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[06/30/06]

CHAPTER 61-**-**
PRESCRIPTION DRUG MONITORING PROGRAM

61--**-01. Adoption by reference of prescription drug monitoring program rules.** The Board of Pharmacy adopts and incorporates by reference the rules adopted by the North Dakota Department of Human Services in chapter 75-02-02.3. The rules incorporated by reference relate to the prescription drug monitoring program described in chapter 413 of the 2005 Session Laws.

History: Effective _____, 2006.
General Authority: NDCC ch. 19-03.1
Law Implemented: S.L. 2005, ch. 413

CHAPTER 75-02-02.3
PRESCRIPTION DRUG MONITORING PROGRAM

75-02-02.3-01. 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 pursuant to chapter 413 of the 2005 Session Laws.

History: Effective _____, 2006.
General Authority: NDCC 50-06-27 and S.L. 2005, ch. 413, § 1
Law Implemented: NDCC 50-06-27

75-02-02.3-02. 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 _____, 2006.
General Authority: NDCC 50-06-27 and section 1 of chapter 413 of the 2005 Session Laws
Law Implemented: NDCC 50-06-27

75-02-02.3-03. Access to program information.

1. Information submitted to the central repository is confidential and may not be disclosed except as provided in this section.

2. The board shall maintain procedures to ensure that the privacy, confidentiality, and security of patient information collected, recorded, transmitted, and maintained is not disclosed except as provided in this section.

3. Unless disclosure is prohibited by law, the board may provide data in the central repository to:

a. A prescriber for the purpose of providing medical care to a patient; a dispenser for the purpose of filling a prescription or providing pharmaceutical care for a patient; a prescriber or dispenser inquiring about the prescriber's or dispenser's own prescribing activity; or a prescriber or dispenser in order to further the purposes of the program;

b. An individual who requests the prescription information of the individual or the individual's minor child;

c. State boards and regulatory agencies that are responsible for the licensing of individuals authorized to prescribe or dispense controlled substances if the board or regulatory agency is seeking information from the central repository that is relevant to an investigation of an individual who holds a license issued by that board or regulatory agency;

d. Local, state and federal law enforcement or prosecutorial officials engaged in the enforcement of laws relating to controlled substances who seek information for the purpose of an investigation or prosecution of the drug-related activity or probation compliance of an individual;

e. The department for purposes regarding the utilization of controlled substances by a medicaid recipient;

f. North Dakota workforce safety and insurance for purposes regarding the utilization of controlled substances by a claimant;

g. Judicial authorities under grand jury subpoena or court order or equivalent judicial process for investigation of criminal violations of controlled substances laws;

h. Public or private entities for statistical, research, or educational purposes after the information is de-identified with respect to any prescriber, dispenser, or patient who received a prescription for a controlled substance; or

i. A peer review committee which means any committee of a health care organization, composed of health care providers, employees, administrators, consultants, agents, or members of the health care organization's governing body, which conducts professional peer review as defined in chapter 23-34 of the North Dakota Century Code.

4. The board shall maintain a record of each person who requests information from the central repository. The board may use the records to document and report statistics and outcomes. The board may provide records of the requests for information to:

a. A board or regulatory agency responsible for the licensing of individuals authorized to prescribe or dispense controlled substances that is engaged in an investigation of the individual who submitted the request for information from the central repository; and

b. Local, state and federal law enforcement or prosecutorial officials engaged in the enforcement of laws relating to controlled substances for the purpose of an active investigation of an individual who requested information from the central repository.

5. Nothing in this chapter shall require a prescriber or dispenser to obtain information about a patient from the central repository prior to prescribing or dispensing a controlled substance. A prescriber, dispenser or other health care practitioner may not be held liable in damages to any person in any civil action on the basis that the prescriber, dispenser or other health care practitioner did or did not seek to obtain information from the central repository. Unless there is shown a lack of good faith, the board, any other state agency, a prescriber, dispenser, or any other individual in proper possession of information provided under this chapter may not be subject to any civil liability by reason of:

a. The furnishing of information under the conditions provided in this chapter;

b. The receipt and use of, or reliance on, such information;

c. The fact that any such information was not furnished; or

d. The fact that such information was factually incorrect or was released by the board to the wrong person or entity.

