## LEGISLATIVE BILL 476

Approved by the Governor May 9, 1983

Introduced by Warner, 25, Kilgarin, 7; H. Peterson, 35; Goodrich, 20; L. Johnson, 15; Kahle, 37; Marsh, 29; Morehead, 30; Wagner, 41

AN ACT relating to public health and welfare; to change provisions relating to the Board of Examiners in Pharmacy; to change provisions relating to examinations and licensing of pharmacists; to development provide for professional of pharmacists; to require inspections of pharmacies; to define and redefine terms; to create a committee; to permit hospital pharmacy technicians to perform certain functions; to change provisions relating to permits to conduct pharmacies; to provide duties for the Department of Health; to change provisions relating to drug production selection; to eliminate a provision which terminates the Board of Examiners in Pharmacy: to amend sections 71-113, 71-116, 71-130, 71-131, 71-140, 71-1,142, 71-1,143, 71-1,145, 71-1,147, 71-1,147.01, 71-1,147.03, 71-1,147.08, 71-1,147.09, 71-5401 to 71-5404, and 71-5407, Reissue Revised Statutes of Nebraska, 1943, and section 81-197, Reissue Revised Statutes of Nebraska, 1943, as amended by section 1, Legislative Bill 413, Bighty-eighth Legislature, First Session, 1983; to repeal the original sections; and to declare an emergency.

Be it enacted by the people of the State of Nebraska,

Section 1. That section 71-113, Reissue Revised Statutes of Nebraska, 1943, be amended to read as follows:

71-113. (1) Each board of examiners shall consist of three members, except that (a) in audiology and speech pathology the board shall consist of four members, (b) in dentistry the board shall consist of seven members, (c) in medicine and surgery the board shall consist of six members, and (d) in embalming and

funeral directing the board shall consist of four members, including one lay person appointed by the Department of Health, and (e) in pharmacy the board shall consist of five members including one lay member. Notwithstanding any other provision of law, the Department of Health may appoint one additional member, who shall be a lay member, to any board of examiners in accordance with the provisions of section 71-114.

(2) Membership on the Board of Examiners in Audiology and Speech Pathology shall consist of two members who are audiologists and two members who are speech pathologists. All members shall be qualified to be licensed in accordance with the provisions of this act. The members appointed to the initial board shall be licensed not later than six months after being appointed to the board. If for any reason a member cannot be licensed within such time period, a new member shall be appointed.

Sec. 2. That section 71-116, Reissue Revised Statutes of Nebraska, 1943, be amended to read as

follows:

71-116. (1) The members of each board of examiners shall be appointed for a term of three years, except that on or after November 1, 1979, the members of each board of examiners shall be appointed for a term of five years and no member shall be appointed for or serve for more than two consecutive full five-year terms.

(2) The members of the Board of Examiners in Dentistry shall be appointed as follows: As of December 1, 1971, one member shall be appointed for a term of five years and one member shall be appointed for a term of three years; as of December 1, 1972, one member shall be appointed for a term of three years; as of December 1, 1973, one member shall be appointed for a term of three years; and as of December 1 of each year thereafter, two members shall be appointed for a term of five years; and as of December 1, 1979, one member, who is a duly licensed dental hygienist and complies with the provisions of sections 71-114 and 71-115 shall be appointed for a term of five years. The dental hygienist member shall have full voting rights, except in matters pertaining to the initial or continuing licensure or competency of a duly licensed practitioner of dentistry. Thereafter successors with like qualifications shall be appointed for five-year terms. No member shall be appointed for or serve for more than two consecutive full five-year terms.

(3) The members of the Board of Examiners in Medicine and Surgery shall be appointed as follows: Within thirty days after May 25, 1943, five members shall be appointed, one of whom shall hold office until December 1, 1944, one until December 1, 1946, one until December 1, 1947, and one

until December 1, 1948; upon the expiration of said several terms, successors shall be appointed for terms of five years each. Within thirty days after October 19, 1963, a sixth member, who shall be a person eligible for appointment to the Board of Examiners in Osteopathy who also has a license to practice medicine and surgery in the State of Nebraska, shall be appointed for a term expiring on December 1, 1968. Thereafter successors with like qualifications shall be appointed for five-year terms. Upon the expiration of the five-year term of such sixth member of the board after August 30, 1981, his or her eligible successor shall be a person who has a license to practice medicine and surgery and a license to practice osteopathy in the State of Nebraska.

license to practice osteopathy in the State of Nebraska.

(4) The members of the Board of Examiners in Audiology and Speech Pathology shall consist of two audiologists and two speech pathologists and shall be appointed as follows: Within sixty days after July 22, 1978, four members shall be appointed, two of whom shall hold office until December 1, 1979, and two until December 1, 1980. Upon the expiration of such terms the successors shall be appointed for terms of five years each. No member shall be appointed for or serve for

more than two consecutive five-year terms.

15) As of December 1, 1983, the Board of Examiners in Pharmacy shall be composed of five members, in Pharmacy shall be composed of five members, in Pharmacy shall be composed of five members, in Pharmacy shall, and a lay member who is interested in the health of the people of Nebraska and is of the age of majority. The members of the Board of Examiners in Pharmacy shall be appointed as follows: As of December 1, 1983, the hospital pharmacist member shall be appointed for a term of five years and the lay member shall be appointed for a term of three years. Upon the expiration of such terms and the terms of existing members, all successors shall be appointed for terms of five years each.

the terms of existing members, all successors shall be appointed for terms of five years each.

