13.8004.01000

Sixty-third
Legislative Assembly
of North Dakota

HOUSE BILL NO. 1071

Introduced by

Judiciary Committee

(At the request of the State Board of Pharmacy)

A BILL for an Act to create and enact section 19-03.1-17.2 of the North Dakota Century Code, relating to licensing procedures to obtain a registration under the Uniform Controlled Substances Act; to amend and reenact sections 19-03.1-01, 19-03.1-16, and 19-03.1-17 of the North Dakota Century Code, relating to controlled substances; and to provide a penalty.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. AMENDMENT. Section 19-03.1-01 of the North Dakota Century Code is amended and reenacted as follows:

19-03.1-01. Definitions.

As used in this chapter and in chapters 19-03.2 and 19-03.4, unless the context otherwise requires:

1. "Administer" means to apply a controlled substance, whether by injection, inhalation, ingestion, or any other means, directly to the body of a patient or research subject by:
   a. A practitioner or, in the practitioner's presence, by the practitioner's authorized agent; or
   b. The patient or research subject at the direction and in the presence of the practitioner.
2. "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.
3. "Anabolic steroids" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, and corticosteroids.
4. "Board" means the state board of pharmacy.

5. "Bureau" means the drug enforcement administration in the United States department of justice or its successor agency.

6. "Controlled premises" means places where records required are kept or places where persons registered or exempted from registration may lawfully hold, manufacture, distribute, dispense, administer, or otherwise dispose of controlled substances.

7. "Controlled substance" means a drug, substance, or immediate precursor in schedules I through V as set out in this chapter.

~~7.~~8. "Counterfeit substance" means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person who in fact manufactured, distributed, or dispensed the substance.

~~8.~~9. "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a controlled substance whether or not there is an agency relationship.

~~9.~~10. "Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.

~~10.~~11. "Dispenser" means a practitioner who dispenses.

~~11.~~12. "Distribute" means to deliver other than by administering or dispensing a controlled substance.

~~12.~~13. "Distributor" means a person who distributes.

~~13.~~14. "Drug" means:

a. Substances recognized as drugs in the official United States pharmacopeia national formulary, or the official homeopathic pharmacopeia of the United States, or any supplement to any of them;

b. Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in individuals or animals;

c. Substances, other than food, intended to affect the structure or any function of the body of individuals or animals; and

d. Substances intended for use as a component of any article specified in subdivision a, b, or c. The term does not include devices or their components, parts, or accessories.

15. "Drug enforcement administration" means the United States department of justice, drug enforcement administration, or its successor agency.

~~14.~~16. "Hashish" means the resin extracted from any part of the plant cannabis with or without its adhering plant parts, whether growing or not, and every compound, manufacture, salt, derivative, mixture, or preparation of the resin.

~~15.~~17. "Immediate precursor" means a substance:

a. That the board has found to be and by rule designates as being the principal compound commonly used or produced primarily for use in the manufacture of a controlled substance;

b. That is an immediate chemical intermediary used or likely to be used in the manufacture of the controlled substance; and

c. The control of which is necessary to prevent, curtail, or limit the manufacture of the controlled substance.

18. "Long-term care facility" means a facility defined in chapter 50-10.1, as any assisted living facility, skilled nursing facility, basic care facility, nursing home as defined in section 43-34-01, or swing bed hospital approved to furnish long-term care services.

~~16.~~19. "Manufacture" means the production, preparation, propagation, compounding, conversion, or processing of a controlled substance, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis and includes any packaging or repackaging of the substance or labeling or relabeling of its container. The term does not include the preparation or compounding of a controlled substance by an individual for the individual's own use or the preparation, compounding, packaging, or labeling of a controlled substance:

a. By a practitioner as an incident to the practitioner's administering or dispensing of a controlled substance in the course of the practitioner's professional practice; or

b. By a practitioner, or by the practitioner's authorized agent under the practitioner's supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale.

~~17.~~20. "Marijuana" means all parts of the plant cannabis whether growing or not; the seeds thereof; the resinous product of the combustion of the plant cannabis; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds. The term does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of mature stalks, fiber, oil, or cake, or the sterilized seed of the plant which is incapable of germination.

~~18.~~21. "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

a. Opium and opiate and any salt, compound, derivative, or preparation of opium or opiate.

b. Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subdivision a, but not including the isoquinoline alkaloids of opium.

c. Opium poppy and poppy straw.

d. Coca leaves and any salt, compound, derivative, or preparation of coca leaves, any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions of coca leaves which do not contain cocaine or ecgonine.

