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# S T A T E  O F  R H O D E  I S L A N D

**IN GENERAL ASSEMBLY**

**JANUARY SESSION, A.D. 2015**

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A N  A C T

RELATING TO BUSINESSES AND PROFESSIONS

Introduced By: Senators Ottiano, Pichardo, Crowley, Miller, and Cote

Date Introduced: February 12, 2015

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

SECTION 1. Sections 5-54-2, 5-54-3, 5-54-5 and 5-54-8 of the General Laws in Chapter 5-54 entitled "Physician Assistants" are hereby amended to read as follows:

**5-54-2. Definitions. --** As used in this chapter, the following words have the following meanings:

(1) "Administrator" means the administrator, division of professional regulation.

(2) "Approved program" means a program for the education and training of physician assistants formally approved by the American Medical Association's (A.M.A.'s) Committee on Allied Health, Education and Accreditation, its successor, the Commission on Accreditation of Allied Health Education Programs (CAAHEP) or its successor.

(3) "Approved program for continuing medical education" means a program for continuing education approved by the American Academy of Physician Assistants (AAPA) or the Accreditation Council for Continuing Medical Education of the American Medical Association (AMA), or the American Academy of Family Physicians (AAPFP) or the American Osteopathic Association Committee on Continuing Medical Education (AOACCME) or any other board approved program.

(4) "Board" means the board of licensure of physician assistants.

(5) "Director" means the director of the department of health.

(6) "Division" means the division of professional regulation, department of health.

(7) [Deleted by P.L. 2013, ch. 320, § 1 and P.L. 2013, ch. 420, § 1].

(8) "Physician" means a person licensed under the provisions of chapter 29 or 37 of this title.

(9) "Physician assistant" means a person who is qualified by academic and practical training ~~to provide those certain patient services under~~ to practice medicine with the supervision~~, control, responsibility and direction~~ of a licensed physician expert in the field of medicine in which the physician assistant practices.

(10) "Supervision" means overseeing the activities of~~, and accepting the responsibility for~~ the medical services rendered by the physician assistants. ~~Supervision is continuous, and under the direct control of a licensed physician expert in the field of medicine in which the physician assistants practice.~~ The constant physical presence of the supervising physician or physician designee is not required. It is the responsibility of the supervising physician and physician assistant to assure an appropriate level of supervision depending on the services being rendered. Each physician or group of physicians, or other health care delivery organization excluding licensed hospital or licensed health care facilities controlled or operated by a licensed hospital employing physician assistants must have on file at the primary practice site ~~a copy of a policy in the form of~~ an agreement between the supervising physicians and physician assistants delineating:

~~(i) The level of supervision provided by the supervising physician or designee with particular reference to differing levels of supervision depending on the type of patient services provided and requirements for communication between the supervising physician or designee and the physician assistant.~~

~~(ii)~~(i) A job description for the physician assistant listing patient care responsibilities and procedures to be performed by the physician assistant.

~~(iii)~~(ii) A program for quality assurance for physician assistant services including requirements for periodic review of the physician assistant services.

~~(iv)~~(iii) Requirements for supervision of physician assistants employed or extended medical staff privileges by licensed hospitals or other licensed health care facilities or employed by other health care delivery agencies shall be delineated by the medical staff by laws and/or applicable governing authority of the facility.

~~(v)~~(iv) The supervising physician or physician designee must be available for easy communication and referral at all times.

(11) "Unprofessional conduct" includes, but is not limited to, the following items or any combination and may be defined by regulations established by the board with prior approval of the director:

(i) Fraudulent or deceptive procuring or use of a license;

(ii) Representation of himself or herself as a physician;

(iii) Conviction of a crime involving moral turpitude; conviction of a felony; conviction of a crime arising out of the practice of medicine. All advertising of medical business, which is intended or has a tendency to deceive the public;

(iv) Abandonment of a patient;

(v) Dependence upon a controlled substance, habitual drunkenness, or rendering professional services to a patient while intoxicated or incapacitated by the use of drugs;

