

August 2008

REGULATION AND LICENSING OF PHARMACISTS AND PHARMACIES - BACKGROUND INFORMATION

Section 2 of House Bill No. 1299 (2007) (attached as an [appendix](#)) provides for a study of:

1. The State Board of Pharmacy, the board's size, the manner of board membership appointment, and whether the board is representative of commercial and noncommercial pharmacists;
2. The state's demographics and the impact changing demographics in rural areas will have on the ability of small, locally owned pharmacies to remain economically viable and on the ability of rural residents to access low-cost pharmaceuticals and pharmacy and pharmacists' services;
3. The pharmacy ownership restrictions, the relevance of those restrictions in terms of marketplace competition, and the impact of those restrictions on the price and availability of pharmaceuticals and on pharmacy and pharmacists' services; and
4. The statutory interplay between the State Board of Pharmacy and the North Dakota Pharmaceutical Association and whether the regulatory function of the board conflicts with the advocacy function of the association.

BACKGROUND

State Board of Pharmacy

North Dakota Century Code Chapter 43-15 governs the regulation of pharmacists and pharmacies. Section 43-15-03 provides for a State Board of Pharmacy consisting of five members appointed by the Governor upon the recommendation of the North Dakota Pharmaceutical Association. The individuals appointed to the board must be licensed pharmacists and must be members of the North Dakota Pharmaceutical Association. Section 43-15-04 provides that the term of office of members of the board is five years. Under Section 43-15-05, board members are entitled to a per diem of \$200 for attendance at board meetings.

Section 43-15-06 requires the board president to be a member of the board, but provides that the secretary and treasurer do not have to be members of the board. The board is required to hire a pharmacist as the full-time executive director.

Section 43-15-09 requires the board to meet at least two times, but not more than four times, each year for the examination of applicants. In addition, the board is authorized to meet as necessary for the performance of its duties.

Section 43-15-10 sets forth the duties of the board. Among its duties, the board is authorized to:

1. Place on probation, reprimand, or fine any pharmacy, pharmacist, or pharmacy intern or pharmacy technician; or refuse to issue or renew, or suspend, revoke, restrict, or cancel, the license, permit, or registration of any pharmacy, pharmacist, or pharmacy intern or pharmacy technician.
2. Adopt rules governing the cancellation or suspension of a license.
3. Examine and license pharmacists.
4. Adopt rules for the guidance of its members, officers, and employees, and to ensure the proper and orderly dispatch of its business.
5. Employ individuals to inspect pharmacies, investigate pharmacies, procure evidence in any proceeding pending before the board, or procure evidence in aid of any prosecution.
6. Employ counsel to advise the board or to prosecute or defend any action or proceeding commenced by or against the board or pending before it.
7. Grant permits and renewals for the establishment and operation of pharmacies.
8. For good cause, cancel, revoke, or suspend permits and renewals for the establishment and operation of pharmacies.
9. Adopt reasonable and nondiscriminatory rules with respect to granting, renewing, canceling, revoking, or suspending permits and renewals for establishing and operating pharmacies.
10. Adopt reasonable rules relating to the physical design of space occupied by a pharmacy to ensure appropriate control of and safeguards over the contents of the pharmacy.
11. Regulate and control the practice of pharmacy in North Dakota.
12. Adopt, amend, and repeal rules for the regulation of pharmacies and pharmacists providing radiopharmaceutical services.
13. Adopt, amend, and repeal rules for the proper administration and enforcement of Chapter 43-15, Chapter 19-02.1 as that chapter pertains to drugs, subject to approval of the director of the State Department of Health, and Chapter 19-03.1.
14. Investigate and gather evidence concerning alleged violations of the provisions of Chapter 43-15, Chapter 19-02.1 as it pertains to drugs, Chapters 19-03.1, 19-03.2, and 19-04, or of the rules of the board.
15. Adopt, amend, and repeal rules to register pharmacy technicians.
16. Require the self-reporting by an applicant or a licensee of any information the board determines may indicate possible deficiencies

in practice, performance, fitness, or qualifications.