~~19.~~22. "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. The term does not include, unless specifically designated as controlled under section 19-03.1-02, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). The term includes its racemic and levorotatory forms.

~~20.~~23. "Opium poppy" means the plant of the species papaver somniferum L., except its seeds.

~~21.~~24. "Over-the-counter sale" means a retail sale of a drug or product other than a controlled, or imitation controlled, substance.

~~22.~~25. "Person" means individual, corporation, limited liability company, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

~~23.~~26. "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

~~24.~~27. "Practitioner" means:

a. A physician, dentist, veterinarian, pharmacist, scientific investigator, or other person licensed, registered, or otherwise permitted by the jurisdiction in which the individual is practicing to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research.

b. A pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state.

28. "Prescribe" or "prescribing" means the ordering of a drug or device to be administered or dispensed to a specific patient.

29. "Prescription" means an order for medication which is dispensed to or for an ultimate user.

~~25.~~30. "Production" includes the manufacturing, planting, cultivating, growing, or harvesting of a controlled substance.

31. "Registration" means a controlled substance registration.

32. "Research protocol" means a detailed description of each research project being initiated.

~~26.~~33. "Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by a person, whether as principal, proprietor, agent, servant, or employee.

~~27.~~34. "Scheduled listed chemical product" means a product that contains ephedrine, pseudoephedrin, or phenylpropanolamine, or each of the salts, optical isomers, and

salts of optical isomers of each chemical, and that may be marketed or distributed in the United States under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] as a nonprescription drug unless prescribed by a licensed physician.

~~28.~~35. "State" when applied to a part of the United States includes any state, district, commonwealth, territory, insular possession thereof, and any area subject to the legal authority of the United States.

~~29.~~36. "Ultimate user" means an individual who lawfully possesses a controlled substance for the individual's own use or for the use of a member of the individual's household or for administering to an animal owned by the individual or by a member of the individual's household.

SECTION 2. AMENDMENT. Section 19-03.1-16 of the North Dakota Century Code is amended and reenacted as follows:

19-03.1-16. Registration requirements - Penalty.

1. ~~Every person who manufactures, distributes, or dispenses any controlled substance within this state or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance within this state shall obtain annually a registration issued by the board in accordance with its rules.~~Every person who manufactures, distributes, prescribes, or dispenses any controlled substance or who proposes to engage in the manufacturing, distributing, prescribing, or dispensing of any controlled substance shall obtain a controlled substance registration from the board prior to engaging in such activities. Only persons actually engaged in such activities are required to register. The performance of such activities in the absence of a valid registration is a class C felony.
2. Persons registered by the board under this chapter to manufacture, distribute, dispense, or conduct research with controlled substances may possess, manufacture, distribute, dispense, or conduct research with those substances to the extent authorized by their registration and in conformity with the other provisions of this chapter.
3. The following persons need not register and may lawfully possess controlled substances under this chapter:

a. ~~An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance if an agent or employee is acting in the usual course of an agent's or employee's business or employment.~~A manufacturer's or distributor's workman, contract carrier, warehouseman, or any employee thereof, whose handling of controlled substances is in the usual course of that person's business or employment while on the premises of the employer or under direct transfer orders of the employer.

b. ~~A common or contract carrier or warehouseman, or an employee thereof, whose possession of any controlled substance is in the usual course of business or employment.~~A person who obtains or possesses a controlled substance pursuant to a valid prescription, either for that person's own use or for the use of a member of that person's household or for the administration to an animal owned by that person or a member of that person's household.

c. ~~An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a practitioner or in lawful possession of a schedule V substance.~~An agent or employee of any licensed manufacturer, distributor, dispenser, or researcher in the course of that person's employment and only on the premises of that person's employer.

4. ~~The board may waive by rule the requirement for registration of certain manufacturers, distributors, or dispensers if it finds it consistent with the public health and safety.~~

~~5.~~ A separate registration is required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances.

~~6.~~5. The board may inspect the establishment of a registrant or applicant for registration in accordance with the rules of the board.

SECTION 3. AMENDMENT. Section 19-03.1-17 of the North Dakota Century Code is amended and reenacted as follows:

19-03.1-17. Registration.