(vi) Promotion of the sale of drugs, devices appliances, or goods or services provided for a patient in a manner that exploits the patient for the financial gain of the physician assistant;

(vii) Immoral conduct of a physician assistant in the practice of medicine;

(viii) Willfully making and filing false reports or records;

(ix) Willful omission to file or record or willfully impeding or obstructing a filing or recording, or inducing another person to omit to file or record medical or other reports as required by law;

(x) Agreeing with clinical or bioanalytical laboratories to accept payments from these laboratories for individual tests or test series for patients;

(xi) Practicing with an unlicensed physician or physician assistant or aiding or abetting these unlicensed persons in the practice of medicine;

(xii) Offering, undertaking or agreeing to cure or treat a disease by a secret method, procedure, treatment or medicine;

(xiii) Professional or mental incompetence;

(xiv) Surrender, revocation, suspension, limitation of privilege based on quality of care provided, or any other disciplinary action against a license or authorization to practice in another state or jurisdiction; or surrender, revocation, suspension, or any other disciplinary action relating to membership on any medical staff or in any medical professional association, or society while under disciplinary investigation by any of those authorities or bodies for acts or conduct similar to acts or conduct which would constitute grounds for action as stated in this chapter;

(xv) Any adverse judgment, settlement, or award arising from a medical liability claim related to acts or conduct, which would constitute grounds for action as stated in this chapter;

(xvi) Failure to furnish the board, the administrator, investigator or representatives, information legally requested by the board;

(xvii) Violation of any provisions of this chapter or the rules and regulations promulgated by the director or an action, stipulation, or agreement of the board;

(xviii) Cheating or attempting to subvert the certifying examination;

(xix) Violating any state or federal law or regulation relating to controlled substances;

(xx) Medical malpractice;

(xxi) Sexual contact between a physician assistant and patient during the existence of the physician assistant/patient relationship;

(xxii) Providing services to a person who is making a claim as a result of a personal injury, who charges or collects from the person any amount in excess of the reimbursement to the physician assistant by the insurer as a condition of providing or continuing to provide services or treatment.

**5-54-3. Exemptions. --** The provisions of this chapter do not apply to services performed in any of the following areas:

(1) The practice of dentistry or dental hygiene as defined in chapter 31.1 of this title.

(2) The practice of chiropractic medicine.

(3) The practice of optometry as defined in chapter 35 of this title.

(4) A physician assistant student enrolled in ~~a physician assistant or surgeon assistant~~ an approved educational program while performing duties in conjunction with a formal training program clinical rotation under the auspices of a recognized degree granting institution.

(5) Technicians, or other assistants or employees of physicians who perform delegated tasks in the office of a physician but who are not rendering services as physician assistant or identifying themselves as a physician assistant.

**5-54-5. Board of licensure. --** (a) The director of the department of health, with the approval of the governor, shall appoint a board consisting of ~~seven (7)~~ nine (9) persons, residents of the state, to constitute a board of licensure for physician assistants with the duties, powers, and authority as stated in this chapter, and that board shall be composed of the following:

(1) Two (2) members shall be licensed physicians under the provisions of chapter 37 of this title who have been actively engaged in the practice of medicine;

(2) One member is a chief executive officer of a health care facility located and licensed in the state or his or her designee who is not licensed in any health care profession;

(3) Two (2) members who are representatives of the general public not employed in any health-related field; and

(4) ~~Two (2)~~ Four (4) members shall be licensed physician assistants.

(b) Members shall be appointed for terms of three (3) years each with no member serving more than two (2) consecutive terms.

(c) In his or her initial appointment, the director shall designate the members of the

board of licensure for physician assistants as follows: two (2) members to serve for terms of three (3) years; two (2) members to serve for a term of two (2) years; and three (3) members to serve for a term of one year. Any additional appointments shall serve for one year.

(d) The director of the department of health may remove any member of the board for cause.

(e) Vacancies shall be filled for the unexpired portion of any term in the same manner as the original appointment.

