

BIENNIAL REPORT OF EXAMINING AND LICENSING BOARDS

**920557** (M.S. - 1987 Supplement, Section 214.07)

**BOARD:** MINNESOTA BOARD OF PHARMACY

**LOCATION:** 2700 University Ave. W. #107, St. Paul, MN 55114

**STATUTORY AUTHORITY:** Minnesota Statute 151

**REPORTING PERIOD:** July 1, 1990 to June 30, 1992

**SUBMITTED BY:** David E. Holmstrom, Executive Director

**DATE:** October 1, 1992

**Distribution:**

- 1 copy to Secretary of Senate
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The function of the Minnesota Board of Pharmacy is to protect the public from adulterated, misbranded, and illicit drugs and to provide the public reasonable assurance of professional competency in the practice of the pharmacy profession through the enforcement of the provisions of the Pharmacy Practice Act, the State Controlled Substances Act, and miscellaneous other acts. Such enforcement involves drug control through testing, licensing, inspecting, and investigating 4,912 pharmacists, 372 pharmacist-interns, 1,213 pharmacies, 357 drug wholesalers, 201 drug manufacturers, 69 drug researchers, and 28 medical gas distributors; through the providing of technical assistance, training and consultation to other health professionals; and through the development of rules and regulations governing storage, distribution, and recordkeeping by persons, institutions, and facilities.

This general function of the Board can essentially be broken down into nine different activities:

(1) Licensing of Pharmacists. Candidates for licensure as pharmacists are examined by Board members in a combination of five professional fields. In addition, a practical examination involving the compounding and dispensing of prescriptions is prepared and administered by the Board members.

Candidates for licensure by reciprocity are cleared through the National Association of Boards of Pharmacy for evidence of proper educational and experience credentials as well as for compliance with pharmacy laws. Only the state exam in pharmaceutical jurisprudence is required of candidates for licensure by reciprocity.

Twice yearly survey/inspections review compliance with: required professional staffing standards, internship training and practice, standards of drug storage and drug quality, minimum equipment, prepackaging activities, bulk compounding, compounding and dispensing, consultation under Medicare requirements, recordkeeping, labeling, security, and miscellaneous practice requirements. In the case of pharmacists in institutional practice, special emphasis is given to the overall drug distribution systems utilized and recognition is given to special compounding and dispensing practices unique to the institutional practice setting.

Beginning with the March 4, 1975 licensing renewal, all pharmacists currently licensed in Minnesota are required to show evidence of having obtained thirty hours of continuing pharmaceutical education every two years in order to maintain their license. Programs from various local, state, and national sponsors must be reviewed and approved for use in meeting the continuing educational requirement. Biennially reports of continuing education attendance and participation must be reviewed and recorded prior to approving the annual registration for pharmacists.

(2) Pharmacy Licensure. Licenses are issued for each pharmacy, community and institutional, in the name of a designated pharmacist-in-charge who must demonstrate that required professional staffing, access, space, security, and equipment standards are met. Each pharmacy is inspected at least annually for compliance with applicable laws and regulations.

(3) Licensure of Drug Wholesalers. All firms handling drugs on a wholesale basis in Minnesota or who are doing business in Minnesota are required to be licensed by the Board. These firms must demonstrate adequate security, temperature and humidity control, sanitation, recordkeeping, and distribution practices at the time of licensing.

Inspection of drug wholesalers are accomplished approximately annually. Attention is given to storage and security capabilities of the firm. Distribution patterns are carefully reviewed to ensure that drugs are sold only to persons legally permitted to possess them. Sanitation is carefully surveyed and environmental control is reviewed.

(4) Licensure of Drug Manufacturers. All firms engaging in the manufacturing, repackaging, or relabeling of drugs are required to be licensed by the Board. At the time of licensure, all firms are required to demonstrate qualification of responsible personnel, records of compliance with drug laws, and equipment and procedures necessary to comply with the good manufacturing procedures of the Food and Drug Administration.

Comprehensive inspections of in-state drug manufacturers are accomplished by the Board's staff on approximately an annual basis. Special attention is given to: source and quality of raw materials; adequacy of building facilities, sanitation, and equipment; design and utilization of master formulas and batch records; manufacturing processes and techniques; in-process security and controls for controlled substances; content and security of labels; packaging control procedures and records; laboratory controls and records; and patterns of distribution of the manufactured product.

(5) Registration of Pharmacist-Interns. Pharmacy students may register as a pharmacist-intern at the end of the third year of the standard five or six year college of pharmacy curricula. Objectives of the internship training program and instructions for performance of pharmacy intern functions and reporting of practical learning experiences are furnished to the interns. Quarterly reports are required of each pharmacy student engaged in the pharmacist-intern practice. Experience as a pharmacist-intern may be obtained in the last two years of the college curriculum and must be commensurate with the interns educational level. Quality of experience is monitored and disciplinary actions taken against pharmacist preceptors or interns who violate internship regulations.

Interns are required to take an internship competency examination prepared by the Board's staff during and at the completion of their internship experience. The examinations are analyzed to show the intern the competency areas in which he/she should strive to gain more experience.