1. As used in this section:

a. "Practitioner" means an individual currently licensed, registered, or otherwise authorized by the appropriate licensing board to prescribe and administer drugs in the course of professional practice.

b. "Department" means the state department of health.

c. "Drug detection canine handler" means an individual qualified to handle canines in the detection of controlled substances.

d. "Drug detection canine trainer" means an individual qualified to conduct experiments using controlled substances in training canines to detect the presence of contraband controlled dangerous substances.

e. "Facility" means an organized health care setting authorized by law and licensed to engage in the provision of health care. This term shall not apply to long-term care facilities.

f. "Narcotic treatment program", also known as an opioid treatment program, is defined as a program licensed or otherwise authorized by the state department of health, the substance abuse and mental health services administration, and the United States drug enforcement administration to operate a narcotic substance abuse program using narcotic replacement procedures for individuals dependent on opium, morphine, heroin, or any derivative or synthetic drug in that group.

g. "Researcher" means an individual qualified to conduct medical, educational, or scientific experiments on animals or humans or in laboratories which require the use of controlled substances. For the purpose of this chapter, manufacturers that use controlled substances in the manufacturing process, but do not manufacture controlled substances as an end product, shall be considered researchers and not manufacturers.

2. The board shall register an applicant to manufacture or distribute controlled substances included in sections 19-03.1-05, 19-03.1-07, 19-03.1-09, 19-03.1-11, and 19-03.1-13 unless it determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the board shall consider the following factors:

a. Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;

b. Compliance with applicable state and local laws;

c. Any convictions of the applicant under any federal and state laws relating to any controlled substance;

d. Past experience in the manufacture or distribution of controlled substances and the existence in the applicant's establishment of effective controls against diversion;

e. Furnishing by the applicant of false or fraudulent material in any application filed under this chapter;

f. Suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law; and

g. Any other factors relevant to and consistent with the public health and safety.

~~2.~~3. Registration under ~~subsection 1~~this section does not entitle a registrant to manufacture and distribute controlled substances in schedule I or II other than those specified in the registration.

~~3.~~4. ~~Practitioners~~Registrants must be registered to dispense any controlled substances or to conduct research with controlled substances in schedules II through V if they are authorized to dispense or conduct research under the laws of this state. The board need not require separate registration under this chapter for ~~practitioners~~registrants engaging in research with nonnarcotic controlled substances in schedules II through V where the registrant is already registered under this chapter in another capacity. ~~Practitioners~~Registrants registered under federal law to conduct research with schedule I substances may conduct research with schedule I substances within this state upon furnishing the ~~state department of health~~board evidence of that federal registration.

~~4. Compliance by manufacturers and distributors with the provisions of the federal law respecting registration (excluding fees) entitles them to be registered under this chapter.~~

5. Practitioners.

a. The registration of a practitioner, and the renewal thereof, shall require the possession of a valid and verifiable license or other credential issued by a standing professional board in the state or other agency of competent jurisdiction.

b. For the purpose of prescribing controlled substances, a registration issued to a practitioner shall be valid in any location in North Dakota; however, the procurement and possession of controlled substances shall require a separate registration for each such location where controlled substances are possessed.

c. A prescribing practitioner desiring to procure and possess controlled substances at only one location need only obtain a single registration.

6. Pharmacies.

a. The issuance of a registration to a pharmacy, and the renewal thereof, shall require the possession of a valid and verifiable permit to operate a pharmacy issued by the board.

b. A registration issued to a pharmacy shall be valid for the premises identified on the license.

c. The possession of controlled substances under the control of the pharmacy at a different location shall require a separate registration for each separate location, including ambulances and emergency kits.

7. Facilities. The issuance of a registration to a facility, and the renewal thereof, shall require the possession of a valid and verifiable license or other credential issued by the department, or its successor.

8. Manufacturers and distributors.

a. The issuance of a registration to a manufacturer, and the renewal thereof, shall require the possession of a valid and verifiable license or other credential from the board.

b. The issuance of a registration to a distributor, and the renewal thereof, shall require the possession of a valid and verifiable license or other credential from the board.

c. The sale or transportation of controlled substances within the state by manufacturers located outside the state shall require the possession of a valid registration issued by the board prior to the engagement in such activities.

9. Narcotic treatment program. The issuance of a registration to a narcotic treatment program, and the renewal thereof, shall require the possession of a valid and verifiable license or other credential issued by the department, or its successor.

10. Researchers.

a. The issuance of a registration to a researcher, and the renewal thereof, shall require the attachment to the application of a properly completed form supplied by the board describing the research, and further, when the research involves human subjects or animal subjects, the attachment to the application of proof of approval by the appropriate institutional review board.

b. A determination of qualification shall be made by the board or its designee.

11. Drug detection canine trainers or handlers.

a. The issuance of a registration to a drug detection canine trainer or handler, and the renewal thereof, shall require the recommendation of at least one law enforcement agent and the attachment to the application of a properly completed form supplied by the board describing the policies and procedures for the use of controlled substances.

b. A determination of qualification shall be made by the board or its designee.

