House Engrossed Senate Bill

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KEN BENNETT
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CHAPTER 102

SENATE BILL 1043

AN ACT

AMENDING SECTIONS 23-908, 32-1501, 32-1901, 32-1904, 32-1929, 32-1963.01 AND 32-1975, ARIZONA REVISED STATUTES; RELATING TO PRESCRIPTION DRUGS.

(TEXT OF BILL BEGINS ON NEXT PAGE)

Be it enacted by the Legislature of the State of Arizona:

Section 1. Section 23-908, Arizona Revised Statutes, is amended to read:

23-908. Injury reports by employer and physician; schedule of fees; violation; classification

A. Every employer THAT IS affected by this chapter, and every physician who attends an injured employee of such employer, shall file with the commission and the employer's insurance carrier from time to time a full and complete report of every known injury to the employee arising out of or in the course of ~~his~~ employment and resulting in loss of life or injury. Such A report shall be furnished to the commission and ~~such~~ THE insurance carrier at times and in the form and detail the commission prescribes, and the report shall make special answers to all questions required by the commission under its rules.

B. The commission shall fix a schedule of fees to be charged by physicians, physical therapists or occupational therapists attending injured employees and, subject to subsection C of this section, for prescription medicines required to treat an injured employee under this chapter. The commission shall annually review the schedule of fees.

C. If a schedule of fees for prescription medicines adopted pursuant to subsection B of this section includes provisions regarding the use of generic equivalent drugs, those provisions shall comply with section 32-1963.01, subsections A and C through ~~K~~ J. If the commission considers the adoption of fee schedule provisions that involve specific prices, values or reimbursements for prescription drugs, the commission shall base the adoption on studies or practices that are validated and accepted in the industry, including the applicability of formulas that use average wholesale price, plus a dispensing fee, and that have been made publicly available for at least one hundred eighty days before any hearing conducted by the commission.

D. Notwithstanding section 12-2235, information obtained by any physician or surgeon examining or treating an injured person shall not be considered a privileged communication, if ~~such~~ THAT information is requested by interested parties for a proper understanding of the case and a determination of the rights involved. Hospital records of an employee concerning an industrial claim shall not be considered privileged if requested by an interested party in order to determine the rights involved. Medical information from any source pertaining to conditions unrelated to the pending industrial claim shall remain privileged.

E. When an accident occurs to an employee, the employee shall forthwith report the accident and the injury resulting therefrom to the employer, and any physician employed by the injured employee shall forthwith report the accident and the injury resulting therefrom to the employer, the insurance carrier and the commission.

F. When an accident occurs to an employee, the employer may designate in writing a physician chosen by the employer, who shall be permitted by the employee, or any person in charge of the employee, to make one examination of the injured employee in order to ascertain the character and extent of the injury occasioned by the accident. The physician so chosen shall forthwith report to the employer, the insurance carrier and the commission the character and extent of the injury as ascertained by him. If the accident is not reported by the employee or his physician forthwith, as required, or if the injured employee or those in charge of him refuse to permit the employer's physician to make the examination, and the injured employee is a party to the refusal, no compensation shall be paid for the injury claimed to have resulted from the accident. The commission may relieve the injured person or his dependents from the loss or forfeiture of compensation if it believes after investigation that the circumstances attending the failure on the part of the employee or his physician to report the accident and injury are such as to have excused them.

G. Within ten days after receiving notice of an accident, the employer shall inform ~~his~~ THE insurance carrier and the commission on such forms and in such manner as may be prescribed by the commission.

H. Immediately ~~upon~~ ON notice to the employer of an accident resulting in an injury to an employee, the employer shall provide the employee with the name and address of the employer's insurance carrier, the policy number and the expiration date.

I. Any person failing or refusing to comply with this section is guilty of a petty offense.

Sec. 2. Section 32-1501, Arizona Revised Statutes, is amended to read:

32-1501. Definitions

In this chapter, unless the context otherwise requires:

1. "Accepted therapeutic purpose" means treatment of a disease, injury, ailment or infirmity that is competent and generally recognized as safe and effective.

2. "Active license" means a current valid license to practice naturopathic medicine.

3. "Adequate medical records" means legible medical records containing, at a minimum, sufficient information to identify the patient, support the diagnosis, describe the treatment, accurately document the results, indicate advice and cautionary warning provided to the patient and provide sufficient information for a similarly qualified practitioner to assume continuity of the patient's care at any point in the course of treatment.

4. "Approved clinical training program" or "clinical training program" means a program for naturopathic medical students in which the training occurred or is being conducted by or in conjunction with an approved school of naturopathic medicine.

5. "Approved internship program" or "internship" means that the program in which the training occurred or is being conducted has been approved for internship training for physicians or for graduates of a school of naturopathic medicine by the board or was approved or accredited by an educational or professional association recognized by the board or by another state's or country's licensing agency recognized by the board.

6. "Approved postdoctoral training" or "postdoctoral training" means that the program in which the training occurred or is being conducted has been approved for specialty training or for graduate medical education in naturopathic medicine by the board or approved or accredited by an educational or professional association recognized by the board or by another state's or country's licensing agency recognized by the board.

7. "Approved preceptorship program" or "preceptorship" means that the program in which the training occurred or is being conducted has been approved for preceptorship training for physicians or for graduates of a school of naturopathic medicine by the board or was approved or accredited by an educational or professional association recognized by the board or by another state's or country's licensing agency recognized by the board.

8. "Approved school of naturopathic medicine" or "school of naturopathic medicine" means a school or college determined by the board to have an educational program that meets standards prescribed by the council on naturopathic medical education, or its successor agency, and that offers a course of study that, on successful completion, results in the awarding of the degree of doctor of naturopathic medicine and whose course of study is either of the following:

(a) Accredited or a candidate for accreditation by an accrediting agency recognized by the United States secretary of education as a specialized accrediting agency for schools of naturopathic medicine or its successor.

(b) Accredited or a candidate for accreditation by an accrediting agency recognized by the council for higher education accreditation or its successor.

9. "Board" means the naturopathic physicians medical board.

10. "Chelation therapy" means an experimental medical therapy to restore cellular homeostasis through the use of intravenous, metal-binding and bioinorganic agents such as ethylene diamine tetraacetic acid. Chelation therapy does not include experimental therapy used to treat heavy metal poisoning.

11. "Completed application" means that the applicant paid the required fees and supplied all documents and information as requested by the board and in a manner acceptable to the board.

12. "Controlled substance" means a drug, substance or immediate precursor in schedules I through V of title 36, chapter 27, article 2.

13. "Direct supervision" means that a physician who is licensed pursuant to this chapter or chapter 13, 17 or 29 of this title:

(a) Is physically present and within sight or sound of the person supervised and is available for consultation regarding procedures that the physician has authorized and for which the physician remains responsible.

(b) Has designated a person licensed pursuant to this chapter or chapter 13, 17 or 29 of this title to provide direct supervision in the physician's absence.