(6) Controlled Substances Regulation. All controlled substances (formerly designated as narcotics or stimulants and depressants) are categorized in M.S. 152 into "Schedules" based on abuse potential. Rescheduling of controlled substances or addition of such substances to one of the existing schedules is accomplished by Board Rule 6800.4200 through 6800.4250. The Board may consult an advisory council on controlled substances on rescheduling proposals and in the consideration of control of newly discovered substances with abuse potential. The Board prescribes recordkeeping requirements for persons authorized to possess controlled substances and will, together with its advisory council, report to the legislature concerning implementation of the Controlled Substances Act and possible amendments to it. This general activity will be perpetual as long as the need for control of such substances with abuse potential exists.

Federal and state drug control activities are coordinated by the Board in a formal agreement with the Federal Drug Enforcement Administration and State Bureau of Criminal Apprehension. This coordination ensures DEA and BCA involvement in "street type" enforcement work and Board of Pharmacy involvement in cases involving illicit drug distribution from any of the various licensed health professionals.

(7) Miscellaneous Drug Control Activities. Investigation of registrants and non-registrants alike for compliance with miscellaneous laws relating to drugs and the provision of special investigative services to other state agencies in the health care and law enforcement areas are involved in Board activities. Other areas of Board activities include:

On-site inspection of distressed drugs which have been subjected to fire, flood, etc., is accomplished by Board staff. Drugs are inspected for evidence of misbranding or adulteration and are embargoed and destroyed if evidence of adulteration or misbranding is present. Similar inspections of distressed drugs which are imported into the state by various salvage companies are performed.

Careless distribution of drug samples is investigated to ensure that all drugs within the state will be distributed legally and safely.

Cases of illegal distribution or possession of hypodermic syringes and needles are investigated.

Compliance with the State Toxic Glue Law is achieved in part by the monitoring of compliance by our licensees.

Special investigations are performed in cooperation with or after requests of other state agencies such as the Department of Health, the Board of Medical Examiners, the Board of Dental Examiners, the Board of Nursing, and the Attorney General.

(8) Registration of Drug Researchers. All individuals seeking to utilize controlled substance drugs in research activities are required to obtain both a state and a federal registration in order to purchase, possess and use these drugs. State registration is carried out through the Board of Pharmacy office and information on these registrants is shared with the federal Drug Enforcement Administration.

(9) Registration of Medical Gas Distributors. Beginning in Fiscal Year 1990, the Board began the registration of those companies engaged in the distribution of prescription medical gases. Certain gaseous substances used for medical purposes are considered "drugs" by FDA. Further, these drugs require a prescriptions for their use. Because of the physical characteristics of gasses, however, they are not dispensed by pharmacies as are other prescription drugs. The Board recently began registering those companies distributing prescription medical gasses to patients and, with the cooperation of FDA, began inspecting these places.

**Clause B: TOTAL NUMBER MEETINGS HELD FY 91 IS 9 MEETINGS, FY 92 IS 10 MEETINGS,  
FY 91 & 92 IS 19 MEETINGS**

BOARD MEMBER'S NAME	TYPE	FY 91	FY 92	FY 91 & 92
Doris Calhoun	Board Meeting	37.5	0	37.5
	Committees	11.5	0	11.5
	Other Meetings	44.5	0	44.5
	Disciplinaries	9	0	9
	Examination	21	0	21
	Grading	1.5	0	1.5
Henry Capiz	Board Meeting	48	49.5	97.5
	Committees	5	3.5	8.5
	Other Meetings	58	36	94
	Disciplinaries	9	6	15
	Examination	36.5	42	78.5
	Grading	6.5	7.5	14
Pat DeLaPointe	Board Meeting	40.5	40.5	81
	Committees	10	2	12
	Other Meetings	54	16	70
	Disciplinaries	9	15	24
	Examination	39	18	57
	Grading	6.5	3.5	10
Patricia Lind	Board Meeting	37.5	0	37.5
	Committees	3	0	3
	Other Meetings	38	0	38
	Disciplinaries	8.5	0	8.5
	Examination	21	0	21
	Grading	2	0	2
George Medich	Board Meeting	35.5	49.5	85
	Committees	0	0	0
	Other Meetings	47	26	73
	Disciplinaries	3.5	6	9.5
	Examination	35.5	43	78.5
	Grading	2	3.5	5.5
Ove Wangenstein	Board Meeting	33.5	52	85.5
	Committees	0	0	0
	Other Meetings	54	38	92
	Disciplinaries	0	8.5	8.5
	Examination	39	29	68
	Grading	7	4	11

Joseph Zastera, Jr.	Board Meeting	32.5	33.5	66
	Committees	3	0	3
	Other Meetings	47	13	60
	Disciplinaries	8.5	7	15.5
	Examination	39	18	57
	Grading	7	3.5	10.5

Denise Groehler	Board Meeting	10.5	58	68.5
	Committees	0	5	5
	Other Meetings	0	39	39
	Disciplinaries	0	8.5	8.5
	Examination	15.5	43	58.5
	Grading	5	7.5	12.5