SECTION 4. Section 19-03.1-17.2 of the North Dakota Century Code is created and enacted as follows:

19-03.1-17.2. Licensing procedures - Penalty.

1. Application for initial issuance of registration.

a. An individual or other entity desiring to obtain a registration shall complete the application form supplied by the board and submit it with the required attachments and appropriate fees.

b. The applicant shall provide a complete street address reflecting the location where the applicant will engage in the activity for which a registration is required. The board shall issue only one registration for each applicant at each such location.

c. The board shall not process applications that are incomplete, or submitted with the incorrect fees.

d. An individual or other entity who knowingly or intentionally submits a false or fraudulent application shall be deemed to be guilty of a class C felony.

e. A registration shall be valid for a period of three years and shall expire annually on the date of initial registration unless revoked sooner.

f. Practitioners in possession of a temporary or restricted license issued by a standing professional board of competent jurisdiction in the state may be issued a temporary or restricted registration adhering to the limitations or restrictions of the practitioner's board license.

2. Application for renewal of registration.

a. A registrant shall complete the application for renewal of a registration and submit the application to the board prior to the expiration date of the current license. The application shall be submitted in such form and contain such data and attachments as the board may require and be accompanied by the appropriate fees.

b. The board shall not process applications that are incomplete or submitted with the incorrect fees.

c. A registration not renewed by the expiration date shall be classified as expired. A registrant shall not engage in any activity requiring a valid registration while the registrant's registration is expired.

d. A registration not renewed within sixty days following the expiration date shall be automatically terminated by the board. The reissuance of a terminated registration shall require compliance with the board's reinstatement procedures.

3. Application for reinstatement of terminated, suspended, or revoked registration.

a. The applicant shall complete an application form for this specific purpose supplied by the board. The application must require the inclusion of the renewal fee and delinquent fee.

b. An application for the reinstatement of a terminated credential which has been expired may be approved by the board's administrative personnel.

c. An application for the reinstatement of a registration suspended or revoked as a consequence of the suspension or revocation of the primary credential by the issuing agency shall require verification of the reinstatement of the primary credential. Where the issuing agency reinstating the primary credential has restricted any privileges for controlled substances, those restrictions shall be attached to the reinstated registration. Where the agency reinstating the primary

credential has placed that credential on probation for any period of time, the registration shall be placed on probation for the same period of time.

d. An application for the reinstatement of a registration suspended or revoked by the board may only be approved by the full board to determine whether the reinstatement of the license is in the public's best interest.

4. Maintenance of a registration.

a. A registration is valid only for the entity or person to whom it is issued and shall not be subject to sale, assignment, or other transfer, voluntary or involuntary, nor shall a registration be valid for any premises other than the business location for which it is issued.

b. In the case that a drug enforcement administration registration is revoked, is suspended, or expires, the registration may be revoked, suspended, or expired as well.

c. The registrant shall inform the board of any and all changes to its business location and address within fourteen days, with documentation, attesting to any change of business location and address, with notice to include both the old and new addresses. A change in business address of a facility may require an inspection by the board or its designee.

d. A duplicate or replacement registration shall be issued upon the written request of the registrant and a fee may be required. A duplicate or replacement registration shall not serve or be used as an additional or second registration.

e. A facility changing ownership shall notify the board in writing fourteen calendar days prior to the transfer of ownership.

(1) A change of ownership is evident under the following conditions:

(a) Sale;

(b) Death of a sole proprietor;

(c) The addition or deletion of one or more partners in a partnership;

(d) Bankruptcy sale; or

(e) A fifty percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original registration.

(2) The new owner shall submit a properly completed application, with all required attachments and appropriate fee, to the board.

(3) Upon the receipt of the new registration, the previous registrant shall:

(a) Notify the board of the transaction, including the identity of the new owner; and

(b) Surrender the previous registrant's registration to the board.

(4) A registration is not transferable from the original owner to a new owner.

(5) A change in ownership may require an inspection by the board or its designee.

5. Fee for a three-year registration.

a. Practitioners - ninety dollars.

b. Pharmacies - ninety dollars.

c. Facilities - ninety dollars.

d. Manufacturers and wholesalers - two hundred and twenty-five dollars.

e. Narcotic treatment programs - ninety dollars.

f. Researchers - ninety dollars.

g. Drug detection canine trainers or handlers - sixty dollars.

h. Late fee - fifty dollars.