

State of Arizona
Senate
Fifty-first Legislature
Second Regular Session
2014

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)

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

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

4 23-908. Injury reports by employer and physician; schedule of
5 fees; violation; classification

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

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

20 C. If a schedule of fees for prescription medicines adopted pursuant
21 to subsection B of this section includes provisions regarding the use of
22 generic equivalent drugs, those provisions shall comply with section
23 32-1963.01, subsections A and C through ~~K~~ **J**. If the commission considers
24 the adoption of fee schedule provisions that involve specific prices, values
25 or reimbursements for prescription drugs, the commission shall base the
26 adoption on studies or practices that are validated and accepted in the
27 industry, including the applicability of formulas that use average wholesale
28 price, plus a dispensing fee, and that have been made publicly available for
29 at least one hundred eighty days before any hearing conducted by the
30 commission.

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

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

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

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

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

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

26 Sec. 2. Section 32-1501, Arizona Revised Statutes, is amended to read:
27 32-1501. Definitions

28 In this chapter, unless the context otherwise requires:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 (ii) Minerals.

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

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

25 (c) Cancer chemotherapeutics classified as legend drugs.

26 (d) Antipsychotics.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

29 32-1901. Definitions

30 In this chapter, unless the context otherwise requires:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 16. "Dangerous drug" has the same meaning prescribed in section
22 13-3401.

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

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

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

32 20. "Device", except as used in paragraph 15 of this section, section
33 32-1965, paragraph 4 and section 32-1967, subsection A, paragraph 15 and
34 subsection C, means instruments, apparatus and contrivances, including their
35 components, parts and accessories, including all such items under the federal
36 act, intended either:

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

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

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

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

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

7 24. "Dispenser" means a practitioner who dispenses.

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

10 26. "Distributor" means a person who distributes.

11 27. "Drug" means:

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

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

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

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

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

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

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

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

37 (a) The applicable official name.

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

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

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

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

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

9 35. "Graduate intern" means a person who has graduated from a college,
10 school or program of pharmacy approved by the board and who meets the
11 qualifications and experience for a pharmacy intern as provided in section
12 32-1923.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 (b) Accompanying that article.

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

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

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

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

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

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

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

33 51. "New drug" means either:

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

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

44 52. "Nonprescription drug" or "over-the-counter drug" means any
45 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.

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

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

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

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

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

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

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

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

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

27 (b) A toxic substance.

28 (c) A highly toxic substance.

29 (d) A corrosive substance.

30 (e) An irritant.

31 (f) A strong sensitizer.

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

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

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

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

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

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

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

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

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

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

19 (g) Maintaining required records of drugs and devices.

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

23 (i) IMPLEMENTING, MONITORING AND MODIFYING DRUG THERAPY PURSUANT TO A
24 PROTOCOL-BASED DRUG THERAPY AGREEMENT WITH A PROVIDER AS OUTLINED IN SECTION
25 32-1970.

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

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

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

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

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

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

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

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

4 75. "Prescription-only device" includes:

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

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

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

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

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

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

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

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

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

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

35 (c) An order initiated by a pharmacist pursuant to a protocol-based
36 drug therapy agreement with a provider as outlined in section 32-1970, or
37 immunizations or vaccines administered by a pharmacist pursuant to section
38 32-1974.

39 78. "Professionally incompetent" means:

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

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

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

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

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

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

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

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

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

20 32-1904. Powers and duties of board; immunity

21 A. The board shall:

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

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

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

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

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

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

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

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

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

8 ~~6-~~ 7. Issue duplicates of lost or destroyed permits on the payment of
9 a fee as prescribed by the board.

10 ~~7-~~ 8. Adopt rules for the rehabilitation of pharmacists and pharmacy
11 interns as provided by this chapter.

12 ~~8-~~ 9. At least once every three months, notify pharmacies regulated
13 pursuant to this chapter of any modifications on prescription writing
14 privileges of podiatrists, dentists, doctors of medicine, registered nurse
15 practitioners, osteopathic physicians, veterinarians, physician assistants,
16 optometrists and homeopathic physicians of which it receives notification
17 from the board of podiatry examiners, board of dental examiners, Arizona
18 medical board, board of nursing, board of osteopathic examiners in medicine
19 and surgery, veterinary medical examining board, Arizona regulatory board of
20 physician assistants, board of optometry or board of homeopathic and
21 integrated medicine examiners.

22 B. The board may:

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

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

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

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

33 (a) For performing inspections and other board functions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

32 32-1929. Biennial registration of pharmacies, wholesalers,
33 manufacturers and similar places; application

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

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

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

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

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

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

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

29 32-1963.01. Substitution for prescription drugs; requirements;
30 label; definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

40 ~~K.~~ J. **IN** FOR THE PURPOSES OF this section:

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

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

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

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

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

10 32-1975. Legend drug products; listing; code identification;
11 exemption; definitions

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

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

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

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

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

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

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

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

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

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