

ARTICLE 61-12
PRESCRIPTION DRUG MONITORING PROGRAM

Chapter

61-12-01 Prescription Drug Monitoring Program

CHAPTER 61-12-01
PRESCRIPTION DRUG MONITORING PROGRAM

Section

61-12-01-01 Definitions

61-12-01-02 Dispenser Reporting

61-12-01-03 Operation of Program

61-12-01-04 Required Use of Certain Dispensing Situations

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

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 September 2011, version 4, release 2.
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; amended effective October 1, 2014.

General Authority: NDCC 19-03.5

Law Implemented: NDCC 19-03.5

61-12-01-03. Operation of program.

1. The board may charge a fee to an individual who requests the individual's own information from the central repository.
2. The board may charge a fee to a person who requests statistical, aggregate, or other de-identified information.
3. The board may allow access to controlled substance records to delegates certified by an authorized individual listed in North Dakota Century Code section 19-03.5-03. The authorized individual shall manage the delegates accessing the repository under their authority.
4. The board shall allow access to controlled substance records to authorized individuals listed in North Dakota Century Code section 19-03.5-03 for a period of three years.

History: Effective December 1, 2006; amended effective October 1, 2019.

General Authority: NDCC 19-03.5

Law Implemented: NDCC 19-03.5

61-12-01-04. Required use for certain dispensing situations.

1. Each dispenser licensed by a regulatory agency in the state of North Dakota who dispenses a controlled substance to a patient shall, at a minimum, request and review a prescription drug monitoring report covering at least a one-year time period or another state's report, or both reports, when applicable and available prior to initially dispensing a prescription, with the exception of prescriptions for a patient in a skilled long-term care facility or a hospice patient. Further reports must be requested and reviewed if the dispenser becomes aware of a person currently:
 - a. Receiving reported drugs from multiple prescribers;
 - b. Receiving reported drugs for more than twelve consecutive weeks;
 - c. Abusing or misusing reported drugs (i.e., over-utilization; early refills; appears overly sedated or intoxicated upon presenting a prescription for a reported drug; or an unfamiliar patient requesting a reported drug by specific name, street name, color, or identifying marks);

- d. Requesting the dispensing of a reported drug from a prescription issued by a prescriber with whom the dispenser is unfamiliar (i.e., the prescriber is located out-of-state or the prescriber is outside the usual pharmacy geographic prescriber care area); or
 - e. Presenting a prescription for reported drugs when the patient resides outside the usual pharmacy geographic patient population.
2. After obtaining an initial prescription drug monitoring report on a patient, a dispenser shall use professional judgment based on prevailing standards of practice in deciding the frequency of requesting and reviewing further prescription drug monitoring reports or other state's reports, or both reports, for that patient.
 3. In the rare event a report is not immediately available, the dispenser shall use professional judgment in determining whether it is appropriate and in the patient's best interest to dispense the prescription prior to receiving and reviewing a report.
 4. For the purpose of compliance with subsection 1, a report could be obtained through a prescription drug monitoring program intergration with software or also a board-approved aggregate tool, for which the NARxCARE will be an approved tool.

History: Effective October 1, 2014; amended effective October 1, 2019.

General Authority: NDCC 19-03.5, 19-03.5-09, 43-15-10(12)

Law Implemented: NDCC 19-03.5