Carol Peterson	Board Meeting	10.5	57	67.5
	Committees	0	0	0
	Other Meetings	0	39	39
	Disciplinaries	0	0	0
	Examination	15.5	41	56.5
	Grading	5	7.5	12.5

Wendy Simenson	Board Meeting	0	17.5	17.5
	Committees	0	0	0
	Other Meetings	0	28	28
	Disciplinaries	0	0	0
	Examination	0	23	23
	Grading	0	4	4

Howard Juni	Board Meeting	0	17.5	17.5
	Committees	0	0	0
	Other Meetings	0	27	27
	Disciplinaries	0	0	0
	Examination	0	24	24
	Grading	0	4	4

**Summary of FY 91 Budget and Disbursements of Road Fund**

	<b>FY 91</b>	<b>FY 92</b>	<b>FY 91 &amp; 92</b>
<b>Total State Appropriations</b>	<b>485,031</b>	<b>544,000</b>	<b>1,029,031</b>
<b>Total Non-Dedicated Fee Receipts</b>	<b>580,537</b>	<b>632,977</b>	<b>1,213,114</b>
<b>Total Disbursements</b>	<b>484,030</b>	<b>543,998</b>	<b>1,028,028</b>



**Clause d:      LIST OF BOARD MEMBERS WHO SERVED DURING FY 91 AND FY 92**

**For easy reference please give:**

- a) Number of Board members required by statute: 7**
- b) The statutory length of term: 4 years**

<b>NAME AND ADDRESS</b>	<b>OCCUPATION</b>	<b>BEGIN AND END DATE OF APPOINTMENT AND EACH REAPPOINTMENT</b>
Patricia Lind Eden Prairie, MN	Sales Person for office supplies	1/87 - 1/91
Doris A. Calhoun Maplewood, MN	Pharmacist	1/87 - 1/91
Joseph F. Zastera, Jr. Two Harbors, MN	Pharmacist	1/88 - 1/92
Patricia DeLaPointe Hibbing, MN	Pharmacist	1/88 - 1/92
George Medich Cloquet, MN	Pharmacist	1/89 - 1/93
Ove M. Wangenstein Olivia, MN	Retired	1/90 - 1/94
Henry T. Capiz St. Paul, MN	Pharmacist	1/90 - 1/94
Carol Peterson Owatonna, MN	Retired	1/91 - 1/95
Denise M. Groehler Milaca, MN	Pharmacist	1/91 - 1/95
Howard A. Juni White Bear Lake, MN	Pharmacist	1/92 - 1/96
Wendy A. Simenson Ramsey, MN	Pharmacist	1/92 - 1/96

**Clause e:**      **LIST BOARD EMPLOYEES WHO WERE EMPLOYED DURING FY 91 AND/OR FY 92**

NAME	JOB CLASSIFICATION/ TITLE AND CLASS	CLASS CODE	FT	PT	DATES OF SERVICE
David Holmstrom	Executive Director	OUNC	X		12/29/71 to Present
Lloyd Pekas	Pharmacy Surveyor	1347	X		11/7/77 to Present
Judy Sande	Clerk Typist II	0980	X		10/15/87 to Present
Patricia Bellino	Pharmacy Surveyor	1347	X		3/16/88 to Present
Stuart Vandenberg	Pharmacy Surveyor	1347	X		4/26/89 to Present
Patricia Eggers	Office Service Supervisor II	0293	X		3/28/90 to Present
E. Kristen Perry	Clerk Typist IV	0666	X		4/11/90 to Present

**Clause f: BRIEF SUMMARY OF BOARD RULES PROPOSED OR ADOPTED DURING THIS REPORTING PERIOD, FY 91 AND FY 92. GIVE APPROPRIATE CITATIONS TO THE STATE REGISTER AND PUBLISHED RULES FOR THOSE ADOPTED.**

On February 18, 1992, the Minnesota Board of Pharmacy adopted the following changes in its rules.

**DRUG MANUFACTURER OR WHOLESALE LICENSE.**

**6800.1400 DRUG MANUFACTURER OR WHOLESALE LICENSE.**

Subpart 1. Licensing; fees. Every person engaged in manufacturing, wholesale distribution, or selling of drugs, medicines, chemicals, or poisons for medicinal purposes other than to the consuming public or patient shall annually be licensed by the board. Upon the filing of an application, and upon payment of a fee of \$150 for manufacturing or wholesale distribution of prescription drugs only, not including medical gases; \$150 for manufacturing or wholesale distribution of prescription and nonprescription drugs, not including medical gases; \$125 for manufacturing or wholesale distribution of nonprescription drugs or veterinary drugs only; \$100 for manufacturing or wholesale distribution of prescription medical gases only; and \$75 for licensed pharmacies engaged in wholesale distribution, the board may issue or renew a license in such form as it may prescribe to the manufacturer or wholesale distributor. The license shall be exposed in a conspicuous place in the manufacturer's or wholesaler's place of business for which it is issued, shall expire at midnight on June 1 of each year, and shall be renewed annually upon the filing of an application therefor, on or before May 1 of each year together with the applicable fee. Renewal applications received after June 1 shall be subject to a late filing fee of one-half of the renewal fee in addition to the amount of the renewal fee.