History: Effective _____, 2006.
General Authority: NDCC 50-06-27 and section 1 of chapter 413 of the 2005 Session Laws
Law Implemented: NDCC 50-06-27

75-02-02.3-04. Operation of program.

1. The board or department may contract with another agency of this state or with a private vendor, as necessary, to ensure the effective operation of the program. Any contractor shall be bound to comply with the provisions regarding confidentiality of prescription information in this chapter.

2. The board may charge a fee to an individual who requests the individual's own information from the central repository.

3. The board may charge a fee to a person who requests statistical, aggregate, or other de-identified information.

History: Effective _____, 2006.
General Authority: NDCC 50-06-27 and section 1 of chapter 413 of the 2005 Session Laws
Law Implemented: NDCC 50-06-27

75-02-02.3-05. Data review and referral. Corrections.

1. The board shall review the information received by the central repository to determine if there is reason to believe:

   a. A prescriber or dispenser may have engaged in an activity that would be a basis for disciplinary action by the board or regulatory agency responsible for the licensing of the prescriber or dispenser; or

   b. A patient may have misused, abused, or diverted a controlled substance.

   If the board determines that there is reason to believe that any of the acts described in this subsection may have occurred, the board may notify the appropriate law enforcement agency or the board or regulatory agency responsible for the licensing of the prescriber or dispenser. The advisory council described in section 75-02-02.3-06 shall recommend guidelines to the board for reviewing data and making determinations with respect to

the referral of patients, prescribers, or dispensers as described in this subsection.

2. A patient, dispenser, or prescriber may request that erroneous information contained in the central repository be corrected or deleted. The board shall review the request to determine if the information is erroneous with respect to the patient, prescriber, or dispenser. The board shall correct any erroneous information it discovers due to the request for review by a patient, prescriber, or dispenser.

3. The board shall adopt a procedure to allow information contained in the central repository to be shared with officials in other states acting for the purpose of controlled substance monitoring and for requesting and receiving similar controlled substance monitoring information from other states.

History: Effective _____, 2006.
General Authority: NDCC 50-06-27 and section 1 of chapter 413 of the 2005 Session Laws
Law Implemented: NDCC 50-06-27

75-02-02.3-06. Advisory council.

1. An advisory council shall be established to advise and make recommendations to the board regarding how to best use the program to improve patient care and foster the goal of reducing misuse, abuse, and

diversion of controlled substances, encourage cooperation and coordination among state, local, and federal agencies and other states to reduce the misuse, abuse, and diversion of controlled substances, and provide advice and recommendations to the board regarding any other matters as requested by the board. The advisory council may have access to central repository information in order to fulfill its duties.

2. The advisory council shall consist of at least seven members made up of:

   a. One dispenser selected by the board;

   b. One physician selected by the North Dakota medical association;

   c. One prescriber selected by the board of nursing;

   d. A designee of the Attorney General;

   e. A designee of the department;

   f. One prescriber selected by the board of medical examiners;

   g. One prescriber selected by the North Dakota nurses association; and

h. Other prescribers or dispensers as determined by the board to be necessary in order to meet a mandate of, or avoid a delay in implementing, an appropriations measure. The number of additional members selected by the board shall be limited to the number necessary to meet the mandate or avoid the delay of an appropriation.

3. The advisory council shall make recommendations to the board regarding:

a. Safeguards for the release of information to those who have access to the information contained in the central repository;

b. The confidentiality of program information and the integrity of the patient's relationship with the patient's health care provider;

c. Advancing the purposes of the program including enhancement of the quality of health care delivery in this state; and

d. The continued benefits of maintaining the program in relationship to the cost and other burdens to the state.

4. The board may provide reimbursement of expenses and per diem to members of the advisory council within the limits provided in state law.

History: Effective _____, 2006.
General Authority: NDCC 50-06-27 and section 1 of chapter 413 of the 2005 Session Laws
Law Implemented: NDCC 50-06-27