(5) (6) The term of each examiner provided for herein shall commence on the first day of December, following the expiration of the term of the member whom such person succeeds, and shall be rotated in such a manner that no more than one examiner shall retire during any year in which a term expires unless the number of members on a board makes it impractical to do

so.

(6) (7) The members of boards for professions, coming under the scope of sections 71-101 to 71-1,196, for the first time shall be appointed within thirty days after the effective date of the act providing for licensing of the profession, the terms of the initial board members to be as follows: One member shall hold office until December 1 of the third year, one until December 1 of the fourth year, and one until December 1

of the fifth year following the year in which the act providing for licensing of the profession became effective.

Sec. 3. That section 71-130, Reissue Revised Statutes of Nebraska, 1943, be amended to read as follows:

71-130. Prior to each examination the Department of Health shall prepare a list of applicants who are eligible to take that examination. In determining such the eligibility requirements to be met for examination, the department shall consult the secretary of the proper board of examiners, or any member thereof.

Sec. 4. That section 71-131, Reissue Revised Statutes of Nebraska, 1943, be amended to read as follows:

71-131. (1) In the absence of any specific requirement or provision relating to any particular profession:

(a) The Department of Health may adopt and promulgate rules and regulations pertaining to the grading of examination papers;

(b) An examinee must obtain an average grade of seventy-five per cent;

(c) An examinee must obtain a grade of sixty per cent in each subject in which examined; and

(d) An examinee who fails to comply with subdivisions (b) and (c) of this subsection may take the entire examination over without charge at any time within fourteen months, except that in the case in which a national standardized examination is utilized by any examining board, which requires the payment of a fee to purchase such examination, the Department of Health shall require the applicant to pay the appropriate examination fee.

(2) In pharmacy, the Board of Examiners in Pharmacy shall prepare rules requiring examinations and grading of examination papers. In the absence of any definite provision relating to grades established by rule of such board, all applicants shall be required to attain an average grade of seventy-five per cent, and not to fall below a grade of sixty per cent in any one subject, except the examination in practical pharmacy, in which a grade of seventy-five per cent must be attained. When an applicant falls below sixty per cent in any but two subjects, except the examination in practical pharmacy, the applicant may take those two over without charge at any time within fourteen months at any regular session of such board held for the purpose of giving examinations, or at the first regular session of the board held for the purpose of giving examinations thereafter, if not held within that time. If an applicant falls below sixty per cent in more than

two subjects, except the examination in practical pharmacy, or if the applicant fails to attain an average grade of seventy-five per cent in all subjects and a grade of seventy-five per cent in the examination in practical pharmacy, the applicant shall take the entire examination over, and may do this without charge at any time within fourteen months at any regular session of the board held for the purpose of giving examinations, or at the first regular session of the board held for the purpose of giving examinations thereafter if not held within that time. Notwithstanding any provision of this section, whenever the Board of Examiners in Pharmacy utilizes a national standardized examination, which requires the payment of a fee to purchase such examination, the Department of Health shall require the applicant to pay the appropriate examination fee.

(3) In medicine and surgery the passing grade shall be determined by the department upon recommendation of the Board of Examiners in Medicine and Surgery. Fees for reexamination shall be determined by the department upon recommendation of the Board of

Examiners in Medicine and Surgery.
Sec. 5. That section 71-140, Reissue Revised Statutes of Nebraska, 1943, be amended to read as follows:

71-140. The Board of Examiners in Pharmacy may in its discretion register recommend to the Department of Health the registration as a pharmacist, without examination, of any person who is duly so registered by examination in some other state in which, under like conditions, reciprocal registration as a pharmacist, without examination, is granted to pharmacists duly registered by examination in this state. The applicant shall produce evidence satisfactory to the board of having had the required secondary and professional education and training, and is being possessed of good character and morals, as demanded of applicants for registration under the provisions of the Nebraska Pharmacy Law. Persons of good character who have become registered as pharmacists by examination in other states prior to September 1, 1939, shall be required to meet only the requirements which existed in this state at the time when they became registered in such other state.

71-1,142, Sec. 6. That section Reissue Revised Statutes of Nebraska, 1943, be amended to read as follows:

71-1,142. As used in this act and section 8 of this act, unless the context otherwise requires:

(1) Practice of pharmacy shall mean (a)

interpretation and evaluation of prescription (b) the compounding, dispensing, and labeling of drugs and devices, except labeling by a manufacturer, packer,

or distributor of nonprescription drugs and commercially packaged legend drugs and devices; (c) the participation in drug selection, drug utilization review, drug source selection, and drug administration; (d) the proper and safe storage of drugs and devices and the maintenance of proper records therefor; (e) the responsibility for advising, when necessary or when regulated, of therapeutic values, content, hazards, and use of drugs and devices; and (f) the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of pharmacy; (a) the preparing, compounding, and dispensing of drugs and medicinal substances, upon the written or oral order of a medical practitioner; (b) the proper and safe storage and distribution of drugs and medicinal substances to the ultimate user; (c) maintenance of proper records; and (d) the relating of pharmaceutical information concerning such drugs and medicinal substances and their therapeutic values, as a consultant, upon request, and within the limits of professional judgment;

(2) Administration shall mean giving a dosage

unit of a drug to a patient;

(3) Board of pharmacy or board shall mean the

Board of Examiners in Pharmacy;

(4) Deliver or delivery shall mean the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for consideration:

(5) Device shall mean an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory, which is required under federal or state law to be prescribed by a medical practitioner and dispensed by a pharmacist;

