing of specific controlled substances
            5. Power of attorney forms if granted and termination forms if executed
        ii. Location of most recent inspection forms by the board of pharmacy, accreditation agencies or the FDA, if applicable

History: Effective July 1, 1990. Amended July 1, 2014

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

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

History: Effective July 1, 1990.Amended July 1, 2014
General Authority: NDCC 28-32-02, 43-15-10(9), 43-15-10(12), 43-15-10(14)
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-02-07.1-12 – Technicians Checking Technicians Activities allowed by law to be performed within a licensed pharmacy by a registered pharmacy technician in the

preparation of a prescription or order for dispensing or administration may be performed by one registered pharmacy technician and verified by another registered pharmacy technician working in the same licensed pharmacy, under the following conditions:

1. The licensed pharmacy where the work is being conducted has policies and procedures specifically describing the scope of the activities to be verified through this practice, included in the policy and procedure manual required under 61-02-01-19.
    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, and
    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 Technician-Checking-Technicians Program.

3. Any error must trigger pharmacist review of the process. This review and subsequent recommendations must be documented.

4. The pharmacy has a system in place to review all quality related events and errors recorded and takes corrective action based on the information to reduce quality related events and eliminate errors reaching the patient.

5. As always, the pharmacist-in-charge and the permit holder are jointly responsible for the final product dispensed or released for administration from the pharmacy.

History: Effective January 1, 2009, Amended July `1,2014

General Authority: NDCC 28-32-02

Law Implemented: NDCC 28-32-03

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

1. Area. The pharmacy serving a long-term care facility as an institutional drug outlet shall have floor space allocated to it to ensure that drugs are prepared in sanitary, well-lighted and enclosed places, and meet the other requirements of this section. Floor space shall be allotted to conduct the activities involved with the scope of pharmaceutical services provided.

2. Equipment and materials. The pharmacy serving a long-term care facility as an institutional drug outlet shall have equipment and physical facilities for proper compounding, dispensing, and storage for drugs, including parenteral preparations. As a minimum, the pharmacy shall have the following:

   a. Minimum equipment listed in section 61-02-01-03.

   b. Drugs to meet the needs of the patients of the long-term care facility.

   c. A pharmacy policy and procedures manual in compliance with 61-02-01-19.

   d. Pharmaceutical reference books, which shall include one recent edition (not over five years from publication date) from at least two of the following categories, one of which must include dispensing information:

      (1) Drug dispensing information from one of the following:

         (a) United States pharmacopoeia dispensing information.

         (b) Facts and comparisons.

         (c) Hospital formulary.

      (2) Categories to choose from:

         Drug interactions - poison and antidote information - chemistry toxicology - pharmacology - bacteriology - sterilization and disinfection - patient counseling – rational therapy - parenteral admixtures.

3. Drug room. The drug room of a long-term care facility may utilize the technical equipment and other requirements of a licensed pharmacy for compliance.

4. Storage.

a. All drugs shall be stored in designated areas within the pharmacy to ensure proper sanitation, temperature, light, ventilation, moisture control, and security. Unattended areas: In the absence of a pharmacist, and whenever any area of a pharmacy serving a long-term facility as an institutional drug outlet is not under the personal and direct supervision of a pharmacist, such areas shall be locked. All areas occupied by a pharmacy serving a long-term care facility as an institutional drug outlet shall be capable of being locked by key or combination, so as to prevent access by unauthorized personnel.

b. When drugs to be dispensed are stored in a long-term facility drug room, the consulting pharmacist shall verify that space will be available at each unit for storage, safeguarding, and preparation of medication doses for administration and shall include provision of at least the following:

(1) A locked drug cabinet or room shall be equipped to ensure physical separation of individual patient prescribed medications. Medications may be stored in these secured individual patient storage areas, or secured portable storage carts providing separate compartments for individual patients may be used.

(2) A container or compartment which is capable of securing controlled substances with a lock or other safeguard system shall be permanently attached to storage carts or medication rooms.

History: Effective August 1, 1983., Amended July 1, 2014

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

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

61-04-11-08. Policy and procedural manual. The pharmacy shall maintain a ~~current~~ policy and procedural manual, with a section related to the administration of medications by injection, in compliance with 61-02-01-19.

History: Effective May 1, 2002., Amended July 1, 2014

General Authority: NDCC 43-15-10

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

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~~ pharmacy, to the time the prescribed drug is dispensed to the patient.

2. Purchasing. All drugs and pharmaceutical products purchased and dispensed by a pharmacy providing home health care pharmacy services must meet national standards of quality (USP-NF standards) and must be clearly and accurately labeled by the manufacturer or distributor as to contents.

3. Procedure manual. A policy and procedure manual must be prepared in accordance with 61-02-01-19 ~~and maintained at each pharmacy providing~~, with a section pertaining to 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:

   a. Policy and procedures manual.

   b. Training manuals.

c. Policies and procedures for cytotoxic waste, if applicable.

d. Such other records and reports as may be required by law and rules of the board of pharmacy.

8. Delivery service. The pharmacist managing the section of the pharmacy providing home health care pharmacy services is responsible for the environment control of all products shipped. Therefore, any compounded, sterile parenteral product that is frozen, or requires refrigeration, must be shipped or delivered to a patient in appropriate coolers and stored appropriately in the patient's home.

History: Effective April 1, 1988., Amended July 1, 2014

General Authority: NDCC 28-32-02

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