**5-54-8. Permitted health care practices by physician assistants. --** (a) Physician assistants shall practice with physician supervision and shall be considered the agents of their supervising physicians in the performance of all practice-related activities. Whenever any provision of general or public law, or regulation, requires a signature, certification, stamp, verification, affidavit or endorsement by a physician, it shall be deemed to include a signature, certification, stamp, verification, affidavit or endorsement by a physician assistant; provided, however, that nothing in this section shall be construed to expand the scope of practice of physician assistants. Physician assistants may perform those duties and responsibilities consistent with the limitations of this section, including prescribing of drugs and medical devices, which are delegated by their supervising physician(s). Physician assistants may request, receive, sign for and distribute professional samples of drugs and medical devices to patients only within the limitations of this section. Notwithstanding any other provisions of law, a physician assistant may perform ~~health care~~ medical services when those services are rendered under the supervision of a licensed physician.

(b) Physician assistants, depending upon their level of professional training and experience, as determined by a supervising physician, may perform ~~health care~~ medical services consistent with their expertise and that of the supervising physician~~, who is a licensed physician in solo practice, in group practice, or in health care facilities~~.

(c) Physician assistants may write prescriptions and medical orders to the extent provided in this paragraph. When employed by or extended medical staff privileges by a licensed hospital or other licensed health care facility a physician assistant may write medical orders for inpatients as delineated by the medical staff bylaws of the facility as well as its credentialing process and applicable governing authority. Physician assistants employed directly by physicians, health maintenance organizations or other health care delivery organizations may prescribe legend medications including schedule II, III, IV and V medications under chapter 28 of title 21 of the Rhode Island Uniform Controlled Substances Act, medical therapies, medical devices and medical diagnostics ~~according to guidelines established by the employing physician, health~~

~~maintenance organization or other health care delivery organization~~.

~~(d) When supervised by a physician licensed under chapter 29 of this title, the service rendered by the physician assistant shall be limited to the foot. The "foot" is defined as the pedal extremity of the human body and its articulations, and includes the tendons and muscles of the lower leg only as they are involved in conditions of the foot.~~

~~(e)~~(d) Hospitals and other licensed health care facilities have discretion to grant privileges to a physician assistant and to define the scope of privileges or services which a physician assistant may deliver in a facility. In no event shall those privileges, if granted, exceed the privileges granted to the supervising physician.

SECTION 2. Sections 21-28-1.02 and 21-28-3.24 of the General Laws in Chapter 21-28 entitled "Uniform Controlled Substances Act" are hereby amended to read as follows:

**21-28-1.02. Definitions. --** Unless the context otherwise requires, the words and phrases as defined in this section are used in this chapter in the sense given them in the following definitions:

(1) "Administer" refers to the direct application of controlled substances to the body of a patient or research subject by:

(i) A practitioner, or, in his or her presence by his or her authorized agent; or

(ii) The patient or research subject at the direction and in the presence of the practitioner whether the application is by injection, inhalation, ingestion, or any other means.

(2) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, wholesaler, distributor, or dispenser; except that these terms do not include a common or contract carrier or warehouse operator, when acting in the usual and lawful course of the carrier's or warehouse operator's business.

(3) "Apothecary" means a registered pharmacist as defined by the laws of this state and, where the context requires, the owner of a licensed pharmacy or other place of business where controlled substances are compounded or dispensed by a registered pharmacist; and includes registered assistant pharmacists as defined by existing law, but nothing in this chapter shall be construed as conferring on a person who is not registered as a pharmacist any authority, right, or privilege that is not granted to him or her by the pharmacy laws of the state.

(4) "Automated data processing system" means a system utilizing computer software and hardware for the purposes of record keeping.

(5) "Computer" means programmable electronic device capable of multi-functions, including, but not limited to, storage, retrieval, and processing of information.

(6) "Control" means to add a drug or other substance or immediate precursor to a

schedule under this chapter, whether by transfer from another schedule or otherwise.

(7) "Controlled substance" means a drug, substance, immediate precursor, or synthetic drug in schedules I -- V of this chapter. The term shall not include distilled spirits, wine, or malt beverages, as those terms are defined or used in chapter 1 of title 3, nor tobacco.