14. "Doctor of naturopathic medicine" or "doctor" means a natural person licensed to practice naturopathic medicine under this chapter.

15. "Drug" has the same meaning prescribed in section 32-1901 but does not include:

(a) Intravenous administration of legend drugs, except for:

(i) Vitamins, chelation therapy and drugs used in emergency resuscitation and stabilization.

(ii) Minerals.

(iii) Nutrients. For the purposes of this item, "nutrient" means a substance that provides nourishment for growth or metabolism and that is manufactured and supplied for intravenous use by a manufacturer registered with the United States food and drug administration or compounded by a pharmacy licensed by the state board of pharmacy.

(b) Controlled substances listed as schedule I or II controlled substances as defined in the federal controlled substances act of 1970 (21 United States Code section 802), except morphine, ANY DRUG THAT IS RECLASSIFIED FROM SCHEDULE III TO SCHEDULE II AFTER JANUARY 1, 2014 and any homeopathic preparations that are also controlled substances.

(c) Cancer chemotherapeutics classified as legend drugs.

(d) Antipsychotics.

16. "General supervision" means that the physician is available for consultation regarding procedures that the physician has authorized and for which the physician remains responsible.

17. "Legend drug" means any drug defined by section 503(b) of the federal food, drug and cosmetic act and under which definition its label is required to bear the statement "Rx only".

18. "Letter of concern" means a nondisciplinary advisory letter that is issued by the board to a person who is regulated under this chapter and that states that while there is insufficient evidence to support disciplinary action the board believes that the person should modify or eliminate certain practices and that continuation of the activities that led to the information being submitted to the board may result in action against the person's license, certificate or registration.

19. "Letter of reprimand" means a disciplinary letter that is issued by the board and that informs a person who is regulated under this chapter that the person's conduct violates state or federal law but does not require the board to restrict the person's license, certificate or registration because the person's conduct did not result in harm to a patient or to the public.

20. "Limit" means taking a nondisciplinary action that alters the physician's practice or professional activities if the board determines that there is evidence that the physician is or may be mentally or physically unable to safely engage in the practice of medicine.

21. "Medical assistant" or "naturopathic medical assistant" means a person who is certified by the board as a medical assistant, who assists a doctor of naturopathic medicine and who may perform delegated procedures that are commensurate with the assistant's education and training under the direct supervision of a doctor of naturopathic medicine and that do not include diagnosing, designing or modifying established treatment programs or those procedures prohibited by the board or by this chapter.

22. "Medically incompetent" means a person who is licensed, certified or registered pursuant to this chapter and who lacks sufficient naturopathic medical knowledge or skills, or both, to a degree that is likely to endanger the health of patients.

23. "Natural substance" means a homeopathic, botanical, nutritional or other supplement that does not require a prescription pursuant to federal law before it is prescribed, dispensed or otherwise furnished to a patient and that is prescribed by a physician licensed pursuant to this chapter to enhance health, prevent disease or treat a medical condition diagnosed by the physician.

24. "Naturopathic medical student" means a person who is enrolled in a course of study at an approved school of naturopathic medicine.

25. "Naturopathic medicine" means medicine as taught in approved schools of naturopathic medicine and in clinical, internship, preceptorship and postdoctoral training programs approved by the board and practiced by a recipient of a degree of doctor of naturopathic medicine licensed pursuant to this chapter.

26. "Nurse" means a person licensed pursuant to chapter 15 of this title.

27. "Physician" means a doctor of naturopathic medicine licensed pursuant to this chapter.

28. "Practice of naturopathic medicine" means a medical system of diagnosing and treating diseases, injuries, ailments, infirmities and other conditions of the human mind and body including by natural means, drugless methods, drugs, nonsurgical methods, devices, physical, electrical, hygienic and sanitary measures and all forms of physical agents and modalities.

29. "Restrict" means taking a disciplinary action that alters the physician's practice or professional activities if the board determines that there is evidence that the physician is or may be medically incompetent or guilty of unprofessional conduct.

30. "Specialist" means a physician who has successfully completed approved postdoctoral training, who is certified by a specialty board of examiners recognized by the board and who is certified by the board to practice the specialty pursuant to this chapter.

31. "Unprofessional conduct" includes the following, whether occurring in this state or elsewhere:

(a) Intentionally disclosing a professional secret or intentionally disclosing a privileged communication except as either of these may otherwise be required by law.

(b) Any dishonorable conduct reflecting unfavorably on the profession.

(c) Committing a felony, whether or not involving moral turpitude, or a misdemeanor involving moral turpitude. In either case conviction by any court of competent jurisdiction or a plea of no contest is conclusive evidence of the commission of the felony or misdemeanor.

(d) Habitual intemperance in the use of alcohol or any substance abuse.

(e) The illegal use of any narcotic or hypnotic drugs, or illegal substances.

(f) Conduct that the board determines is gross malpractice, repeated malpractice or any malpractice resulting in the death of a patient.

(g) Impersonating another doctor of naturopathic medicine or any other practitioner of the healing arts.

(h) Falsely acting or assuming to act as a member, an employee or an authorized agent of the board.

(i) Procuring or attempting to procure a license or a certificate pursuant to this chapter by fraud, by misrepresentation or by knowingly taking advantage of the mistake of another person or agency.

(j) Having professional connection with or lending one's name to enhance or continue the activities of an illegal physician or an illegal practitioner of any healing art.

(k) Representing that a manifestly incurable disease, injury, ailment or infirmity can be permanently cured, or falsely or fraudulently representing that a curable disease, injury, ailment or infirmity can be cured within a stated time.

(l) Offering, undertaking or agreeing to cure or treat a disease, injury, ailment or infirmity by a secret means, method, treatment, medicine, substance, device or instrumentality.

(m) Refusing to divulge to the board on demand the means, method, treatment, medicine, substance, device or instrumentality used in the treatment of a disease, injury, ailment or infirmity.

(n) Giving or receiving, or aiding or abetting the giving or receiving of, rebates, either directly or indirectly.

(o) Knowingly making any false or fraudulent statement, written or oral, in connection with the practice of naturopathic medicine or any naturopathic treatment method.

(p) Immorality or misconduct that tends to discredit the naturopathic profession.

(q) Refusal, revocation or suspension of a license by any other state, district or territory of the United States or any other country, unless it can be shown that this action was not due to reasons that relate to the ability to safely and skillfully practice as a doctor of naturopathic medicine or to any act of unprofessional conduct in this paragraph.

(r) Any conduct or practice that is contrary to recognized standards of ethics of the naturopathic profession, any conduct or practice that does or might constitute a danger to the health, welfare or safety of the patient or the public, or any conduct, practice or condition that does or might impair the ability to safely and skillfully practice as a doctor of naturopathic medicine.

(s) Failure to observe any federal, state, county or municipal law relating to public health as a physician in this state.

(t) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate this chapter or board rules.