Subp. 2. Prohibition. No license may be issued to any manufacturer or wholesale distributor whose intended place of business is a personal residence.

Subp. 3. Separate licenses required. A separate license is required for each separate location where drugs are stored within this state. Out-of-state wholesale drug distributors shipping drugs into Minnesota who do not maintain or operate a physical facility within Minnesota are not required to license each separate location from which drugs are shipped to Minnesota, but may instead obtain licensure for the primary location of the parent entity and any divisions, subsidiaries, or affiliated companies.

**6800.1410 MINIMUM INFORMATION REQUIRED FOR LICENSURE.**

The following information is required from each wholesale drug distributor applying for licensure or renewal:

- A. the name, full business address, and telephone number of the licensee;
- B. all trade or business names used by the licensee;

C. addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of drugs;

D. whether the ownership or operation is a partnership, corporation, or sole proprietorship; and

E. the name of the owner and operator of the licensee, including:

(1) if an individual, the name of the individual;

(2) if a partnership, the name of each partner, and the name of the partnership;

(3) if a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and

(4) if a sole proprietorship, the full name of the sole proprietor, and the name of the business entity.

Changes in any information in items A to E shall be submitted to the board within 30 days of the change.

#### 6800.1420 MINIMUM QUALIFICATIONS.

The board may deny, suspend, revoke, or refuse to renew any license for a wholesale drug distributor based on the board's finding of any of the following factors:

A. any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

B. any felony convictions of the applicant under federal, state, or local law;

C. the lack of previous experience on the part of the applicant in the manufacture or distribution of drugs, including controlled substances;

D. the furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

E. the suspension or revocation by federal, state, or local government bodies of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

F. the lack of compliance by the applicant with licensing requirements under previously granted licenses, if any;

G. the lack of compliance by the applicant with requirements to maintain or make available to the board of pharmacy or to federal, state, or local law enforcement officials those records required under this part; and

H. the lack of compliance by the applicant with requirements for the storage and handling of drugs as specified in part 6800.1440.

#### 6800.1430 PERSONNEL.

Each wholesale drug distributor shall require each person employed in any prescription drug wholesale activity to have enough education, training, and experience, in any combination, sufficient for that person: (1) to do assigned work in a manner that maintains the quality, safety, and security of the drug products in accordance with parts 6800.1400 to 6800.1440; and (2) to assume responsibility for compliance with the licensing requirements of parts 6800.1400 to 6800.1440.

#### 6800.1440 MINIMUM REQUIREMENTS FOR STORAGE AND HANDLING OF DRUGS AND FOR ESTABLISHMENT AND MAINTENANCE OF DRUG DISTRIBUTION RECORDS.

Subpart 1. Application. The minimum requirements in this part apply to all wholesale drug distributors located in this state and to their officers, agents, representatives, and employees.

Subp. 2. Incorporation by reference. "United States Pharmacopeia/National Formulary" means the United States Pharmacopeia/National Formulary published by the United States Pharmacopeial Convention Inc. (Rockville, Maryland, 1990), which is incorporated by reference. The United States Pharmacopeia/National Formulary is subject to frequent change. The book is available for inspection and copying at the Biomedical Library, University of Minnesota, Diehl Hall, 505 Essex Street S.E., Minneapolis, Minnesota 55455, or through the Minitex interlibrary loan system.

Subp. 3. Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

A. be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

B. have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

C. have a physically separate area for storage of all prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

D. be maintained in a clean and orderly condition; and

E. be free from infestation by insects, rodents, birds, or vermin of any kind.

Subp. 4 Security. The requirements in items A to C govern security.

A. All facilities used for wholesale drug distribution shall be secure from unauthorized entry as follows:

(1) access from outside the premises shall be kept to a minimum and be well-controlled;

(2) the outside perimeter of the premises shall be well-lighted; and

(3) entry into areas where prescription drugs are held shall be limited to authorized personnel.

B. All facilities shall be equipped with an alarm system to detect entry after hours.

C. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

**Subp. 5. Storage. Items A to D govern storage of drugs.**

A. All drugs shall be stored at temperatures and under conditions in accordance with the requirements, if any, in the labeling of such drugs, or with requirements in the current edition of the United States Pharmacopeia/National Formulary.

B. If no storage requirements are established for a drug, the drug may be held at "controlled room temperature," as defined in the United States Pharmacopeia/National Formulary, to help ensure that its identity, strength, quality, and purity are not adversely affected.

C. Manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be used to document proper storage of prescription drugs.

D. The record keeping requirements in subpart 8 shall be followed for all stored drugs.

**Subp. 6. Examination of materials.** Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs or drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

The record keeping requirements in subpart 8 shall be followed for all incoming and outgoing drugs.

Subp. 7 Returned, damaged, and outdate drugs. Items A to D govern returned, damaged, outdated, deteriorated, misbranded, and adulterated drugs.

A. Drugs that are damaged, outdated, deteriorated, misbranded, or adulterated shall be physically separated from other drugs until they are destroyed or returned to their supplier.

B. Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be physically separated from other drugs until they are either destroyed or returned to the supplier.