(8) "Counterfeit substance" means a controlled substance which, 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 them, of a manufacturer, distributor, or dispenser, other than the person or persons who in fact manufactured, distributed, or dispensed the substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, the other manufacturer, distributor, or dispenser, or which substance is falsely purported to be or represented to be one of the controlled substances by a manufacturer, distributor, or dispenser.

(9) "CRT" means cathode ray tube used to impose visual information on a screen.

(10) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a controlled substance or imitation controlled substance, whether or not there exists an agency relationship.

(11) "Department" means the department of health of this state.

(12) "Depressant or stimulant drug" means:

(i) A drug which contains any quantity of:

(A) Barbituric acid or derivatives, compounds, mixtures, or preparations of barbituric acid; and

(B) "Barbiturate" or "barbiturates" includes all hypnotic and/or somnifacient drugs, whether or not derivatives of barbituric acid, except that this definition shall not include bromides and narcotics.

(ii) A drug which contains any quantity of:

(A) Amphetamine or any of its optical isomers;

(B) Any salt of amphetamine and/or desoxyephedrine or any salt of an optical isomer of amphetamine and/or desoxyephedrine, or any compound, mixture, or preparation of them.

(iii) A drug which contains any quantity of coca leaves. "Coca leaves" includes cocaine, or any compound, manufacture, salt, derivative, mixture, or preparation of coca leaves, except derivatives of coca leaves, which do not contain cocaine, ecgonine, or substance from which cocaine or ecgonine may be synthesized or made.

(iv) Any other drug or substance which contains any quantity of a substance which the attorney general of the United States, or the director of health, after investigation, has found to

have, or by regulation designates as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system.

(13) "Director" means the director of health.

(14) "Dispense" means to deliver, distribute, leave with, give away, or dispose of a controlled substance to the ultimate user or human research subject by or pursuant to the lawful order of a practitioner, including the packaging, labeling, or compounding necessary to prepare the substance for that delivery.

(15) "Dispenser" is a practitioner who delivers a controlled substance to the ultimate user or human research subject.

(16) "Distribute" means to deliver (other than by administering or dispensing) a controlled substance or an imitation controlled substance and includes actual constructive, or attempted transfer. "Distributor" means a person who so delivers a controlled substance or an imitation controlled substance.

(17) "Downtime" means that period of time when a computer is not operable.

(18) "Drug addicted person" means a person who exhibits a maladaptive pattern of behavior resulting from drug use, including one or more of the following: impaired control over drug use; compulsive use; and/or continued use despite harm, and craving.

(19) "Drug Enforcement Administration" means the Drug Enforcement Administration United States Department of Justice or its successor.

(20) "Federal law" means the Comprehensive Drug Abuse Prevention and Control Act of 1970, (84 stat. 1236)(see generally 21 U.S.C. § 801 et seq.), and all regulations pertaining to that federal act.

(21) "Hardware" means the fixed component parts of a computer.

(22) "Hospital" means an institution as defined in chapter 17 of title 23.

(23) "Imitation controlled substance" means a substance that is not a controlled substance, which by dosage unit, appearance (including color, shape, size, and markings), or by representations made, would lead a reasonable person to believe that the substance is a controlled substance and, which imitation controlled substances contain substances which if ingested, could be injurious to the health of a person. In those cases when the appearance of the dosage unit is not reasonably sufficient to establish that the substance is an "imitation controlled substance" (for example in the case of powder or liquid), the court or authority concerned should consider, in addition to all other logically relevant factors, the following factors as related to "representations made" in determining whether the substance is an "imitation controlled substance":

(i) Statement made by an owner, possessor, transferor, recipient, or by anyone else in

control of the substance concerning the nature of the substance, or its use or effect.

(ii) Statements made by the owner, possessor, or transferor, to the recipient that the substance may be resold for substantial profit.

(iii) Whether the substance is packaged in a manner reasonably similar to packaging of illicit controlled substances.

(iv) Whether the distribution or attempted distribution included an exchange of or demand for money or other property as consideration, and whether the amount of the consideration was substantially greater than the reasonable value of the non-controlled substance.