(u) False, fraudulent, deceptive or misleading advertising or advertising the quality of a medical or health care service by a physician or by the physician's staff, employer or representative.

(v) Failing or refusing to maintain adequate medical records on a patient or failing or refusing to make medical records in the physician's possession promptly available to another physician or health care provider who is licensed pursuant to chapter 7, 8, 13, 15, 17 or 29 of this title on request and receipt of proper authorization to do so from the patient, a minor patient's parent, the patient's legal guardian or the patient's authorized representative or failing to comply with title 12, chapter 13, article 7.1.

(w) Referring a patient to a diagnostic or treatment facility or prescribing goods and services without disclosing in writing to the patient that the physician has a pecuniary interest in the facility, goods or services to which the patient is referred or prescribed. This subdivision does not apply to a referral by one physician or practitioner to another physician or practitioner within a group of physicians or practitioners practicing together.

(x) Sexual intimacies with a patient in the course of direct treatment.

(y) Failing to dispense drugs and devices in compliance with article 4 of this chapter.

(z) Administering, dispensing or prescribing any drug or a device for other than an accepted therapeutic purpose.

(aa) Falsely representing or holding oneself out as being a specialist or representation by a doctor of naturopathic medicine or the doctor's staff, employer or representative that the doctor is boarded or board certified if this is not true or that standing is not current.

(bb) Delegating professional duties and responsibilities to a person if the person has not been approved or qualified by licensure or by certification to perform these duties or responsibilities.

(cc) Failing to appropriately supervise a naturopathic medical student, a nurse, a medical assistant, a health care provider or a technician employed by or assigned to the physician during the performance of delegated professional duties and responsibilities.

(dd) Using experimental forms of diagnosis or treatment without adequate informed consent of the patient or the patient's legal guardian and without conforming to experimental criteria including protocols, detailed records, periodic analysis of results and periodic review by a medical peer review committee as approved by the federal food and drug administration or its successor agency.

(ee) Failing to furnish information in a timely manner to the board or investigators or representatives of the board if this information is legally requested by the board and failing to allow properly authorized board personnel on demand to examine and have access to documents, reports and records maintained by the physician that relate to the physician's medical practice or medically related activities.

(ff) Failing to report in writing to the board evidence that a person licensed, certified or registered pursuant to this chapter is or may be medically incompetent, guilty of unprofessional conduct or mentally or physically unable to safely practice or assist in the practice of naturopathic medicine.

(gg) Conducting or engaging in an internship, preceptorship or clinical training program in naturopathic medicine without being approved and registered by the board for that internship, preceptorship or clinical training program.

(hh) Signing a blank, undated or predated prescription form.

(ii) Conduct that the board determines is gross negligence, repeated negligence or negligence resulting in harm or death to a patient.

(jj) Knowingly making a false or misleading statement in oral testimony to the board on a form required by the board or in written correspondence to the board, including attachments to that correspondence.

(kk) The failure of a physician who is the chief medical officer, the executive officer or the chief of staff of an internship, a preceptorship or a clinical training program to report in writing to the board that the privileges of a doctor of naturopathic medicine, a naturopathic medical student or a medical assistant have been denied, limited, revoked or suspended because that doctor's, student's or assistant's actions appear to indicate that the person is or may be medically incompetent, is or may be guilty of unprofessional conduct or is or may be unable to safely engage or assist in the practice of naturopathic medicine.

(ll) Action taken against a doctor of naturopathic medicine by a licensing or regulatory board in another jurisdiction due to that doctor's mental or physical inability to engage safely in the practice of naturopathic medicine or the doctor's medical incompetence or for unprofessional conduct as defined by that licensing or regulatory board and that corresponds directly or indirectly to an act of unprofessional conduct prescribed by this paragraph. The action taken may include refusing, denying, revoking or suspending a license, otherwise limiting, restricting or monitoring a licensee or placing a licensee on probation by that licensing or regulatory board.

(mm) Sanctions imposed by an agency of the federal government, including restricting, suspending, limiting or removing a person from the practice of naturopathic medicine or restricting that person's ability to obtain financial remuneration.

(nn) Violating any formal order, probation, consent agreement or stipulation issued or entered into by the board pursuant to this chapter.

(oo) Refusing to submit to a body fluid examination pursuant to a board investigation of alleged substance abuse by a doctor of naturopathic medicine.

(pp) Charging a fee for services not rendered or dividing a professional fee for patient referrals among health care providers or health care institutions or between these providers and institutions or a contractual arrangement that has this effect.

(qq) Obtaining a fee by fraud, deceit or misrepresentation.

(rr) Charging or collecting a clearly excessive fee. In determining if a fee is clearly excessive, the board shall consider the fee or range of fees customarily charged in this state for similar services, in light of modifying factors such as the time required, the complexity of the service and the skill required to perform the service properly. This subdivision does not apply if there is a clear written contract for a fixed fee between the physician and the patient that was entered into before the service was provided.

(ss) With the exception of heavy metal poisoning, using chelation therapy in the treatment of arteriosclerosis or as any other form of therapy without adequate informed patient consent and without conforming to generally accepted experimental criteria, including protocols, detailed records, periodic analysis of results and periodic review by a medical peer review committee.

(tt) Using a controlled substance unless it is prescribed by another physician for use during a prescribed course of treatment.

(uu) Prescribing, dispensing or administering anabolic androgenic steroids for other than therapeutic purposes.

(vv) Except in an emergency or urgent care situation, prescribing or dispensing a controlled substance to a member of the naturopathic physician's immediate family.

(ww) Prescribing, dispensing or furnishing a prescription medication or a prescription-only device as defined in section 32-1901 to a person unless the licensee first conducts a physical examination of that person or has previously established a doctor-patient relationship. This subdivision does not apply to:

(i) A licensee who provides temporary patient supervision on behalf of the patient's regular treating licensed health care professional.

(ii) An emergency medical situation as defined in section 41-1831.

(iii) Prescriptions written to prepare a patient for a medical examination.

(iv) Prescriptions written or prescription medications issued for use by a county or tribal public health department for immunization programs or emergency treatment or in response to an infectious disease investigation, a public health emergency, an infectious disease outbreak or an act of bioterrorism. For the purposes of this item, "bioterrorism" has the same meaning prescribed in section 36-781.

(v) Prescriptions written or antimicrobials dispensed to a contact as defined in section 36-661 who is believed to have had significant exposure risk as defined in section 36-661 with another person who has been diagnosed with a communicable disease as defined in section 36-661 by the prescribing or dispensing physician.

(xx) If medical treatment is considered experimental or investigational, failing to include in a patient's record a consent to treatment document that is signed by the patient or the patient's parent or legal guardian and that indicates that the patient or the patient's parent or legal guardian has been informed of the risk of any treatment to be provided and the expected cost of that treatment.