16) Dispense or dispensing shall mean the preparation and delivery of a prescription drug pursuant to a lawful order of a medical practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug;

(7) Distribute shall mean the delivery of a

drug other than by administering or dispensing;

(8) Person shall mean an individual, corporation, partnership, association, or other legal entity:

(9) Labeling shall mean the process of preparing and affixing of a label to any drug container, exclusive of the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label shall include all information required by federal and state law or regulation;

(a) is engaged in the business of selling, offering or exposing for sale, drugs and medicinal substances at retail licensed by the State of Nebraska to practice pharmacy; (b) compounds or dispenses drugs and medicines, or fills the prescriptions of medical practitioners; or (c) advertises Brugs, Brug Store, Pharmacy, Apothecary, Hospital Pharmacy, Bispensary drugs, drug store, pharmacy, apothecary, hospital pharmacy, dispensary, or any combination of such titles, or any title or description of like import;

(3) flll Pharmacy shall mean (a) any establishment, place, or location, which is advertised as a Pharmacy, Brug Store, Apothecary pharmacy, drug store, apothecary, or any establishment where the practice of pharmacy is carried on except as exempted in section 71-1,143; and (b) any establishment, place, or location which is used as a pick-up point, or drop point, including klosks, for prescriptions to be filled or where prescription medication is made ready for

delivery to the patient;

(4) (12) Drugs, medicines, and medicinal substances, shall mean all poisonous, dangerous, or deleterious substances and preparations for external or internal use, and (a) articles recognized in the official United States Pharmacopoeia, the Homeopathic Pharmacopoeia of the United States, the official National Pormulary, or any supplement to any of them; (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in manhumans; (c) articles, except food, intended to affect the structure or any function of the human body; of man; and (d) articles intended for use as a component of any articles specified in subdivision (a), (b), or (c) of this subdivision, except any device or its components, parts, or accessories, and except patent and proprietary medicines;

(5) (13) Medical practitioner shall mean any licensed physician, surgeon, podiatrist, dentist, or other person licensed to write prescriptions intended for treatment or prevention of disease or body function

in man; and humans;

pharmacist in charge shall mean a pharmacist licensed by the State of Nebraska to practice pharmacy who has been designated on a pharmacy permit or designated by a public or private hospital licensed by the Department of Health as being responsible for the practice of pharmacy in the pharmacy for which such permit is issued or such hospital's inpatient pharmacy;

practice of pharmacy in the pharmacy for which such permit is issued or such hospital's inpatient pharmacy;

(6) (15) Pharmacy intern shall mean a student currently enrolled in, or a graduate of, an accredited college or school of pharmacy serving his or her internship. Such pharmacy intern may compound and

dispense drugs and medicines and fill prescriptions only in the presence of and under the immediate personal supervision of a registered <u>licensed</u> pharmacist who must

supervision of a registered licensed pharmacist who must either be the person to whom the pharmacy permit is issued or in the actual employ of the permittee; 
(16) Prescription drug or legend drug shall mean a drug which under federal law is required, prior to being dispensed or delivered, to be labeled with either of the following statements: (a) Caution rederial law problems dispensing without prescription. Federal law prohibits dispensing without prescription, or (b) Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian; or a drug which is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by medical practitioners only;

(17) Prescription drug order or prescription shall mean a lawful written or verbal order of a medical

practitioner for a drug;

(18) Nonprescription drugs shall mean nonnarcotic medicines or drugs which may be sold without a prescription and which are prepackaged for use by the consumer and labeled in accordance with the requirements of the laws and regulations of this state and the federal government; and

(19) Supportive pharmacy personnel shall mean any individual who is trained and qualified, according to the written standards of the employing hospital inpatient pharmacy, to perform routine pharmacy functions, under the supervision of a pharmacist, which do not require the use of professional in connection with the preparation and judgment, distribution of medications.

Sec. 7. That section 71-1,143, Reissue Revised Statutes of Nebraska, 1943, be amended to read

as follows:

71-1,143. Sections 71-1,142 and 71-1,147

shall not be construed to include persons who:

 Sell, offer or expose for sale, denatured alcohol or concentrated lye, completely denatured

insecticides, and fungicides in original packages;
(2) Are medical practitioners who dispense drugs and medicines as an incident to the practice of their profession but shall not exempt such practitioner, other than a licensed veterinarian who regularly engages in dispensing such medicinal substances to his <u>or her</u> patients for which such patients are charged either separately or for other professional with together charges services, from obtaining a pharmacy permit and complying with all recordkeeping, record-keeping, dispensing, labeling, and all other requirements of the practice of pharmacy as set forth in this act or by federal and state laws as they pertain to the regulation of the

practice of pharmacy; such regular and routine dispensing shall not be considered to be incident to practice, nor may such a practitioner delegate such dispensing to any other person:

(3) Sell, offer or expose for sale, patent nonprescription drugs, or proprietary medicines, the sale of which is not in itself a violation of the law

relating to intoxicating liquors;

(4) are licensed physicians in any village where there is no registered pharmacist;

(5) Persons (4) Are known as medical representatives, detail men persons, or by some name of like import, but only to the extent of permitting the relating of pharmaceutical information as set forth in section 74-1,142, subsection (1), subdivision (d) to health care practitioners; and

(6) (5) Are licensed veterinarians. Sec. 8. (1) Any hospital inpatie Sec. 8. (1) Any hospital inpatient pharmacy
may employ supportive pharmacy personnel to perform
tasks not requiring professional judgment to assist in
the preparation, compounding, distribution, and
dispensing of medications, including, but not limited
to: Maintaining patient medication records; setting up,
packaging, and labeling medication doses; filling and
dispensing routing orders for stock supplies: dispensing routine orders for stock supplies; and mixing, labeling, and preparing drugs with parentheral fluids. The pharmacist in charge shall be responsible for the practice of pharmacy and supportive pharmacy personnel in the hospital. Supportive pharmacy personnel employed by the hospital shall be under the supervision of a licensed pharmacist.