17. Require information regarding an applicant's or licensee's fitness, qualifications, and previous professional record and performance from recognized data sources, licensing and disciplinary authorities of other jurisdictions, professional education and training institutions, liability insurers, health care institutions, and law enforcement agencies be reported to the board.

North Dakota Pharmaceutical Association

Section 43-15-13.2 provides that the North Dakota Pharmaceutical Association consists of every person:

1. Who has secured a current annual license to practice pharmacy in this state.
2. Who has paid an annual membership fee directly to the association as determined and permitted by the association and who does not hold a current license to practice pharmacy in this state.

Section 43-15-30 provides that licensure as a pharmacist by the board entitles the person so licensed to a one-year membership in the North Dakota Pharmaceutical Association.

Section 43-15-13.3 provides that the members of the association who have secured a current annual license to practice pharmacy in this state are entitled to all the rights and privileges of the association and may vote, serve as an officer or director of the association, and participate in all the meetings of the association. The members of the association who have not secured a current annual license to practice pharmacy are entitled to all the rights and privileges of the association, except that they may not vote at the meetings or serve as an officer or director of the association.

Section 43-15-13.4 mandates that the association is to receive 50 percent of the fees received by the board for license renewals. The section allows the association to use the funds for payment of expenses of the association including continuing pharmaceutical education, pharmacist discipline, the impaired pharmacist program, matters related to pharmacist registration standards, professional service standards, and general operating expenses.

Pharmacist Licensing

Section 43-15-15 requires that an applicant for a pharmacist license must be at least 18 years of age, be of good moral character, and be a graduate of a school or college of pharmacy recognized by the board as an approved school. Section 43-15-22 provides for licensing of pharmacists from other states or foreign countries without an examination if the qualifications from the other state or country are equivalent to those in this state.

Section 43-15-25 provides that a license is valid for one year and establishes a renewal fee not to exceed \$200. Before a renewal may be issued, a pharmacist

is required under Section 43-15-25.1 to complete an accredited program of continuing education. The continuing education requirements may not exceed 30 hours in each biennium.

Pharmacy Operation

Section 43-15-32 provides a registered pharmacist must be in charge of every store, dispensary, pharmacy, laboratory, or office, selling, dispensing, or compounding drugs, medicines, or chemicals, or compounding or dispensing prescriptions of medical practitioners in the state, and every business carried on under a name which contains the words "drugs," "drugstore," or "pharmacy," or which is described or referred to in such terms by advertisements, circulars, posters, signs, or otherwise.

Section 43-15-34 prohibits any person from opening, establishing, operating, or maintaining a pharmacy in the state without obtaining a permit from the board. Section 43-15-34.1 requires an out-of-state pharmacy that ships or delivers a dispensed prescription drug or legend drug into the state to hold a pharmacy permit issued by the board. The section also provides that the part of the pharmacy operation dispensing the prescription for a resident of this state abide by state law and rules of the board.

Section 43-15-35 sets forth the requirements to operate a pharmacy in the state. The section requires that the management of a pharmacy must be under the personal charge of a pharmacist licensed in this state. In addition, the section establishes pharmacy ownership requirements. Those requirements have been the subject of litigation twice since the adoption of the requirements in 1963.

The 1963 Legislative Assembly adopted legislation that provided that an applicant for a permit to operate a pharmacy must be a registered pharmacist or a partnership, each active member of which is a registered pharmacist, or a corporation or an association, the majority of stock of which is owned by registered pharmacists actively and regularly employed and responsible for the management, supervision, and operation of the pharmacy. The legislation included an exception for the holder of a permit on July 1, 1963, if otherwise qualified to conduct the pharmacy, for so long as the permitholder continues operations and renews the permit. The legislation also included an exception for hospital pharmacies furnishing service only to patients in the hospital.