Sec. 3. Section 32-1901, Arizona Revised Statutes, is amended to read:

32-1901. Definitions

In this chapter, unless the context otherwise requires:

1. "Administer" means the direct application of a controlled substance, prescription-only drug, dangerous drug or narcotic drug, whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by a practitioner or by the practitioner's authorized agent or the patient or research subject at the direction of the practitioner.

2. "Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of drugs, devices, poisons or hazardous substances.

3. "Advisory letter" means a nondisciplinary letter to notify a licensee or permittee that either:

(a) While there is insufficient evidence to support disciplinary action, the board believes that continuation of the activities that led to

the investigation may result in further board action against the licensee or permittee.

(b) The violation is a minor or technical violation that is not of sufficient merit to warrant disciplinary action.

(c) While the licensee or permittee has demonstrated substantial compliance through rehabilitation, remediation or reeducation that has mitigated the need for disciplinary action, the board believes that repetition of the activities that led to the investigation may result in further board action against the licensee or permittee.

4. "Antiseptic", if a drug is represented as such on its label, means a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment or dusting powder or other use that involves prolonged contact with the body.

5. "Authorized officers of the law" means legally empowered peace officers, compliance officers of the state board of pharmacy and agents of the division of narcotics enforcement and criminal intelligence of the department of public safety.

6. "Board" or "board of pharmacy" means the Arizona state board of pharmacy.

7. "Color additive" means a material that either:

(a) Is any dye, pigment or other substance made by a process of synthesis or similar artifice, or extracted, isolated or otherwise derived, with or without intermediate or final change of identity, from any vegetable, animal, mineral or other source.

(b) If added or applied to a drug, or to the human body or any part of the human body, is capable of imparting color, except that color additive does not include any material that has been or may be exempted under the federal act. Color includes black, white and intermediate grays.

8. "Compounding" means the preparation, mixing, assembling, packaging or labeling of a drug by a pharmacist or an intern or pharmacy technician under the pharmacist's supervision, for the purpose of dispensing to a patient based on a valid prescription order. Compounding includes the preparation of drugs in anticipation of prescription orders prepared on routine, regularly observed prescribing patterns and the preparation of drugs as an incident to research, teaching or chemical analysis or for administration by a medical practitioner to the medical practitioner's patient and not for sale or dispensing. Compounding does not include the preparation of commercially available products from bulk compounds or the preparation of drugs for sale to pharmacies, practitioners or entities for the purpose of dispensing or distribution.

9. "Compressed medical gas distributor" means a person who holds a current permit issued by the board to distribute compressed medical gases pursuant to a compressed medical gas order to compressed medical gas

suppliers and other entities that are registered, licensed or permitted to use, administer or distribute compressed medical gases.

10. "Compressed medical gas order" means an order for compressed medical gases that is issued by a medical practitioner.

11. "Compressed medical gas supplier" means a person who holds a current permit issued by the board to supply compressed medical gases pursuant to a compressed medical gas order and only to the consumer or the patient.

12. "Compressed medical gases" means gases and liquid oxygen that a compressed medical gas distributor or manufacturer has labeled in compliance with federal law.

13. "Controlled substance" means a drug, substance or immediate precursor identified, defined or listed in title 36, chapter 27, article 2.

14. "Corrosive" means any substance that when it comes in contact with living tissue will cause destruction of tissue by chemical action.

15. "Counterfeit drug" means a drug that, or the container or labeling of which, without authorization, bears the trademark, trade name or other identifying mark, imprint, number or device, or any likeness of these, of a manufacturer, distributor or dispenser other than the person who in fact manufactured, distributed or dispensed that drug.

16. "Dangerous drug" has the same meaning prescribed in section 13-3401.

17. "Decree of censure" means an official action that is taken by the board and that may include a requirement for restitution of fees to a patient or consumer.

18. "Deliver" or "delivery" means the actual, constructive or attempted transfer from one person to another whether or not there is an agency relationship.

19. "Deputy director" means a pharmacist WHO IS employed by the board and selected by the executive director to perform duties as prescribed by the executive director.

20. "Device", except as used in paragraph 15 of this section, section 32-1965, paragraph 4 and section 32-1967, subsection A, paragraph 15 and subsection C, means instruments, apparatus and contrivances, including their components, parts and accessories, including all such items under the federal act, intended either:

(a) For use in the diagnosis, cure, mitigation, treatment or prevention of disease in the human body or other animals.

(b) To affect the structure or any function of the human body or other animals.

21. "Direct supervision of a pharmacist" means the pharmacist is present. If relating to the sale of certain items, direct supervision of a pharmacist means that a pharmacist determines the legitimacy or advisability of a proposed purchase of those items.

22. "Director" means the director of the division of narcotics enforcement and criminal investigation of the department of public safety.

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

24. "Dispenser" means a practitioner who dispenses.

25. "Distribute" means to deliver, other than by administering or dispensing.

26. "Distributor" means a person who distributes.

27. "Drug" means:

(a) Articles recognized, or for which standards or specifications are prescribed, in the official compendium.

(b) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in the human body or other animals.

(c) Articles other than food intended to affect the structure or any function of the human body or other animals.

(d) Articles intended for use as a component of any articles specified in subdivision (a), (b) or (c) of this paragraph but does not include devices or their components, parts or accessories.

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

29. "Drug or device manufacturing" means the production, preparation, propagation or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis and includes any packaging or repackaging of substances or labeling or relabeling of its container and the promotion and marketing of the same. Drug or device manufacturing does not include compounding.

30. "Economic poison" means any substance that alone, in chemical combination or in formulation with one or more other substances is a pesticide within the meaning of the laws of this state or the federal insecticide, fungicide and rodenticide act and that is used in the production, storage or transportation of raw agricultural commodities.

31. "Established name", with respect to a drug or ingredient of a drug, means any of the following:

(a) The applicable official name.

(b) If there is no such name and the drug or ingredient is an article recognized in an official compendium, ~~then~~ the official title in an official compendium.

(c) If neither subdivision (a) nor (b) of this paragraph applies, ~~then~~ the common or usual name of such drug.

32. "Executive director" means the executive director of the board of pharmacy.

33. "Federal act" means the federal laws and regulations that pertain to drugs, devices, poisons and hazardous substances and that are official at the time any drug, device, poison or hazardous substance is affected by this chapter.

34. "Full service wholesale permittee" means a permittee who may distribute prescription-only drugs and devices, controlled substances and over-the-counter drugs and devices to pharmacies or other legal outlets from a place devoted in whole or in part to wholesaling these items.

35. "Graduate intern" means a person who has graduated from a college, school or program of pharmacy approved by the board and who meets the qualifications and experience for a pharmacy intern as provided in section 32-1923.

36. "Highly toxic" means any substance that falls within any of the following categories:

(a) Produces death within fourteen days in half or more than half of a group of ten or more laboratory white rats each weighing between two hundred and three hundred grams, at a single dose of fifty milligrams or less per kilogram of body weight, when orally administered.