Written control procedures and quidelines 121\_ the supervision of supportive pharmacy personnel by registered pharmacists shall be established by the pharmacist in charge of any hospital inpatient pharmacy which employs supportive pharmacy personnel. Such quidelines shall be subject to periodic review by the

board or its representatives.

(3) The board may review and approve written control procedures and quidelines for the use of supportive pharmacy personnel in all hospital inpatient

pharmacies which employ them.

(4) (a) If supportive pharmacy personnel in a hospital perform functions not specified in this section or under other control procedures and quidelines or perform functions without supervision, and such acts are known to the pharmacist in charge or are of such a nature that they should have been known to a reasonable person, they may be considered acts of unprofessional conduct on the part of the pharmacist in charge pursuant to section 71-147 against whom disciplinary measures may be taken.

(b) Acts described in subdivision (a) of this

subsection may be grounds for the Department of Health, upon the recommendation of the board, to apply to the district court in the judicial district in which the hospital is located for an order to cease and desist from the performance of any unauthorized acts. On such application, or at any time after such application, such court may, in its discretion, issue an order restraining such hospital or its agents or employees from the performance of unauthorized acts. After a full hearing the court shall either grant or deny the application. Such order shall continue until the court, after a like hearing, finds the basis for such order has been removed.

Sec. 9. (1) Commencing in 1984, standards for relicensure for each pharmacist within the State of Nebraska shall require that such pharmacist biennially complete thirty hours of continuing education, as prescribed in sections 9 to 13 of this act.

(2) As used in sections 9 to 13 of this act,

unless the context otherwise requires:

one or more of the general areas of socioeconomic, administrative, managerial, and legal aspects of health care; the properties and actions of drugs and dosage forms; etiology; characteristics and therapeutics of the disease state; and related topics appropriate to the pharmacist in his or her role which are offered by an approved provider but not part of a formal degree program. The activity shall be a planned learning experience designed to promote the continual development of knowledge, skills, and attitudes on the part of the practitioner;

(b) Approved provider shall mean an institution or organization meeting the same quality standards as those established in the Criteria for Quality of the American Council on Pharmaceutical Education:

(c) Continuing education unit shall mean tencontact hours of participation in an organized continuing education experience, under responsible sponsorship, capable direction, and qualified instruction as defined by the American Council on Pharmaceutical Education;

(d) Board shall mean the Board of Examiners

in Pharmacy:

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(e) Department shall mean the Department of Health; and (f) Committee shall mean the Committee on

Continuing Pharmacy Education.

Sec. 10. There is hereby created the Committee on Continuing Pharmacy Education. The Committee shall consist of four members appointed by the board for terms of four years, except that of the

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members first appointed one shall be appointed for a term of one year, one for two years, one for three years, and one for four years. One member shall represent hospital pharmacists, one shall represent practicing pharmacists other than those practicing in hospitals, and two shall represent postsecondary educational institutions in the state which have a school or college of pharmacy. Members of the committee shall receive no compensation but shall be reimbursed for actual expenses as provided in sections 84-306.01 to 84-306.05 for state employees.

Sec. 11. Every pharmacist licensed by the department, except those exempt under subsection (2) of section 12 of this act, shall accumulate continuing education credit equaling at least three continuing education units during each twenty-four month licensure pursuant to section 9 of this act. Credit earned in excess of the requirement may not be carried into

subsequent periods.

Only continuing education credits awarded by approved providers shall be accepted as fulfilling the

continuing education requirement.

Acceptable modes of instruction shall include conferences, lectures, seminars, discussion groups, case studies, correspondence and home-study courses which may utilize audio or videotape presentations, computer-assisted instruction, conferences by telephone or television, whenever the criteria for quality as outlined by the American Council on Pharmaceutical Education are achieved by the approved provider.

Sec. 12. (1) Each pharmacist shall provide a listing of continuing education activities participated in or attended, the amount of credit received for each activity, and the date, location, and name of the approved provider which sponsored the activity on a separate form or portion of the license renewal application as may be designed by the department. Each pharmacist shall be responsible for maintaining in his or her personal files such certificates or records of credit from continuing education activities received

from approved providers.

The board shall biennially select, in a random manner, a representative sample of the license renewal applications for audit of continuing education credits. The names, addresses, and a copy of the section of the application form which lists continuing education credits shall be forwarded to the committee which shall cause the pharmacist to submit certificates or other

records of attendance which were received from the approved provider for review by the committee.

(2) The following licensees shall be exempted from the requirements of subsection (1) of this section:

(a) Any person holding a Nebraska license but

who does not reside or practice pharmacy in Nebraska;

[b] Any licensee serving in the regular armed

forces of the United States during any part of the twelve months immediately preceding the annual license renewal date;

(c) Any licensee submitting proof that he or she was suffering from a serious or disabling illness or physical disability which prevented attendance at continuing education activities within the State of Nebraska during the twelve months preceding the annual license renewal date, thereby preventing accumulation of the prescribed amount of continuing education credit;

(d) Any licensee initially licensed by the

board within the twelve months immediately preceding the

annual license renewal date; and

(e) Any licensee successfully completing two or more semester hours of formal credit instruction biennially offered by an accredited school or college of pharmacy\_which contributes to meeting the requirements
of an advanced degree in pharmacy.