C. If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

D. The record keeping requirements in subpart 8 shall be followed for all damaged, outdated, deteriorated, misbranded, or adulterated drugs.

Subp. 8. Record keeping. Items A to C govern record keeping.

A. Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs. These records shall include the following information:

(1) the source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

(2) the identity and quantity of the drugs received and distributed or disposed of; and

(3) the dates of receipt and distribution or other disposition of the drugs.

B. Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two years following disposition of the drugs.

C. Records described in this part that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of a federal, state, or local law enforcement agency.

Subp. 9. Written policies and procedures. Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of drugs. They must include policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include the written policies and procedures described in items A to D.

A. A procedure where the oldest approved stock of a drug product is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate.

B. A procedure to be followed for handling recalls and withdrawals of drugs. The procedure shall be adequate to deal with recalls and withdrawals due to:

(1) any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the board of pharmacy;

(2) any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(3) any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

C. A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

D. A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated drugs. This documentation shall be maintained for two years after disposition of the outdated drugs.

Subp. 10. Responsible persons. Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

Subp. 11. Compliance with federal, state, and local law. Wholesale drug distributors shall operated in compliance with applicable federal, state, and local laws and regulations.

Wholesale drug distributors shall permit the board of pharmacy and authorized federal, state, and local law enforcement officials to enter and inspect both their premises and delivery vehicles and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.



Wholesale drug distributors who deal in controlled substances shall register with the board of pharmacy and with the Drug Enforcement Administration, and shall comply with all applicable state, local, and Drug Enforcement Administration regulations.

Subp. 12. Salvaging and reprocessing. Wholesale drug distributors are subject to any applicable federal, state, or local laws or regulations that relate to drug product salvaging or reprocessing, including Code of Federal Regulations, title 21, parts 207, 210, and 211, and Minnesota Statutes, section 151.39.

On April 13, 1992, the Minnesota Board of Pharmacy adopted the following changes in its rules.

#### ANNUAL RENEWAL, FEES, AND POSTING.

##### 6800.1150 ANNUAL RENEWAL, FEES, AND POSTING.

Each pharmacist license shall expire on March 1 of each year and shall be renewed annually by filing an application for license renewal on or before February 1 of each year, together with a fee of \$75. Any pharmacist license renewal application submitted after March 1 shall be subject to a late filing fee of an amount equal to 50 percent of the renewal fee in addition to the renewal fee.

Each pharmacist shall post the license or renewal in a conspicuous place within the pharmacy in which the pharmacist is practicing. For community pharmacies, this place shall be a place which is readily visible to the public.

##### 6800.1250 APPLICATIONS FOR LICENSURE.

Subpart 1. Submitting. Applicants for licensure by examination shall submit a completed application for examination including affidavits of internship, a copy of applicant's birth certificate, and a recent photograph. All applicants shall show evidence of graduation with a bachelor of science degree or doctor of pharmacy degree, as the first professional undergraduate degree in pharmacy, from a college of pharmacy or a department of pharmacy of a university approved by the board and meeting at least the minimum standards set by the American Council on Pharmaceutical Education in the current edition of its accreditation manual. The evidence shall be shown by submitting an official final transcript showing the date on which degree was conferred. The above listed documents together with a check for \$250 must be submitted to the board at least 45 days prior to the examination. An applicant who is a graduate of a school or college of pharmacy located outside the United States, which has not been recognized and approved by the board, but who is otherwise qualified to apply for a license to practice pharmacy in this state, is considered to have

satisfied the requirements of graduation if the applicant verifies to the board the applicant's academic record and the applicant's graduation. Before taking the licensing examination, a foreign graduate applicant shall pass the Foreign Pharmacy Graduate Equivalency Examination, which is recognized and approved by the board, given by the Foreign Pharmacy Graduate Examination Commission and demonstrate proficiency in the English language by passing the Test of English as a Foreign Language, which is recognized and approved by the board, given by the Educational Testing Service as a prerequisite to taking the licensure examination.

Subp. 2. Retaking exam. Any applicant who has failed to pass the examination required by Minnesota Statutes, section 151.06, 151.07, 151.10, or 151.12, may retake the examination within the next ensuing 14 months, provided that no applicant who has failed in three examinations shall be permitted to take a further examination, except upon petition setting forth facts acceptable to the board. The applicant shall, at least 45 days before an examination, notify the board in writing of the intention to retake the examination, certifying that information furnished on the original application remains true and correct, or reporting any changes therein, including additional education and experience, and shall submit a fee of \$250 payable to the Minnesota Board of Pharmacy. The board reserves the right to request a full and complete application.

#### 6800.1300. RECIPROCITY.

Subpart 1. Applications. Applications for reciprocal licensure (licensure as a pharmacist on the basis of licensure as a pharmacist in another state) together with a fee of \$175 shall be filed with the secretary of the board at least 30 days before the date the application is to be considered by the board. The board will consider applications for reciprocity in at least January and June of each calendar year.