(b) Produces death within fourteen days in half or more than half of a group of ten or more laboratory white rats each weighing between two hundred and three hundred grams, if inhaled continuously for a period of one hour or less at an atmospheric concentration of two hundred parts per million by volume or less of gas or vapor or two milligrams per liter by volume or less of mist or dust, provided the concentration is likely to be encountered by humans if the substance is used in any reasonably foreseeable manner.

(c) Produces death within fourteen days in half or more than half of a group of ten or more rabbits tested in a dosage of two hundred milligrams or less per kilogram of body weight, if administered by continuous contact with the bare skin for twenty-four hours or less.

If the board finds that available data on human experience with any substance indicate results different from those obtained on animals in the dosages or concentrations prescribed in this paragraph, the human data shall take precedence.

37. "Hospital" means any institution for the care and treatment of the sick and injured that is approved and licensed as a hospital by the department of health services.

38. "Intern" means a pharmacy intern and a graduate intern.

39. "Internship" means the practical, experiential, hands-on training of a pharmacy intern under the supervision of a preceptor.

40. "Irritant" means any substance, other than a corrosive, that on immediate, prolonged or repeated contact with normal living tissue will induce a local inflammatory reaction.

41. "Jurisprudence examination" means a board approved pharmacy law examination that is written and administered in cooperation with the national

association of boards of pharmacy or another board approved pharmacy law examination.

42. "Label" means a display of written, printed or graphic matter on the immediate container of any article that, unless easily legible through the outside wrapper or container, also appears on the outside wrapper or container of the article's retail package. For the purposes of this paragraph, the immediate container does not include package liners.

43. "Labeling" means all labels and other written, printed or graphic matter either:

(a) On any article or any of its containers or wrappers.

(b) Accompanying that article.

44. "Letter of reprimand" means a disciplinary letter that is a public document issued by the board and that informs a licensee or permittee that the licensee's or permittee's conduct violates state or federal law and may require the board to monitor the licensee or permittee.

45. "Limited service pharmacy" means a pharmacy THAT IS approved by the board to practice a limited segment of pharmacy as indicated by the permit issued by the board.

46. "Manufacture" or "manufacturer" means every person who prepares, derives, produces, compounds, processes, packages or repackages or labels any drug in a place, other than a pharmacy, devoted to manufacturing the drug.

47. "Marijuana" has the same meaning prescribed in section 13-3401.

48. "Medical practitioner" means any medical doctor, doctor of osteopathy, dentist, podiatrist, veterinarian or other person licensed and authorized by law to use and prescribe drugs and devices for the treatment of sick and injured human beings or animals or for the diagnosis or prevention of sickness in human beings or animals in this state or any state, territory or district of the United States.

49. "Medication order" means a written or verbal order from a medical practitioner or that person's authorized agent to administer a drug or device.

50. "Narcotic drug" has the same meaning prescribed in section 13-3401.

51. "New drug" means either:

(a) Any drug the composition of which is such that the drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling.

(b) Any drug the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but that has not, other than in the investigations, been used to a material extent or for a material time under those conditions.

52. "Nonprescription drug" or "over-the-counter drug" means any nonnarcotic medicine or drug that may be sold without a prescription and is

1 prepackaged and labeled for use by the consumer in accordance with the
2 requirements of the laws of this state and federal law. Nonprescription drug
3 does not include:
4 (a) A drug that is primarily advertised and promoted professionally to
5 medical practitioners and pharmacists by manufacturers or primary
6 distributors.
7 (b) A controlled substance.
8 (c) A drug that is required to bear a label that states "Rx only."
9 (d) A drug intended for human use by hypodermic injection.
10 53. "Nonprescription drug wholesale permittee" means a permittee who
11 may distribute only over-the-counter drugs and devices to pharmacies or other
12 lawful outlets from a place devoted in whole or in part to wholesaling these
13 items.
14 54. "Notice" means personal service or the mailing of a copy of the
15 notice by certified mail addressed either to the person at the person's
16 latest address of record in the board office or to the person's attorney.
17 55. "Official compendium" means the latest revision of the United
18 States pharmacopeia and the national formulary or any current supplement.
19 56. "Other jurisdiction" means one of the other forty-nine states, the
20 District of Columbia, the Commonwealth of Puerto Rico or a territory of the
21 United States of America.
22 57. "Package" means a receptacle defined or described in the United
23 States pharmacopeia and the national formulary as adopted by the board.
24 58. "Packaging" means the act or process of placing a drug item or
25 device in a container for the purpose or intent of dispensing or distributing
26 the item or device to another.
27 59. "Person" means an individual, partnership, corporation and
28 association, and their duly authorized agents.
29 60. "Pharmaceutical care" means the provision of drug therapy and other
30 pharmaceutical patient care services.
31 61. "Pharmacist" means an individual currently licensed by the board to
32 practice the profession of pharmacy in this state.
33 62. "Pharmacist in charge" means the pharmacist who is responsible to
34 the board for a licensed establishment's compliance with the laws and
35 administrative rules of this state and of the federal government pertaining
36 to the practice of pharmacy, the manufacturing of drugs and the distribution
37 of drugs and devices.
38 63. "Pharmacist licensure examination" means a board approved
39 examination that is written and administered in cooperation with the national
40 association of boards of pharmacy or any other board approved pharmacist
41 licensure examination.
42 64. "Pharmacy" means any place:
43 (a) Where drugs, devices, poisons or related hazardous substances are
44 offered for sale at retail.

(b) In which the profession of pharmacy is practiced or where prescription orders are compounded and dispensed.

(c) That has displayed on it or in it the words~~,~~ "pharmacist," "pharmaceutical chemist," "apothecary," "druggist," "pharmacy," "drugstore," "drugs~~,~~" OR "drug sundries" or any of these words or combinations of these words, or words of similar import either in English or any other language, or that is advertised by any sign containing any of these words.

(d) Where the characteristic symbols of pharmacy or the characteristic prescription sign "Rx" is exhibited.

(e) Or a portion of any building or structure that is leased, used or controlled by the permittee to conduct the business authorized by the board at the address for which the permit was issued and that is enclosed and secured when a pharmacist is not in attendance.

65. "Pharmacy intern" means a person who has all of the qualifications and experience prescribed in section 32-1923.

66. "Pharmacy technician" means a person WHO IS licensed pursuant to this chapter.

67. "Pharmacy technician trainee" means a person WHO IS licensed pursuant to this chapter.

68. "Poison" or "hazardous substance" includes, but is not limited to, any of the following if intended and suitable for household use or use by children:

(a) Any substance that, according to standard works on medicine, pharmacology, pharmacognosy or toxicology, if applied to, introduced into or developed within the body in relatively small quantities by its inherent action uniformly produces serious bodily injury, disease or death.

(b) A toxic substance.

(c) A highly toxic substance.

(d) A corrosive substance.

(e) An irritant.

(f) A strong sensitizer.

(g) A mixture of any of the substances described in this paragraph, if the substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.