Sec. 13. Any person failing to comply with sections 9 to 13 of this act shall be denied reneval of his or her license. The procedures for denial of renewal of the license shall be identical to those for nonpayment of renewal fees as provided in sections 71-149 and 71-161.10.

Sec. 14. That section 71-1,145, Reissue

Revised Statutes of Nebraska, 1943, be amended to read

as follows:

71-1,145. Every applicant for examination and registration as a pharmacist shall be not less than twenty-one years of age, of good moral character and temperate habits, a graduate of an accredited school or college of pharmacy, or an accredited department pharmacy of a university, recognized by the Board Examiners in Pharmacy, except that an applicant who is a graduate of a school, college, or university department of pharmacy located outside of the United States and or pharmacy located outside of the United States and which is not accredited, shall be deemed to have satisfied the requirement of being a graduate of an accredited school, college, or department of pharmacy upon providing evidence satisfactory to the Board of Examiners in Pharmacy, of graduation from such foreign school, college, or department of pharmacy and upon successfully passing an equivalency examination approved by the Board of Examiners in Pharmacy.

Every applicant shall file proof of sufficient internship experience in a community retail or hospital pharmacy, under the supervision of a registered or licensed pharmacist, as may be required by the Board of Examiners in Pharmacy, which shall comply with national requirements for internship as set forth by the National Association of Boards of Pharmacy, shall

satisfactorily completed at least five years of college of which at least three years shall have been in accredited school or college of pharmacy, or in accredited department of pharmacy of a university; and shall pass an examination satisfactory to the Board of Examiners in Pharmacy. Proof of the qualifications for registration prescribed in this section shall be made to the satisfaction of the Board of Examiners in Pharmacy, substantiated by proper affidavits: PROVIDED, that in all cases the actual time of attendance at an accredited school or college of pharmacy, or an accredited department of pharmacy of a university, is certified by the appropriate college or university authority by the issuance of the degree granted to a graduate of such school, college or department of pharmacy. Service and experience in a retail or hospital pharmacy under the supervision of a registered pharmacist, as required in this section, shall be predominantly related to the practice of pharmacy, and shall include the keeping of records and the making of reports required under state and federal statutes. The Department of Health, upon the recommendation of the Board of Examiners in Pharmacy, shall promulgate rules and regulations as may be required to establish standards for internship which shall comply with national requirements to effect reciprocity with other states which have similar requirements for licensure. The fee for pharmacy internship shall be forty dollars and shall accompany the application and shall be transmitted to the State Treasurer for deposit in the Nebraska Pharmaceutical Fund for expenditure in the manner prescribed by section 71-1, 147.02.

Sec. 15. That section 71-1,147, Reissue Revised Statutes of Nebraska, 1943, be amended to read as follows:

71-1,147. (1) No Except as provided in section 8 of this act, no person other than a licensed registered pharmacist or a pharmacy intern, shall, as described in this act, compound and dispense drugs and medicines and fill the prescription of a medical practitioner.

(2) It Except as provided in section 8 of this act, it shall be unlawful for any person to permit or direct a person, not a pharmacy intern, or licensed registered pharmacist, to compound and dispense drugs and medicines or fill the prescription of a medical practitioner.

(3) For the purpose of this section, nothing contained herein shall be construed to prohibit any registered nurse employed by a hospital from administering single doses of drugs from original drug containers, or properly labeled prepackaged drug containers, to any person registered as

a patient or confined in a hospital, upon the order or prescription of a medical practitioner; or to prohibit such registered nurse employed by a hospital from procuring the original drug container or properly labeled prepackaged drug container for the purpose of single dose drug administration to any person registered as a patient or confined in the hospital, upon the order or prescription of a medical practitioner.

That section 71-1, 147.01, Sec. 16. Reissue Revised Statutes of Nebraska, 1943, be amended to read

as follows:

71-1,147.01. No person shall engage conduct, or carry on a pharmacy or engage in the practice of pharmacy in this state unless the Department of Health has issued a permit to conduct such pharmacy, upon the recommendation of the Board of Examiners in Pharmacy board. to conduct such pharmacy. Each permit shall be issued to a specific person and for a specific location. Separate permits shall be issued for each of the premises of any business establishment having more than one location.

Nothing contained in this section shall be construed to require a public or private institution licensed as a hospital by the Department of Health which is engaged in the compounding and dispensing of drugs or medicines and the filling of prescriptions of medical practitioners for persons registered as patients or confined in the hospital to obtain a permit as provided in this act, either in the name of the hospital, an employee thereof, or any other person. This exemption from the requirement to obtain a permit to conduct a pharmacy or to engage in the practice of pharmacy as provided in this act does not include any public or private institution licensed as a hospital by the department which is primarily engaged in the compounding and dispensing of drugs and medicines the filling of prescriptions of medical practitioners for persons not registered as patients, or confined to hospital; PROVIDED, this exemption shall not allow such hospital exemption from any other laws of this state or of the United States pertaining to pharmacy and the dispensing of drugs and medicines.