(24) "Immediate precursor" means a substance:

(i) Which the director of health has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance;

(ii) Which is an immediate chemical intermediary used or likely to be used in the manufacture of those controlled substances; and

(iii) The control of which is necessary to prevent, curtail, or limit the manufacture of that controlled substance.

(25) "Laboratory" means a laboratory approved by the department of health as proper to be entrusted with controlled substances and the use of controlled substances for scientific and medical purposes and for the purposes of instruction.

(26) "Marijuana" means all parts of the plant cannabis sativa L., whether growing or not; the seeds of the plant; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin, but shall not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of mature stalks, (except the resin extracted from it), fiber, oil or cake, or the sterilized seed from the plant which is incapable of germination.

(27) "Manufacture" means the production, preparation, propagation, cultivation, compounding, or processing of a drug or other substance, including an imitation controlled substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis and includes any packaging or repackaging of the substance or labeling or relabeling of its container in conformity with the general laws of this state except by a practitioner as an incident to his or her administration or dispensing of the drug or substance in the course of his or her professional practice.

(28) "Manufacturer" means a person who manufactures but does not include an apothecary who compounds controlled substances to be sold or dispensed on prescriptions.

(29) "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

(i) Opium and opiates.

(ii) A compound, manufacture, salt, derivative, or preparation of opium or opiates.

(iii) A substance (and any compound, manufacture, salt, derivative, or preparation of it) which is chemically identical with any of the substances referred to in paragraphs (i) and (ii) of this subdivision.

(iv) Any other substance which the attorney general of the United States, or his or her successor, or the director of health, after investigation, has found to have, and by regulation designates as having, a potential for abuse similar to opium and opiates.

(30) "Official written order" means an order written on a form provided for that purpose by the Drug Enforcement Administration under any laws of the United States making provision for an official form, if order forms are authorized and required by federal law, and if no order form is provided then on an official form provided for that purpose by the director of health.

(31) "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability.

(32) "Opium poppy" means the plant of the species papaver somniferum L., except the seeds of the plant.

(33) "Ounce" means an avoirdupois ounce as applied to solids and semi-solids, and a fluid ounce as applied to liquids.

(34) "Person" means any corporation, association, partnership, or one or more individuals.

(35) "Physical dependence" means a state of adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.

(36) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(37) "Practitioner" means:

(i) A physician, ~~osteopath,~~ physician assistant, advanced practice registered nurse, dentist, ~~chiropodist,~~ veterinarian, scientific investigator, or other person licensed, registered or permitted to distribute, dispense, conduct research with respect to or to administer a controlled

substance in the course of professional practice or research in this state.

(ii) A pharmacy, hospital, or other institution licensed, registered or permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state.

(38) "Printout" means a hard copy produced by computer that is readable without the aid of any special device.

(39) "Production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(40) "Researcher" means a person authorized by the director of health to conduct a laboratory as defined in this chapter.

(41) "Sell" includes sale, barter, gift, transfer, or delivery in any manner to another, or to offer or agree to do the same.

(42) "Software" means programs, procedures and storage of required information data.

(43) "Synthetic drugs" means any synthetic cannabinoids or piperazines or any synthetic cathinones as provided for in schedule I.

(44) "Ultimate user" means a person who lawfully possesses a controlled substance for his or her own use or for the use of a member of his or her household, or for administering to an animal owned by him or her or by a member of his or her household.

(45) "Wholesaler" means a person who sells, vends, or distributes at wholesale, or as a jobber, broker agent, or distributor, or for resale in any manner in this state any controlled substance.

**21-28-3.24. Examination before use of controlled substances. --** No physician, dentist, osteopath, ~~chiropodist,~~ physician assistant, advanced practice registered nurse or veterinarian shall administer, dispense, or prescribe any controlled substance in schedules II, III, and IV, except after an original physical examination of the person for whom, or the animal for which the controlled substance is intended.

SECTION 3. Sections 21-31-2 and 21-31-16.1 of the General Laws in Chapter 21-31 entitled "Rhode Island Food, Drugs, and Cosmetics Act" are hereby amended to read as follows:

**21-31-2. Definitions. --** For the purpose of this chapter:

(1) "Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics.