(h) A substance designated by the board to be a poison or hazardous substance. This subdivision does not apply to radioactive substances, economic poisons subject to the federal insecticide, fungicide and rodenticide act or the state pesticide act, foods, drugs and cosmetics subject to state laws or the federal act or substances intended for use as fuels when stored in containers and used in the heating, cooking or refrigeration system of a house. This subdivision applies to any substance or article that is not itself an economic poison within the meaning of the federal insecticide, fungicide and rodenticide act or the state pesticide

act, but that is a poison or hazardous substance within the meaning of this paragraph by reason of bearing or containing an economic poison or hazardous substance.

69. "Practice of pharmacy" means FURNISHING THE FOLLOWING HEALTH CARE SERVICES AS A MEDICAL PROFESSIONAL:

(a) Interpreting, evaluating and dispensing prescription orders in the patient's best interests.

(b) Compounding drugs pursuant to or in anticipation of a prescription order.

(c) Labeling of drugs and devices in compliance with state and federal requirements.

(d) Participating in drug selection and drug utilization reviews, drug administration, drug or drug-related research and drug therapy monitoring or management.

(e) Providing patient counseling necessary to provide pharmaceutical care.

(f) Properly and safely storing drugs and devices in anticipation of dispensing.

(g) Maintaining required records of drugs and devices.

(h) Offering or performing of acts, services, operations or transactions necessary in the conduct, operation, management and control of a pharmacy.

(i) IMPLEMENTING, MONITORING AND MODIFYING DRUG THERAPY PURSUANT TO A PROTOCOL-BASED DRUG THERAPY AGREEMENT WITH A PROVIDER AS OUTLINED IN SECTION 32-1970.

(j) INITIATING AND ADMINISTERING IMMUNIZATIONS OR VACCINES PURSUANT TO SECTION 32-1974.

70. "Practitioner" means any physician, dentist, veterinarian, scientific investigator or other person WHO IS licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or administer a controlled substance in the course of professional practice or research in this state, or any pharmacy, hospital or other institution THAT IS licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or administer a controlled substance in the course of professional practice or research in this state.

71. "Preceptor" means a pharmacist who is serving as the practical instructor of an intern and complies with section 32-1923.

72. "Precursor chemical" means a substance that is:

(a) The principal compound that is commonly used or that is produced primarily for use and that is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail or limit manufacture.

(b) Listed in section 13-3401, paragraph 26 or 27.

73. "Prescription" means either a prescription order or a prescription medication.

74. "Prescription medication" means any drug, including label and container according to context, that is dispensed pursuant to a prescription order.

75. "Prescription-only device" includes:

(a) Any device that is limited by the federal act to use under the supervision of a medical practitioner.

(b) Any device required by the federal act to bear on its label essentially the legend "Rx only".

76. "Prescription-only drug" does not include a controlled substance but does include:

(a) Any drug that because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use is not generally recognized among experts, qualified by scientific training and experience to evaluate its safety and efficacy, as safe for use except by or under the supervision of a medical practitioner.

(b) Any drug that is limited by an approved new drug application under the federal act or section 32-1962 to use under the supervision of a medical practitioner.

(c) Every potentially harmful drug, the labeling of which does not bear or contain full and adequate directions for use by the consumer.

(d) Any drug, other than a controlled substance, required by the federal act to bear on its label the legend "Rx only".

77. "Prescription order" means any of the following:

(a) An order to a pharmacist for drugs or devices issued and signed by a duly licensed medical practitioner in the authorized course of the practitioner's professional practice.

(b) An order transmitted to a pharmacist through word of mouth, telephone or other means of communication directed by that medical practitioner. Prescription orders received by word of mouth, telephone or other means of communication shall be maintained by the pharmacist pursuant to section 32-1964, and the record so made by the pharmacist constitutes the original prescription order to be dispensed by the pharmacist. This paragraph does not alter or affect laws of this state or any federal act requiring a written prescription order.

(c) An order initiated by a pharmacist pursuant to a protocol-based drug therapy agreement with a provider as outlined in section 32-1970, or immunizations or vaccines administered by a pharmacist pursuant to section 32-1974.

78. "Professionally incompetent" means:

(a) Incompetence based on a variety of factors including a lack of sufficient pharmaceutical knowledge or skills or experience to a degree likely to endanger the health of patients.

(b) When considered with other indications of professional incompetence, a pharmacist, pharmacy intern or graduate intern who fails to obtain a passing score on a board approved pharmacist licensure examination

or a pharmacy technician or pharmacy technician trainee who fails to obtain a passing score on a board approved pharmacy technician licensure examination.

79. "Radioactive substance" means a substance that emits ionizing radiation.

80. "Safely engage in employment duties" means that a permittee or the permittee's employee is able to safely engage in employment duties related to the manufacture, sale, distribution or dispensing of drugs, devices, poisons, hazardous substances, controlled substances or precursor chemicals.

81. "Symbol" means the characteristic symbols that have historically identified pharmacy, including "show globes", "mortar and pestle" and the sign "Rx".

82. "Toxic substance" means a substance, other than a radioactive substance, that has the capacity to produce injury or illness in humans through ingestion, inhalation or absorption through any body surface.

83. "Ultimate user" means a person who lawfully possesses a drug or controlled substance for that person's own use, for the use of a member of that person's household or for administering to an animal owned by that person or by a member of that person's household.

Sec. 4. Section 32-1904, Arizona Revised Statutes, is amended to read:

32-1904. Powers and duties of board; immunity

A. The board shall:

1. Make bylaws and adopt rules that are necessary for the protection of the public and that pertain to the practice of pharmacy, the manufacturing, wholesaling or supplying of drugs, devices, poisons or hazardous substances, the use of pharmacy technicians and support personnel and the lawful performance of its duties.

2. Fix standards and requirements for the registration and reregistration of pharmacies, except as otherwise specified.

3. Investigate compliance as to the quality, label and labeling of all drugs, devices, poisons or hazardous substances and take action necessary to prevent the sale of these if they do not conform to the standards prescribed in this chapter, the official compendium or the federal act.

4. Enforce its rules. In so doing, the board or its agents have free access at all reasonable hours to any pharmacy, manufacturer, wholesaler, nonprescription drug permittee or other establishment in which drugs, devices, poisons or hazardous substances are manufactured, processed, packed or held, or to enter any vehicle being used to transport or hold such drugs, devices, poisons or hazardous substances for the purpose of:

(a) Inspecting the establishment or vehicle to determine if any provisions of this chapter or the federal act are being violated.

(b) Securing samples or specimens of any drug, device, poison or hazardous substance after paying or offering to pay for such sample.

(c) Detaining or embargoing a drug, device, poison or hazardous substance in accordance with section 32-1994.