<u>Rach public or private hospital which is</u> licensed by the Department of Health shall designate a full-time, part-time, or consultant pharmacist licensed in this state as being the pharmacist in charge and responsible for the practice of pharmacy in such hospital. The board or its designated representatives shall have the authority to examine and inspect the practice of pharmacy in any public or private hospital licensed by the Department of Health.

Any medical practitioner who regularly engages

in the dispensing of drugs or medicinal substances to his or her patients, as described in subdivision (2) of section 71-1,143, shall be required to obtain a permit, except that a medical practitioner who dispenses drugs or medicinal substances incident to his or her practice shall not be required to obtain a permit.
Sec. 17. That section 71-1, 147.03,

Reissue Revised Statutes of Nebraska, 1943, be amended

as follows:

71-1,147.03. If a person applying for a permit to conduct a pharmacy is not a <u>licensed</u> 71-1,147.03. registered pharmacist in this state, the permit when issued shall also bear the name of the pharmacist licensed registered in this state, designated on the application as being the pharmacist in charge and responsible for the practice of pharmacy in the establishment for which the permit is sought, except that a medical practitioner who dispenses drugs or medicinal substances to his or her own patients, with a pharmacy permit, may assume the same responsibilities as a pharmacist in charge. If such registered pharmacist in charge subsequently severs his or her position in the pharmacy, the permit shall be automatically suspended until such time as the person holding the permit informs the board Board of Examiners in Pharmacy of the name of the new registered pharmacist in charge designated as being responsible for the practice of pharmacy in the establishment for which the permit is sought, when, upon the recommendation of the Board of Examiners in Pharmacy <u>board</u>, an amended permit shall be issued by the Department of Health upon return of the original permit

and payment of a fee of ten dollars.

No pharmacist shall be designated pharmacist in charge of more than one pharmacy, except that a pharmacist may be pharmacist in charge of two pharmacies, if (1) the pharmacies are not open simultaneously and (2) at least one of the pharmacies is

open no nore than twenty hours per week.

Sec. 18. That section 71-1,147.08, Reissue Revised Statutes of Nebraska, 1943, be amended to read

as follows:

71-1,147.08. \* (1) Except as otherwise provided in section 71-1,147.01, a person desiring to open a new pharmacy must file an application for a permit not less than thirty days prior to the contemplated opening date. Before a permit may be granted for the operation of a new pharmacy, an inspection shall be made by a duly qualified representative of the board Board of Examiners in Pharmacy to determine whether all of the requirements for such a permit have been fulfilled. If all of the requirements have been fulfilled, upon recommendation of the Board of Examiners in Pharmacy board, the Department

of Health shall issue a permit for the operation of the new pharmacy. The fee for such permit, to accompany the application, shall be one hundred dollars.

12) Any person desiring to open a new pharmacy who is not required to obtain a permit under section 71-1,147.01 shall file an application for initial inspection at least thirty days prior to the contemplated opening date. Upon satisfactory completion of the inspection the Department of Health shall issue the pharmacy an initial inspection certificate. The pharmacy shall post such certificate in a conspicuous place within view of the public. The fee for such place within view of the public. The fee for such certificates issued on the basis of an inspection conducted after the effective date of this act shall be fifty dollars. Within six months after the effective date of this act the Department of Health shall issue an initial certificate to each pharmacy existing on the effective date of this act which was initially inspected prior to such date and which was not required to obtain a permit pursuant to section 71-1,147.01.

(3) Commencing six months after the effective date of this act any public or private hospital pharmacy which does not display an initial inspection certificate issued pursuant to subsection (2) of this section shall be subject to a six-month suspension of the license of the public or private hospital.

(4) The Department of Health shall, except as provided in subsection (5) of this section, inspect each pharmacy in the state at least once every two years. The Division of Licensure and Standards of the Department of Health shall have primary authority to inspect pharmacies of public and private hospitals licensed by the department and shall coordinate routine inspections of pharmacies in hospitals licensed by the department. The board or its representatives shall immediately report any suspected violation of the minimum pharmacy standard to the Division of Licensure and Standards of the Department of Health, which shall take remedial action. Such violation, if proved, shall be grounds for denial, suspension, or revocation of the license of the hospital under section 71-2023.

(5) The Department of Health may, upon recommendation by the board and the Division of Licensure and Standards of the Department of Health, accept the inspection of a hospital pharmacy conducted by the Joint Commission on the Accreditation of Hospitals in lieu of the inspection required pursuant to subsection (4) of this section if the Director of Health determines that the commission standards are equal to or more stringent than the standards of the department.

(6) The department shall charge an annual inspection fee for each pharmacy inspected pursuant to subsection (4) or (5) of this section which does not

possess a permit issued pursuant to section 71-1,147.07. Such fee shall be fifty dollars and shall be paid into the Nebraska Pharmaceutical Fund.

Sec. 19. That section 71-1, 147.09, Revised Statutes of Nebraska, 1943, be amended to read

as follows:

71-1,147.09. The Department of Health, upon recommendation of the Board of Examiners in Pharmacy board, is hereby authorized to promulgate rules and regulations:

(1) For the enforcement of this act;

(2) To establish minimum requirements regarding adequate facilities for the safe storage of narcotic drugs and other drugs requiring refrigeration or other special storage;

(3) For equipment, facilities, and utilities

for the prescription department; and

(4) To establish minimum standards governing sanitation, orderliness, cleanliness, library standards requirements, ventilation, and prescription and other record-keeping recordkeeping: -

(5) To establish minimum standards governing the definition and application of computers or other

electronic record systems in pharmacy;

(6) To establish minimum standards for the

practice of nuclear pharmacy; and

[7] To establish minimum standards for the dispensing of drugs or medicinal substances in unit dose or unit of use containers.