**Clause g:**

**LIST THE NUMBER OF PERSON HAVING EACH TYPE OF LICENSE AND  
REGISTRATION ISSUED BY THE BOARD AS OF JUNE 30, 1992 (IN THE YEAR  
OF THE REPORT)**

TYPE OF LICENSE/REGISTRATION	TOTAL NUMBER IN EFFECT
Pharmacist	4,912
Pharmacy	1,213
Drug Wholesaler	357
Drug Manufacturer	201
Drug Researcher	69
Pharmacist-Intern	372
Medical Gas Distributors	28

**Clause h:        ADMINISTRATION OF EXAMINATIONS BY BOARD**

LOCATION	TYPES OF LICENSE/REGISTRATION	DATES	TYPE OF EXAM
Radisson University	Pharmacist/Reciprocity	10/30/90	Written, Oral
Radisson University	Pharmacist/Reciprocity	1/22/91	Written/Oral
Radisson University	Pharmacist/Examination	1/22/91	Written
Radisson University UofM College of Phcy.	Pharmacist/Examination	1/23/91	Written Practical
Radisson University	Pharmacist/Reciprocity	4/3/91	Written/Oral
MN Dept. of Health	Pharmacist/Reciprocity	6/25/91	Written/Oral
Radisson University	Pharmacist/Examination	6/25/91	Written
Radisson University UofM College of Phcy.	Pharmacist/Examination	6/26/91	Written Practical
MN Dept. of Health	Pharmacist/Reciprocity	10/15/91	Written/Oral
MN Dept. of Health	Pharmacist/Reciprocity	1/28/92	Written/Oral
Radisson University	Pharmacist/Examination	1/28/92	Written
Radisson University UofM College of Phcy.	Pharmacist/Examination	1/29/92	Written Practical
Sheraton-Midway Hotel	Pharmacist/Reciprocity	4/8/92	Written/Oral
Sheraton-Midway Hotel	Pharmacist/Reciprocity	6/23/92	Written/Oral
Radisson University	Pharmacist/Examination	6/23/92	Written
Radisson University UofM College of Phcy.	Pharmacist/Examination	6/24/92	Written Practical

**Clauses 1. j. k: MINNESOTA RESIDENTS BY TYPE OF LICENSE/REGISTRATION**

**Type of License/Registration: Pharmacist**

**FY 91**

Age Group	Male	Female	Total
18 - 25	15 Passed 0 Failed	26 Passed 6 Failed	41 Passed 6 Failed
26 - 34	6 Passed 1 Failed	12 Passed 1 Failed	18 Passed 2 Failed
35 - 59	2 Passed 0 Failed	5 Passed 0 Failed	7 Passed 0 Failed

**FY 92**

Age Group	Male	Female	Total
18 - 25	19 Passed 0 Failed	32 Passed 1 Failed	51 Passed 1 Failed
26 - 34	16 Passed 1 Failed	15 Passed 2 Failed	31 Passed 3 Failed
35 - 59	1 Passed 0 Failed	5 Passed 1 Failed	6 Passed 1 Failed

**FY 91 & 92**

Age Group	Male	Female	Total
18 - 25	34 Passed 0 Failed	58 Passed 7 Failed	92 Passed 7 Failed
26 - 34	22 Passed 2 Failed	27 Passed 3 Failed	49 Passed 5 Failed
35 - 59	3 Passed 0 Failed	10 Passed 1 Failed	13 Passed 1 Failed

Clauses 1. 1. k:      NON-MINNESOTA RESIDENTS BY TYPE OF LICENSE/REGISTRATION

Type of License/Registration: Pharmacist

**FY 91**

Age Group	Male	Female	Total
18 - 25	20 Passed 4 Failed	38 Passed 7 Failed	58 Passed 11 Failed
26 - 34	17 Passed 6 Failed	35 Passed 6 Failed	52 Passed 12 Failed
35 - 59	18 Passed 4 Failed	6 Passed 3 Failed	24 Passed 7 Failed
60 - 65	0 Passed 0 Failed	0 Passed 0 Failed	0 Passed 0 Failed

**FY 92**

Age Group	Male	Female	Total
18 - 25	20 Passed 2 Failed	44 Passed 6 Failed	64 Passed 8 Failed
26 - 34	18 Passed 5 Failed	30 Passed 5 Failed	48 Passed 10 Failed
35 - 59	15 Passed 7 Failed	4 Passed 1 Failed	19 Passed 8 Failed
60 - 65	0 Passed 0 Failed	0 Passed 0 Failed	0 Passed 0 Failed

**FY 91 & 92**

Age Group	Male	Female	Total
18 - 25	40 Passed 6 Failed	82 Passed 13 Failed	122 Passed 19 Failed
26 - 34	35 Passed 11 Failed	65 Passed 11 Failed	100 Passed 22 Failed
35 - 59	33 Passed 11 Failed	10 Passed 4 Failed	43 Passed 15 Failed
60 - 65	0 Passed 0 Failed	0 Passed 0 Failed	0 Passed 0 Failed

## Total number of non-residents by state

FY 91:

STATE	MALE		FEMALE		TOTAL	
	PASSED	FAILED	PASSED	FAILED	PASSED	FAILED
AL	0	0	0	1	0	1
AZ	5	0	1	0	6	0
CA	1	0	0	0	1	0
CO	3	0	1	0	4	0
CT	0	0	2	0	2	0
GA	1	0	1	0	2	0
IL	4	1	3	1	7	2
IN	3	2	2	0	5	2
IA	3	0	6	1	9	1
KS	1	1	0	0	1	1
MD	1	0	1	1	2	1
MA	0	0	2	1	2	1
MI	2	2	3	0	5	2
MO	1	0	1	1	2	1
MT	0	0	1	0	1	0
NE	2	3	3	0	5	3
NV	1	0	0	0	1	0
NY	0	0	3	1	3	1
ND	12	2	32	5	44	7
OH	1	0	1	0	2	0
OR	0	0	1	0	1	0
PA	1	1	0	0	1	1
SD	6	0	5	1	11	1
TX	3	1	2	0	5	1
TN	1	0	0	0	1	0
WA	1	0	1	0	2	0
WI	3	1	4	2	7	3
WY	2	0	0	0	2	0
Foreign	0	0	0	2	0	2

FY 92:

STATE	MALE		FEMALE		TOTAL	
	PASSED	FAILED	PASSED	FAILED	PASSED	FAILED
AL	0	0	1	0	1	0
AZ	3	0	3	1	6	1
CA	1	1	0	0	1	1
CT	0	0	1	0	1	0
GA	0	0	1	0	1	0
ID	0	0	1	0	1	0
IL	1	1	3	0	4	1
IN	2	1	2	0	4	1
IA	7	4	7	3	14	7
KY	0	1	2	0	2	1
MA	1	1	2	0	3	1
MI	1	0	3	1	4	1
MO	0	0	3	1	3	1
MT	1	0	1	0	2	0
NE	0	0	2	2	2	2
NJ	0	0	1	0	1	0
NV	0	0	1	0	1	0
NY	0	0	1	0	1	0
ND	16	2	19	1	35	3
OH	0	0	1	0	1	0
PA	1	0	1	0	2	0
PR	0	0	1	0	1	0
SC	1	0	1	0	2	0
SD	3	3	7	1	10	4
TN	1	0	0	0	1	0
UT	0	0	1	1	1	1
VA	0	0	2	0	2	0
WA	0	0	1	1	1	1
WV	0	0	1	0	1	0
WI	9	0	7	1	16	1
WY	2	0	0	0	2	0
Foreign	0	0	1	0	1	0



STATE	MALE		FEMALE		TOTAL	
	PASSED	FAILED	PASSED	FAILED	PASSED	FAILED
AL	0	0	1	1	1	1
AZ	8	0	4	1	12	1
CA	2	1	0	0	2	1
CO	3	0	1	0	4	0
CT	0	0	3	0	3	0
GA	1	0	2	0	3	0
ID	0	0	1	0	1	0
IL	5	2	6	1	11	3
IN	5	3	4	0	9	3
IA	10	4	13	4	23	8
KS	1	1	0	0	1	1
KY	0	1	2	0	2	1
MA	1	1	4	1	5	2
MD	1	0	1	1	2	1
MI	3	2	6	1	9	3
MO	1	0	4	2	5	2
MT	1	0	2	0	3	0
NE	2	3	5	2	7	5
NJ	0	0	1	0	1	0
NV	1	0	1	0	2	0
NY	0	0	4	1	4	1
ND	28	4	51	6	79	10
OH	1	0	2	0	3	0
OR	0	0	1	0	1	0
PA	2	1	1	0	3	1
PR	0	0	1	0	1	0
SC	1	0	1	0	2	0
SD	9	3	12	2	21	5
TN	2	0	0	0	2	0
TX	3	1	2	0	5	1
UT	0	0	1	1	1	1
VA	0	0	2	0	2	0
WA	1	0	2	1	3	1
WV	0	0	1	0	1	0
WI	12	1	11	3	23	4
WY	4	0	0	0	4	0
Foreign	0	0	1	2	1	2

**Clause 1:**

**THE NUMBER OF PERSONS NOT TAKING EXAMINATIONS WHO WERE LICENSED OR REGISTERED BY THE BOARD OR WHO WERE DENIED LICENSING OR REGISTRATION WITH THE REASONS FOR THE LICENSING OR REGISTRATION OR DENIAL THEREOF.**

**Total number of persons not taking exams and granted licenses or registration:**

FY 91 = None  
FY 92 = None  
FY 91 & 92 = None

**Total number of persons not taking exams and denied licenses or registration:**

FY 91 = None  
FY 92 = None  
FY 91 & 92 = None

**Clause m:**

PERSONS PREVIOUSLY LICENSED OR REGISTERED BY THE BOARD WHOSE LICENSES OR REGISTRATIONS WERE REVOKED, SUSPENDED OR OTHERWISE ALTERED IN STATUS, WITH BRIEF STATEMENTS OF THE REASONS FOR THE REVOCATION, SUSPENSION OR ALTERATIONS.

	FY 91	FY 92	FY 91 & 92
TOTAL number of revocations	106	70	176
TOTAL number of suspensions	1	5	6
TOTAL number of other status changes	23	25	48

Type of license or registration: All cases involved pharmacists.