The 1963 legislation, which was codified as Section 43-15-35, faced a constitutional challenge that was ultimately decided by the United States Supreme Court in 1973. In 1972 the State Board of Pharmacy denied a permit to Snyder's Drug Stores because the board determined the applicant "did not comply with the stock-ownership requirements of the statute, it appearing that all the common stock of Snyder's was owned by Red Owl Stores and it not being shown if any Red Owl shareholders were pharmacists registered and in good standing in North Dakota."

North Dakota Pharmacy Bd. v. Snyder's Stores, 414 U.S. 156 (1973). Although the North Dakota Supreme Court found the pharmacy ownership requirements to be unconstitutional, the United States Supreme Court overruled the decision upon which the North Dakota Supreme Court based its decision, reversed the decision, and remanded the case to the North Dakota Supreme Court. The North Dakota Supreme Court then upheld the constitutionality of the law.

The pharmacy ownership law was challenged again in the mid-1990s. In 1996 Medcenter One Hospital decided to expand its pharmacy at the hospital to make pharmacy sales to the general public. The State Board of Pharmacy, through its legal counsel, informed Medcenter One that the "exemption for community/retail pharmacies set forth in N.D.C.C. 43-15-35 would [not] be available to Medcenter One Hospital Pharmacy." The opinion of the board's legal counsel concluded that:

Before July 1, 1963, there were two type[s] of pharmacy permits for two types of pharmacy practice, one for hospitals serving only patients in that hospital and one for community/retail pharmacies. When N.D.C.C. 43-15-35 was amended effective July 1, 1963, the legislature recognized that distinction in permits and pharmacy practice and codified that distinction by providing that N.D.C.C. 43-15-35 does not apply to hospital pharmacies furnishing service only to patients in such hospital or to community/retail pharmacies holding a permit on July 1, 1963.

Because the Bismarck Hospital Pharmacy was the beneficiary of the hospital exemption since that was the type of pharmacy practice it was engaged in on July 1, 1963, the opinion concluded that "Medcenter One Pharmacy is not now (32 years later) entitled to an additional exemption for community/retail pharmacies, because it was not engaged in that type of practice on July 1, 1963."

Medcenter One Hospital sought and received a declaratory judgment from the district court which concluded that the unambiguous language of Section 43-15-35 did not differentiate between hospital and retail pharmacy permits and held that Medcenter One Hospital, as the continuous holder of a permit since before 1963, was exempt from the pharmacist ownership requirements. The North Dakota Supreme Court affirmed the decision in *Medcenter One v. State Bd. of Pharmacy*, 561 N.W.2d 634 (1997). The Supreme Court stated that Section 43-15-35 clearly and unambiguously describes two exemptions to the pharmacist ownership requirements. The first exemption is for pharmacies that held permits on July 1, 1963, and have not discontinued operations or failed to renew their permit. The court concluded the plain language of that exemption applies to all pharmacy permitholders on that date, not just retail or nonhospital pharmacies. The second exemption applies to hospital pharmacies furnishing service only to patients in the hospital. The court concluded if the

Legislative Assembly had intended the first exemption only to apply to retail or nonhospital pharmacies, it would have limited that exemption with appropriate language.

Section 43-15-35, as amended by the Legislative Assembly in 2007, retains the pharmacist ownership requirements. House Bill No. 1299 (2007) created an exception from the requirements for an applicant for a permit to operate a pharmacy which is a hospital if the pharmacy for which the hospital seeks a permit to operate is a retail pharmacy that is the sole provider of pharmacy services in the community and is a retail pharmacy that was in existence before the hospital took over operations. A hospital operating a pharmacy under that exception may operate the pharmacy at any location in the community. House Bill No. 1350 (2007) established an exception from the ownership requirements for an applicant for a permit to operate a pharmacy which is the owner of a postgraduate medical residency training program if the pharmacy is collocated with and is run in direct conjunction with the postgraduate medical residency training program.