The minimum standards and requirements for the practice of pharmacy and for public or private hospital pharmacies licensed by the Department of Health shall be consistent with and no more or less stringent than the minimum requirements and standards established by the department under sections 71-2017 to 71-2029.

Sec. 20. That section 71-5401, Reissue

That section 71-5401, Revised Statutes of Nebraska, 1943, be amended to read

as follows:

71-5401. The Legislature declares it to be public policy of this state that its citizens receive chemically and therapeutically equivalent and bioequivalent drug products at the most reasonable price consistent with a high standard of pharmacy practice.

Sec. 21. That section 71-5402, Reissue Revised Statutes of Nebraska, 1943, be amended to read

as follows:

71-5402. As used in sections 71-1,147.10 and 71-5401 to 71-5408, unless the context otherwise requires:

(1) Brand name shall mean the proprietary or trade name selected by the manufacturer and placed upon a drug, its container, label, or wrapping at the time of packaging:

(2) Generic name shall mean the official title a drug or drug combination as determined by the United States Adopted Names and accepted by the federal Food and Drug Administration of those drug products having exactly the same active chemical ingredients in

exactly the same strength and quantity;
(3) Drug product select shall mean to dispense, without the duly licensed prescriber's express authorization, a chemically and therapeutically equivalent and bioequivalent drug product in place of equivalent and <u>bioequivalent</u> drug product in place of the drug <u>product</u> ordered or prescribed;

(4) Chemically equivalent shall mean drug products that contain amounts of the identical therapeutically active ingredients in the identical strength, quantity, and dosage form and that meet

present compendial standards;

(5) Therapeutically equivalent shall mean t are approved by the Food and Brug Administration for interstate distribution and that will provide essentially the same efficacy and toxicity, as determined by the pharmacist in his professional judgment, when administered to an individual in the same dosage regimen. No drug shall be considered therapeutically equivalent if such drug has been determined by the Food and Brug Administration or the Department of Health not to provide the same demonstrated and documented efficacy or toxicity as the brand name drug prescribed. The department shall be required to publish such list, either federal or state, wherein such nonequivalency has been demonstrated and documented; to all duly certified pharmacies and duly licensed physicians practicing in the State of Mebraska at the time of publication of such a list; Bioequivalent shall mean drug products that:

(a) Are legally marketed under regulations promulgated by the federal Food and Drug Administration;

(b) Are the same dosage form of the identical active ingredients in the identical amounts as the drug product prescribed;

(c) Comply with compendial standards and are consistent from lot to lot with respect to (i) purity of ingredients, (ii) weight variation, (iii) uniformity of

content, and (iv) stability; and

(d) For which the federal Food and Drug Administration has established bioequivalent standards or has determined that no bioequivalence problems exist; (6) Pharmacist shall mean a pharmacist duly

licensed in accordance with the provisions of licensure of Chapter 71, article 1;

(7) Medical practitioner shall mean a licensed physician, physician and surgeon, practitioner of osteopathic medicine, dentist, podiatrist, or veterinarian licensed in accordance with the provisions

of Chapter 71, article 1; and

(8) Department shall mean the Department of Health.

Sec. 22. That section 71-5403, Reissue Revised Statutes of Nebraska, 1943, be amended to read as follows:

71-5403. (1) Except as limited (a) by this section, when a medical practitioner designates that no drug product selection is permitted, and (b) by subsection (1) of section 71-5404, unless the purchaser instructs otherwise, the pharmacist may drug product select a drug product with the same generic name in the same strength, quantity, dose, and dosage form as the prescribed drug which is, in the pharmacist's professional opinion, therapeutically equivalent bioequivalent, except that products designated as controlled substances as listed in Schedule I or II of section 28-47+47 28-405 shall not be interchanged. It shall be the responsibility of the purchaser or the ultimate user to advise or instruct the pharmacist that he or she does not desire drug product selection, and it shall not be mandatory for the pharmacist to drug product select against his or her professional judgment.

(2) The department may promulgate necessary rules and regulations, upon the joint recommendation of the Board of Examiners in Medicine and Surgery and the Board of Examiners in Pharmacy, relating to (a) bioavailability, (b) fraudulent or misleading advertising pertaining to drug product selection, and (c) the control of conditions in which the prescribing practitioner or purchaser should be advised when drug product selection has been made by the pharmacist.

(3) A medical practitioner duly authorized to prescribe drugs, medicinal substances, or controlled substances may specify in writing or by telephonic communication on each prescription that there shall be no drug product selection for the specified brand name drug in any prescription. The phrase no drug product selection or the notation N.D.P.S. shall be specified on the prescription form or orally communicated by the medical practitioner. The pharmacist shall note N.D.P.S. on the face of the prescription if such is communicated orally by the prescribing medical practitioner.

(4) Each pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed stating that this pharmacy may be able to select a less expensive drug product which is bioequivalent therapeutically equivalent to the one prescribed by the prescriber unless the purchaser does not approve. The sign shall be provided by the department, at a cost to the pharmacy which shall not exceed the actual cost of printing to the department,

and the printing on the sign shall be in block letters not less than one inch in height.

(5) A pharmacist shall not drug product select a product under the provisions of this section unless:
(a) The product, if it is in solid dosage form, has been marked with an identification code or monogram directly on the dosage unit; (b) the product has been labeled with an expiration date; (c) the manufacturer provides reasonable services to accept return products that have reached their expiration date; and (d) the manufacturer maintains recall capabilities for unsafe or defective drugs.