TYPE OF STATUS CHANGE

REVOKED	SUSPENDED	OTHER (SPECIFY)	REASON FOR CHANGE
176			Non-payment of Fees
	3		Chemical Dependency
	2		Recordkeeping
	1		Unprofessional Conduct/ Recordkeeping/Chemical Dependency
		2 Suspension-Stayed	Chemical Dependency
		1 Suspension-Stayed	Staffing/Recordkeeping
		1 Probation	Unprofessional Conduct/ Poor Recordkeeping
		2 Probation	Unprofessional Conduct
		6 Probation	Chemical Dependency
		1 Probation	Misbranding Drugs
		3 Probation	Recordkeeping
		1 Probation	Theft of Controlled Substances
		1 Probation	Recordkeeping/Chemical Dependency
		1 Probation	Staffing/Recordkeeping

1 Warning Letter	Unprofessional Conduct
3 Off Suspension	Chemical Dependency
1 Off Suspension	Voluntary Surrender of License
1 Off Suspension	Unprofessional Conduct/ Recordkeeping/Chemical Dependency
2 Off Suspension	Recordkeeping
1 Off Suspension	Unprofessional Conduct/ Poor Recordkeeping
1 Off Suspension	Non-Renewal of License/ Violation of Probation
1 Off Probation	Drug Abuse
5 Off Probation	Chemical Dependency
8 Off Probation	Unprofessional Conduct
1 Off Probation	Chemical Dependency/ Theft of Drugs
2 Off Probation	Welfare Fraud
1 Off Probation	Practicing without a License
1 Off Probation	Unprofessional Conduct/ Poor Recordkeeping

Clause n:

LIST THE NUMBER OF COMPLAINTS AND OTHER COMMUNICATIONS RECEIVED  
BY THE EXECUTIVE DIRECTOR, EACH BOARD MEMBER, EMPLOYEE OR OTHER  
PERSON PERFORMING SERVICES FOR THE BOARD

That allege or imply a violation of a statute or rule which the Board is empowered to enforce. These totals include cases referred to the attorney general's staff who are assigned to assist your board.

	FY 91	FY 92
Written	47	61
Oral	2	5

Which are forwarded to other agencies as required by M.S. 214.10.

	FY 91	FY 92
Written	14	12
Oral	0	0

Please indicate the number of complaints referred to each other governmental agency (federal, state and local) in each fiscal year:

	FY 91	FY 92
Medical Board	13	8
Dental Board	1	2
Nursing Board		1
Chiropractic Board		1

**Clause o:**

**SUMMARIZE, BY SPECIFIC CATEGORY, THE SUBSTANCE OF THE COMPLAINTS AND COMMUNICATIONS REFERRED TO IN CLAUSE (N) OF M.S. 214.07 AND, FOR EACH SPECIFIC CATEGORY, THE RESPONSES OR DISPOSITIONS THEROF PURSUANT TO M.S. 214.10 AND 214.11 (INDICATE AUTHORITY/CITATIONS FOR DISPOSITION).**

**SUMMARY OF COMPLAINTS AND COMMUNICATIONS  
BY SPECIFIC CATEGORY.**

**SUMMARY OF RESPONSES AND  
DISPOSITION FOR EACH SPECIFIC  
CATEGORY**

**54 Prescription Errors**

All complaints investigated, no disciplinary action taken. All pharmacists were subject to educational sessions as per 214.10

**23 Unprofessional Conduct**

Dismissed (214.10)

**7 Pricing Issues**

Dismissed (214.10)

**2 Labeling errors**

Dismissed (214.10)

**6 Billing errors**

Dismissed (214.10)

**2 No Pharmacist On Duty**

Dismissed (214.10)

**2 Chemical Dependency**

Dismissed (214.10)

**2 Advertising**

Dismissed (214.10)

**4 Outdated Drugs**

Dismissed (214.10)

**5 Unauthorized Refills**

Dismissed (214.10)

**1 Improper Use of Supportive Personnel**

Dismissed (214.10)

**Clause p:**      **STATE ANY OTHER OBJECTIVE INFORMATION WHICH THE BOARD MEMBERS BELIEVE WILL BE USEFUL IN REVIEWING BOARD ACTIVITIES.**

Many warning letters (over 100) were written and several formal disciplinary actions took place as a result of inspections by our staff.

1. An informal, but yet effective, sharing of information is in effect between the health licensing boards. With all health licensing boards located in the same building, communication is continually on-going.
2. Minnesota Board of Pharmacy participates in a national disciplinary clearing house mediated through the National Association of Boards of Pharmacy.

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FOR ALL HEALTH CARE PROVIDERS. REPORT THE BOARD OF HEALTH  
IMMEDIATELY. THE H.S.A. 1984 REGULATIONS, SECTION 213.10, SUBD. 1(2);  
ISSUE A SUMMARY OF EACH INDIVIDUAL CASE (COMPLAINT OR OTHER  
COMMUNICATION) THAT INVOLVED POSSIBLE SEXUAL CONTACT OF A  
LICENSEE WITH A PATIENT OR CLIENT

None.