2007 LEGISLATION

In addition to the two bills that created exceptions to the pharmacist ownership requirements, two other bills were considered by the Legislative Assembly which related to the State Board of Pharmacy and the North Dakota Pharmaceutical Association. House Bill No. 1148 (2007), which failed, would have repealed the statutory provisions relating to the North Dakota Pharmaceutical Association and would have removed the requirement that the members of the State Board of Pharmacy be appointed upon the recommendation of the association. The bill also would have prohibited the board from requiring that a pharmacist be a member of any association as a requirement for initial licensure or for license renewal and would have prohibited the board from using licensure fees to pay a pharmacist's membership dues to a professional association. Senate Bill No. 2387 (2007), which also failed, was identical to 2007 House Bill No. 1148.

PHARMACIST REGULATION IN NEIGHBORING STATES

South Dakota

The South Dakota Codified Laws provide for a State Board of Pharmacy consisting of four professional members and one laymember. The term of office of the members is three years.

South Dakota law provides that participation in the South Dakota Pharmacists Association by pharmacists is elective. The State Board of Pharmacy is authorized to pay to the South Dakota Pharmacists Association 80 percent of all fees the board receives for renewals of certificates as registration as a pharmacist. The association is required to use the funds for continuing education, matters related to registration standards for pharmacists, professional

service standards, and general operating expenses related to those activities. The association is also required to use funds received to pay any legislated assessment to support a diversion program for chemically impaired pharmacists.

Under South Dakota law, the State Board of Pharmacy may not issue a permit to conduct a pharmacy to any pharmacist applicant unless the applicant is owner, or part-owner, of the merchandise and fixtures of the place of business for which the pharmacy registration is applied; the application is made jointly with a registered pharmacist owner; or the nonpharmacist owner of the merchandise and fixtures of the place of business for which pharmacy registration is applied, has made an affidavit delegating complete responsibility for the pharmaceutical services in the place of business to the pharmacist applicant. The board also is authorized to issue to pharmacists in good standing a permit to conduct a part-time, limited, or conditional pharmacy in hospitals, nursing homes, or related facilities if the pharmacy services are limited to patients.

Montana

The Montana Code Annotated provides for a Board of Pharmacy consisting of six members, three of whom must be licensed pharmacists, two of whom must be from the general public, and one of whom must be a registered pharmacy technician. The term of office of the members is five years. The members are appointed by the Governor with the consent of the Senate.

Montana law prohibits the Board of Pharmacy from issuing a license to a pharmacy unless the pharmacy is operated by a pharmacist registered by the board.

The Montana Pharmacy Association provides continuing education opportunities, advocacy, and pharmacy information. The association is a voluntary organization.

Minnesota

The Minnesota State Board of Pharmacy consists of five pharmacists and two public members appointed by the Governor for a term of office of four years. The Minnesota Statutes provide that the Minnesota State Pharmaceutical Association and the Minnesota Society of Hospital Pharmacists jointly may recommend five names for each pharmacist to be appointed.

Under rules adopted by the Minnesota State Board of Pharmacy, a pharmacy must be licensed in at least one of the following categories of licensure: a community/retail pharmacy; a hospital pharmacy; a parenteral-enteral/home health care pharmacy; a long-term care pharmacy; a nuclear pharmacy; or a central service pharmacy.

The Minnesota State Pharmaceutical Association is a voluntary association that provides advocacy, professional development and education, communications, and products and services.

SUGGESTED STUDY APPROACH

In conducting this study, the committee may choose to:

1. Receive information from the State Board of Pharmacy, the North Dakota Pharmaceutical Association, other pharmacy groups, hospital and other health care facility groups, and individual pharmacists regarding the structure of the board, access to pharmacy services, the restrictions on pharmacist ownership, and the relationship between the board and association.
2. Develop recommendations and draft legislation, if necessary to implement the recommendations, to address any concerns identified.

ATTACH:1