(6) A pharmacist shall not drug product

select a product under this section that is:

[a] An enteric-coated tablet or capsule:

(b) An injectable suspension other than an antibiotic or insulin;

(c) A controlled-release product;

(d) A suppository containing active ingredients for which systemic absorption is necessary; or

(e) A different delivery system for aerosol

(e) A di

[7] The department shall maintain a list of drug products for which bioequivalency has been demonstrated and documented either federally or by the state.

Sec. 23. That section 71-5404, Reissue Revised Statutes of Nebraska, 1943, be amended to read as follows:

71-5404. (1) A pharmacist may drug product select a drug product pursuant to subsection (1) of section 71-5403 only when there will be a savings in cost to the purchaser, except that, if a pharmacy does not have in stock the prescribed drug product and the medical practitioner has not indicated N.D.P.S., and the only equivalent drug product in stock is the same or higher priced, the pharmacist, with the consent of the purchaser, may substitute the same or the higher priced drug product. Any savings resulting from drug product selection shall be reflected in the price charged the purchaser by the pharmacist.

purchaser by the pharmacist.

(2) Whenever a drug product has been prescribed with the notation that no drug product selection is permitted for a patient who has a contract whereunder he or she is reimbursed for the cost of health care, directly or indirectly, the party that has contracted to reimburse the patient, directly or indirectly, shall make reimbursements on the basis of the brand name price and not on the basis of the permitted or the remaining of the price of the price and not on the basis of the generic, or chemical, or the permitted or bioequivalent drug price, unless the contract specifically requires generic reimbursement under the

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Code of Federal Regulations.

(3) If the physician prescribes a drug by its generic name, the pharmacist shall, consistent with reasonable professional judgment, dispense an effective brand which is the lowest retail cost brand in stock.

(4) All prescriptions dispensed shall upon the label the name of the medication in the container unless the prescriber writes do not label or words of similar import on the prescription or so designates in an oral transmission of the prescription.

(5) Nothing in this section shall require a

pharmacy, which prices prescriptions upon a professional fee basis, to charge less than its established minimum

price for the filling of any prescription.

16) Whenever a purchaser or patient presents a prescription that may be filled with a product selected by the pharmacist under the provisions of this section and the pharmacist chooses to make such selection, the pharmacist shall advise the purchaser or patient that he or she may indicate orally or in writing that he or she does not desire drug product selection and in that instance the prescription shall be filled as ordered. On all subsequent refills the drug product dispensed shall be distributed by the same company as the drug product dispensed on the original prescription.

(7) When a pharmacist chooses to exercise the provisions of this section when dispensing prescriptions for patients in long-term care facilities, the pharmacist shall advise either the patient, a representative of the patient, or a staff nurse of the facility that he or she has exercised the provisions of this section, and either the patient or his or her representative or a staff nurse of the facility may indicate orally or in writing that he or she does not desire drug product selection, and in that instance the

prescription shall be filled as written.

[8] Nothing contained in this section shall be construed to prohibit any hospital licensed by the Department of Health from establishing rules and regulations regarding the method by which medications are prescribed and dispensed for patients of such hospitals.

Sec. 24. That section 71-5407, Reissue Revised Statutes of Nebraska, 1943, be amended to read as follows:

71-5407. (1) In addition to any other penalties provided by law, any person who shall violate the provisions of sections 71-1,147.10 and 71-5401 to 71-5408 or any rule promulgated under se 71-1,147.10 and 71-5401 to 71-5408 shall, sections conviction thereof, be punished by a fine of not more than two hundred fifty dollars for each violation.

(2) It shall be unlawful for any employer or

an employer's agent to coerce a pharmacist to dispense a prescription drug against the professional judgment of the pharmacist or as ordered by the

prescribing medical practitioner.

(3) Violation of the provisions of sections 71-5401 to 71-5408 or commission of any act described in subdivisions (1) to (2) of section 71-1,147.10 by a licensed pharmacist shall be considered an act of unprofessional conduct for purposes of section 71-147

and shall subject the pharmacist to disciplinary action under section 71-147.

Sec. 25. That section 81-197, Reissue Revised Statutes of Nebraska, 1943, as amended by section 1, Legislative Bill 413, Eighty-eight Legislature, First

Session, 1983, be amended to read as follows:

81-197. The following agencies, boards, commissions shall terminate on July 1, 1984:
(1) Board of Examiners in Chiropractic,

created by sections 71-111 and 71-112;

(2) Board of Examiners in Dentistry, created by sections 71-111 and 71-112;

(3) State Board of Examiners of Psychologists, created by section 71-3803; and

(4) Board of Nursing, created by section 71-1,132.07.

7. ; and
(5) Board of Examiners in Pharmacy; created by sections 74-444 and 74-442.

Sec. 26. That original sections 71-113, 71-130, 71-131, 71-140, 71-1,142, 71-1,143, 71-1,147, 71-1,147-01, 71-1,147-03, 08, 71-1,147-09, 71-5401 to 71-5404, and 71-116, 71-1,145, 71-1,147.08, 71-5407, Reissue Revised Statutes of Nebraska, 1943, and section 81-197, Reissue Revised Statutes of Nebraska, 1943, as amended by section 1, Legislative Bill 413, Eighty-eighth Legislature, First Session, 1983, repealed.

Sec. 27. Since an emergency exists, this act shall be in full force and take effect, from and after its passage and approval, according to law.