5. Examine and license as pharmacists and pharmacy interns all qualified applicants as provided by this chapter.

6. REQUIRE EACH APPLICANT FOR AN INITIAL LICENSE TO SUBMIT TO THE BOARD A FULL SET OF FINGERPRINTS FOR THE PURPOSE OF OBTAINING A STATE AND FEDERAL CRIMINAL RECORDS CHECK PURSUANT TO SECTION 41-1750 AND PUBLIC LAW 92-544. THE DEPARTMENT OF PUBLIC SAFETY MAY EXCHANGE THIS FINGERPRINT DATA WITH THE FEDERAL BUREAU OF INVESTIGATION.

~~6.~~ 7. Issue duplicates of lost or destroyed permits on the payment of a fee as prescribed by the board.

~~7.~~ 8. Adopt rules for the rehabilitation of pharmacists and pharmacy interns as provided by this chapter.

~~8.~~ 9. At least once every three months, notify pharmacies regulated pursuant to this chapter of any modifications on prescription writing privileges of podiatrists, dentists, doctors of medicine, registered nurse practitioners, osteopathic physicians, veterinarians, physician assistants, optometrists and homeopathic physicians of which it receives notification from the board of podiatry examiners, board of dental examiners, Arizona medical board, board of nursing, board of osteopathic examiners in medicine and surgery, veterinary medical examining board, Arizona regulatory board of physician assistants, board of optometry or board of homeopathic and integrated medicine examiners.

B. The board may:

1. Employ chemists, compliance officers, clerical help and other employees subject to title 41, chapter 4, article 4 and provide laboratory facilities for the proper conduct of its business.

2. Provide, by education of and information to the licensees and to the public, assistance in the curtailment of abuse in the use of drugs, devices, poisons and hazardous substances.

3. Approve or reject the manner of storage and security of drugs, devices, poisons and hazardous substances.

4. Accept monies and services to assist in the enforcement of this chapter from other than licensees:

(a) For performing inspections and other board functions.

(b) For the cost of copies of the pharmacy and controlled substances laws, the annual report of the board and other information from the board.

5. Adopt rules for professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession of pharmacy.

6. Grant permission to deviate from a state requirement for experimentation and technological advances.

7. Adopt rules for the training and practice of pharmacy interns, pharmacy technicians and support personnel.

8. Investigate alleged violations of this chapter, conduct hearings in respect to violations, subpoena witnesses and take such action as it deems necessary to revoke or suspend a license or a permit, place a licensee or

permittee on probation or warn a licensee or permittee under this chapter or to bring notice of violations to the county attorney of the county in which a violation took place or to the attorney general.

9. By rule, approve colleges or schools of pharmacy.

10. By rule, approve programs of practical experience, clinical programs, internship training programs, programs of remedial academic work and preliminary equivalency examinations as provided by this chapter.

11. Assist in the continuing education of pharmacists and pharmacy interns.

12. Issue inactive status licenses as provided by this chapter.

13. Accept monies and services from the federal government or others for educational, research or other purposes pertaining to the enforcement of this chapter.

14. By rule, except from the application of all or any part of this chapter any material, compound, mixture or preparation containing any stimulant or depressant substance included in section 13-3401, paragraph 6, subdivision (c) or (d) from the definition of dangerous drug if the material, compound, mixture or preparation contains one or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system, provided that such admixtures are included in such combinations, quantity, proportion or concentration as to vitiate the potential for abuse of the substances that do have a stimulant or depressant effect on the central nervous system.

15. Adopt rules for the revocation, suspension or reinstatement of licenses or permits or the probation of licensees or permittees as provided by this chapter.

C. The executive director and other personnel or agents of the board are not subject to civil liability for any act done or proceeding undertaken or performed in good faith and in furtherance of the purposes of this chapter.

Sec. 5. Section 32-1929, Arizona Revised Statutes, is amended to read:

32-1929. <u>Biennial registration of pharmacies, wholesalers, manufacturers and similar places; application</u>

A. Except as provided in section 32-4301, the board shall require and provide for biennial registration of every pharmacy, wholesaler~~,~~ AND manufacturer and any other place in which or from which drugs are sold, compounded, dispensed, stocked, exposed, manufactured or offered for sale.

B. Any person desiring to operate, maintain, open or establish a pharmacy, wholesaling firm~~,~~ OR manufacturing plant, or any other place in which or from which drugs are manufactured, compounded, dispensed, stocked, exposed, sold~~,~~ or offered for sale, shall apply to the board for a permit before engaging in any such activity.

C. The application for a permit TO OPERATE A PHARMACY, DRUG MANUFACTURING FACILITY OR WHOLESALING FACILITY IN THIS STATE shall be made on a form prescribed and furnished by the board, which, when properly executed,

~~shall indicate~~ INDICATES the ownership, trustee, receiver or other person or persons desiring the permit, including the pharmacist responsible to the board for the operation of a pharmacy or drug manufacturing facility, or other individual approved by and responsible to the board for the operation of wholesaling facilities, as well as the location, including the street name and number, and such other information as required by the board to establish THE identity, exact location~~,~~ and extent of activities, in which or from which drugs are sold, manufactured, compounded, dispensed, stocked, exposed or offered for sale.

D. THE APPLICATION FOR A PERMIT TO OPERATE A PHARMACY, DRUG MANUFACTURING FACILITY OR WHOLESALING FACILITY OUTSIDE OF THIS STATE THAT WILL DISPENSE, SELL, TRANSFER OR DISTRIBUTE DRUGS INTO THIS STATE SHALL BE MADE ON A FORM PRESCRIBED AND FURNISHED BY THE BOARD, WHICH, WHEN PROPERLY EXECUTED, INDICATES THE OWNERSHIP, TRUSTEE, RECEIVER OR OTHER PERSON OR PERSONS DESIRING THE PERMIT, INCLUDING THE INDIVIDUAL APPROVED BY AND RESPONSIBLE TO THE BOARD FOR THE OPERATION OF THE PHARMACY, DRUG MANUFACTURING FACILITY OR WHOLESALING FACILITY, AS WELL AS THE LOCATION, INCLUDING THE STREET NAME AND NUMBER, AND SUCH OTHER INFORMATION AS REQUIRED BY THE BOARD TO ESTABLISH THE IDENTITY, EXACT LOCATION AND EXTENT OF ACTIVITIES, IN WHICH OR FROM WHICH DRUGS ARE SOLD, MANUFACTURED, COMPOUNDED, DISPENSED, STOCKED, EXPOSED OR OFFERED FOR SALE.

~~D.~~ E. If it is desired to operate, maintain, open or establish more than one pharmacy, or any other place of business in which or from which drugs are sold, manufactured, compounded, dispensed, stocked, exposed or offered for sale, a separate application shall be made and a separate permit shall be issued for each place, business~~,~~ or outlet.

Sec. 6. Section 32-1963.01, Arizona Revised Statutes, is amended to read:

32-1963.01. <u>Substitution for prescription drugs; requirements; label; definitions</u>

A. If a medical practitioner prescribes a brand name drug and does not indicate an intent to prevent substitution as prescribed in subsection D of this section, a pharmacist may fill the prescription with a generic equivalent drug.