(2) "Contaminated with filth" applies to any food, drug, device, or cosmetic not securely protected from dust, dirt, and, as far as may be necessary by all reasonable means, from all

foreign or injurious contaminations.

(3) "Cosmetics" means: (i) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or applied to the humanbody or any part of the body for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (ii) articles intended for use as a component of any articles described in this subdivision, except that this term shall not include soap.

(4) "Device" (except when used in subdivision (23) of this section and in §§ 21-31-3(10), 21-31-11(6), 21-31-15(a)(3), and 21-31-18(3)) means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended: (i) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; or (ii) to affect the structure or any function of the body of humans or other animals.

(5) "Director" means the director of health.

(6) "Distressed merchandise" means any food which has had the label lost or which has been subjected to possible damage due to accident, fire, flood, adverse weather, or to any other similar cause, and which may have been rendered unsafe or unsuitable for human or animal consumption or use.

(7) "Dosage form" means the form of the completed drug product (such as tablet, syrup, or suppository).

(8) "Drug" means: (i) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (ii) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (iii) articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and (iv) articles intended for use as a component of any article specified in paragraphs (i), (ii) or (iii) of this subdivision; but does not include devices or their components, parts, or accessories.

(9) "Drug product" means a dosage form containing one or more active therapeutic ingredients along with other substances included during the manufacturing process.

(10) (i) "Equivalent and interchangeable" means having the same generic name, dosage form, and labeled potency, meeting standards of the United States Pharmacopoeia or National Formulary, or their successors, if applicable, and not found in violation of the requirements of the United States Food and Drug Administration, or its successor agency, or the department of health.

(ii) "Generic" means the chemical or established name of a drug or drug product.

(11) "Federal Act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq.

(12)"Food" means: (i) articles used for food or drink for humans or other animals, (ii) chewing gum, and (iii) articles used for components of any article described in this subdivision.

(13) (i) "Label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appearing on the label shall not be considered to be complied with unless the word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of the article, or is easily legible through the outside container or wrapper.

(ii) "Immediate container" does not include package liners.

(iii) "Labeling" means all labels and other written, printed, or graphic matter: (A) upon an article or any of its containers or wrappers, or (B) accompanying the article.

(iv) If an article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then in determining whether the labeling or advertisement is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or in any combination of them, but also the extent to which the labeling or advertisement fails to reveal facts material in the light of the representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement or under the conditions of use that are customary or usual.

(14) "Native" means a product harvested in Rhode Island and is limited to the following:

(i) "Bay scallop" means Argopecten irradians.

(ii) "Bay quahog" means Mercenaria mercenaria.

(iii) "Steamer clams" means Mya arenaria.

(iv) "Mussels" means Mytilus edulis.

(v) "Oysters" means Crassostrea virginica.

(15) "New drug" means: (i) 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 of drugs as safe for use under conditions prescribed, recommended, or suggested in the labeling of it; or (ii) any drug the composition of which is such that the drug, as a result of investigations to determine its safety for use under those conditions has become so recognized, but which has not, otherwise than in the investigations, been used to a material extent or for a material time under those conditions.

(16) "Official compendium" means the official United States Pharmacopoeia, official

Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.

(17) "Patient" means, as the case may be: (i) the individual medically requiring a drug, for whom a drug is prescribed; or (ii) the owner or the agent of the owner of an animal medically requiring a drug, for which a drug is prescribed.

(18) "Person" includes individual, partnership, corporation, and association.

(19) "Pharmacist" means a person duly registered with the board of pharmacy as a compounder, dispenser, or supplier of drugs upon prescription, including registered assistant pharmacists as defined by law.

(20) "Pharmacy" means a place where drugs, medicines, or poisons are sold at retail or where prescriptions of physicians, dentists, veterinarians, and other practitioners authorized to issue prescriptions for drugs, medicines, and poisons are compounded, dispensed, supplied or sold.

