CHAPTER 61-02-09
CONTINUOUS QUALITY IMPROVEMENT

61-02-09-01. 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 thirty days of identifying the error.

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

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

    a. Variation from the prescriber's prescription drug order, including:

        (1) Incorrect drug;

        (2) Incorrect drug strength;

        (3) Incorrect dosage form;

        (4) Incorrect patient; or

        (5) Inadequate or incorrect packaging, labeling, or directions.

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

        (1) Therapeutic duplication;

        (2) Drug-disease contraindications, if known;

        (3) Drug-drug interactions, if known;

        (4) Incorrect drug dosage or duration of drug treatment, interactions;

        (5) A clinically significant, avoidable delay in therapy; or

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

    c. Deliver of a drug to incorrect patient.

    d. Variation in bulk repackaging or filling of automated devices, including:

        (1) Incorrect drug;

        (2) Incorrect drug strength;

        (3) Incorrect dosage form; or

        (4) Inadequate or incorrect packaging or labeling.

4. "Incident" means a patient safety event that reached the patient, whether or not the patient is harmed.

5. "Near miss" means a patient safety event that did not or could not have reached the patient.

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

7. "Unsafe condition" means any circumstance that increases the probability of a patient safety event.

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General Authority: NDCC 28-32-02, 43-15-10, 23-34
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61-02-09-02. Continuous quality improvement program.

1. Each pharmacy permittee shall establish continuous quality improvement program for the purpose of detecting, documenting, assessing, and preventing incidents, near misses, and unsafe conditions.

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

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

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

      (1) A contracted patient safety organization that is listed as an agency for health research and quality on www.ahrq.com whose primary mission is pharmacy continuous quality improvement; or

      (2) An internal program to the pharmacy which is acceptable to the board where proper documentation and evaluation can be completed.

3. At a minimum, a continuous quality improvement program must include provisions to:

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

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

4. The policies and procedures must be in compliance with this section must include:

   a. Training all pharmacy personnel in relevant phases of the continuous quality improvement program;

   b. Identifying and documenting reportable incidents and near misses and unsafe events;

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

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

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

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

5. Quality self-audit. Each pharmacy shall conduct a quality self-audit at least quarterly to determine whether the occurrence of incidents, near misses, and unsafe conditions has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the continuous quality improvement program in the future. Each pharmacy shall conduct a quality self-audit upon change of pharmacist-in-charge to familiarize that person with the pharmacy's continuous quality improvement program.

6. Protection from discovery:

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

   b. Records that are generated as a component of a pharmacy's ongoing quality assurance program and which are maintained for that program are confidential and may not be released, distributed, or communicated in any manner, except as provided by these rules or the 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 does not compromise the confidentiality and privilege of such information.

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

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

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

9. Not withstanding subsections 6 and 8, if a pharmacy is reporting to a patient safety organization whose primary mission is continuous quality improvement all data and records are privileged and confidential as provided in the Patient Safety and Quality Improvement Act of 2005 and implementing regulations.

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