B. Any pharmacy personnel shall notify the person presenting the prescription of the amount of the price difference between the brand name drug prescribed and the generic equivalent drug, if both of the following apply:

1. The medical practitioner does not indicate an intent to prevent substitution with a generic equivalent drug.

2. The transaction is not subject to third-party reimbursement.

C. The pharmacist shall place on the container the name of the drug dispensed followed by the words "generic equivalent for" followed by the brand or trade name of the product that is being replaced by the generic

equivalent. The pharmacist shall include the brand or trade name on the container or label of any contact lenses dispensed pursuant to this chapter.

D. A prescription generated in this state must be dispensed as written only if the prescriber writes or clearly displays "DAW", "dispense as written", "do not substitute", "medically necessary" or any statement by the prescriber that clearly indicates an intent to prevent substitution on the face of the prescription form. A prescription from out of state or from agencies of the United States government must be dispensed as written only if the prescriber writes or clearly displays "do not substitute", "dispense as written" or "medically necessary" or any statement by the prescriber that clearly indicates an intent to prevent substitution on the face of the prescription form.

E. This section applies to all prescriptions, including those presented by or on behalf of persons receiving state or federal assistance payments.

F. An employer or agent of an employer of a pharmacist shall not require the pharmacist to dispense any specific generic equivalent drug or substitute any specific generic equivalent drug for a brand name drug against the professional judgment of the pharmacist or the order of the prescriber.

G. The liability of a pharmacist in substituting according to this section shall be no greater than that which is incurred in the filling of a generically written prescription. This subsection does not limit or diminish the responsibility for the strength, purity or quality of drugs provided in section 32-1963. The failure of a prescriber to specify that no substitution is authorized does not constitute evidence of negligence.

H. A pharmacist may not make a substitution pursuant to this section unless the manufacturer or distributor of the generic drug has shown that:

1. All products dispensed have an expiration date on the original package.

2. The manufacturer or distributor maintains recall and return capabilities for unsafe or defective drugs.

I. The labeling and oral notification requirements of this section do not apply to pharmacies serving patients in a health care institution as defined in section 36-401. However, in order for this exemption to apply to hospitals, the hospital must have a formulary to which all medical practitioners of that hospital have agreed and that is available for inspection by the board.

~~J. The board by rule shall establish a list of drugs that shall not be used by dispensing pharmacists as generic equivalents for substitution.~~

~~K.~~ J. ~~In~~ FOR THE PURPOSES OF this section:

1. "Brand name drug" means a drug with a proprietary name assigned to it by the manufacturer or distributor.

2. "Formulary" means a list of medicinal drugs.

3. "Generic equivalent" or "generically equivalent" means a drug that has an identical amount of the same active chemical ingredients in the same

dosage form, that meets applicable standards of strength, quality and purity according to the United States pharmacopeia or other nationally recognized compendium and that, if administered in the same amounts, will provide comparable therapeutic effects. Generic equivalent or generically equivalent does not include a drug that is listed by the federal food and drug administration as having unresolved bioequivalence concerns according to the administration's most recent publication of approved drug products with therapeutic equivalence evaluations.

Sec. 7. Section 32-1975, Arizona Revised Statutes, is amended to read:

32-1975. Legend drug products; listing; code identification; exemption; definitions

A. A legend drug product in finished solid ~~oral~~ dosage form shall not be manufactured or commercially distributed within this state unless it is clearly or prominently marked or imprinted with a code imprint identifying the drug product and the manufacturer or distributor of the drug.

B. All manufacturers or distributors of legend drugs in solid dosage form shall make available on request to the board a listing of all such legend drugs identifying by code imprint the manufacturer or distributor and the specific type of drug. The listing shall at all times be kept current by all manufacturers and distributors subject to this section.

~~C. The board shall adopt rules for implementing this section.~~

~~D.~~ C. The board may grant exemptions from the requirements of this section on application of any drug manufacturer or distributor showing size, physical characteristics or other unique characteristics ~~which~~ THAT render the application of a code imprint to a legend drug subject to this section impractical or impossible. Any exemption granted by the board shall be included by the manufacturer or distributor in the listing required by subsection B of this section, describing the physical characteristics and type of drug to which the exemption relates.

~~E.~~ D. This section does not apply to drug products compounded by a pharmacist licensed under section 32-1924 in a pharmacy operating under a permit issued by the board.

~~F.~~ E. For the purposes of this section:

1. "Code imprint" means a series of letters or numbers assigned by the manufacturer or distributor to a specific drug or marks or monograms unique to the manufacturer or distributor of the drug, or both.

2. "Distributor" means a person who distributes for resale a drug in solid dosage form under that person's own label even if that person is not the actual manufacturer of the drug.

3. "Legend drug" means any drug defined by section 503(b) of the federal food, drug and cosmetic act and under which definition its label is required to bear the statement "Rx only".

4. "Solid dosage form" means capsules or tablets intended for oral use.

APPROVED BY THE GOVERNOR APRIL 22, 2014.

FILED IN THE OFFICE OF THE SECRETARY OF STATE APRIL 23, 2014.

Passed the House April 15, 2014,

by the following vote: 60 Ayes,

0 Nays, 0 Not Voting

Speaker of the House

Cheryl Laube

Chief Clerk of the House

Passed the Senate February 3, 2014,

by the following vote: 29 Ayes,

0 Nays, 1 Not Voting

President of the Senate

Secretary of the Senate

EXECUTIVE DEPARTMENT OF ARIZONA
OFFICE OF GOVERNOR
This Bill was received by the Governor this

_____ day of _____, 20____,

at _____ o'clock _____ M.

Secretary to the Governor

Approved this _____ day of

_____, 20_____,

at _____ o'clock _____ M.

Governor of Arizona

EXECUTIVE DEPARTMENT OF ARIZONA
OFFICE OF SECRETARY OF STATE

This Bill was received by the Secretary of State

this _____ day of _____, 20____,

at _____ o'clock _____ M.

Secretary of State

S.B. 1043

SENATE CONCURS IN HOUSE AMENDMENTS AND FINAL PASSAGE

Passed the Senate April 16, 20 14

by the following vote: 28 **Ayes,**

0 **Nays,** 2 **Not Voting**

President of the Senate

Secretary of the Senate

EXECUTIVE DEPARTMENT OF ARIZONA
OFFICE OF GOVERNOR

This Bill received by the Governor this

17 **day of** April, 20 14

at 8:20 **o'clock** A **M.**

Mikhaila Howard
Secretary to the Governor

Approved this 22nd **day of**

April

at 4:01 **o'clock** P **M.**

Governor of Arizona

EXECUTIVE DEPARTMENT OF ARIZONA
OFFICE OF SECRETARY OF STATE

This Bill received by the Secretary of State

this 23rd **day of** April, 20 14

at 9:40 **o'clock** a **M.**

Secretary of State

S.B. 1043