(21) "Practitioner" means a ~~person authorized by law to practice medicine, dentistry, osteopathy, chiropody, or veterinary medicine in this state~~ physician licensed under the provisions of chapter 37 of title 5, a physician assistant licensed under the provisions of chapter 54 of title 5, an advanced practice registered nurse licensed under the provisions of chapter 34 of title 5, a dentist licensed under the provisions of chapter 31.1 of title 5, a podiatrist licensed under the provisions of chapter 29 of title 5, an optometrist licensed under the provisions of chapter 35.1 of title 5, or a veterinarian licensed under the provisions of chapter 25 of title 5.

(22) "Prescription" means an order, issued in good faith in the course of professional practice only, by a practitioner to a pharmacist for a drug for a particular patient, which specifies the date of its issue, the name and address of the practitioner, the name and address of the patient (and, if the drug is prescribed for an animal, the species of the animal), the name and quantity of the drug prescribed, directions for the use of the drug, and the signature of the practitioner; provided, that a prescription received by word of mouth, telephone, or other means of communication shall be reduced promptly to writing by the pharmacist in the form prescribed in this subdivision, and the record so made shall constitute the original prescription to be filed and preserved by the pharmacist; and, provided, further, that any refill authorization received by word of mouth, telephone, or other means of communication shall be reduced promptly to writing by the pharmacist, with the date of it on the face or on the reverse side of the original prescription.

(23) The representation of a drug, in its labeling or advertisement, as an antiseptic shall be considered to be 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, dusting

powder, or any other use that involves prolonged contact with the body.

(24) The provisions of this chapter regarding the selling of food, drugs, devices, or cosmetics shall be considered to include the manufacture, production, processing, packing, exposure, offer, possession, and holding of any article for sale, and the sale, dispensing, and giving of any article, and the supplying or applying of the articles in the conduct of any food, drug, or cosmetic establishment.

**21-31-16.1. Substitution of generic drugs. --** (a) Product selection. - The director shall permit substitution of less expensive generic, chemical, or brand name drugs and pharmaceuticals considered by the director as therapeutically equivalent and interchangeable with specific brand name drugs and pharmaceuticals, if they are found to be in compliance with § 21-31-16 and standards set forth by the United States Food and Drug Administration under §§ 505 and 507 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 355 and 357. The director shall consider, but not be limited to, the determination of the United States Food and Drug Administration, or its successor agency, as published under §§ 505 and 507 of the Federal Food, Drug, and Cosmetic Act. The director shall provide for the distribution of copies of lists of prescription drug products that the director deems after evaluation not to be therapeutically equivalent, and revisions to the lists, among ~~physicians~~ practitioners and pharmacists licensed and actively engaged in practice within the state, and other appropriate individuals, and shall supply a copy to any person on request. The list shall be revised from time to time so as to include new pertinent information on approved prescription drug products, reflecting current information as to standards for quality, safety, effectiveness, and therapeutic equivalence.

(b) Appropriations. - The director shall provide necessary space, personnel, and material to carry out the provisions of this section.

(c) Liability. - There shall be no civil liability incurred and no cause of action of any nature shall arise against the director, designated agents, or employees, as a result of the listing or omission of drugs or pharmaceuticals for product selection.

(d) Annual reports. - The director shall make annual reports to the general assembly by February 10 of each year showing a list of approved prescription drug products with therapeutic equivalence, and an estimate of the average savings to the general public.

(e) Pharmacists. - When a pharmacist dispenses a therapeutically equivalent drug product, there shall be no additional liability imposed on the prescriber who authorizes that product selection, or on the pharmacist dispensing the product selection from a physician's oral or written order.

(f) Enforcement provisions. - It is made the duty of the department of health, its agents

designated by the director of health, and of all peace officers within the state to enforce all provisions of this section and of §§ 5-19.1-19, 5-37-18 -- 5-37-18.2, and 21-31-3.

SECTION 4. Sections 23-3-1, 23-3-16 and 23-3-17 of the General Laws in Chapter 23-3 entitled "Vital Records" are hereby amended to read as follows:

**23-3-1. Definitions. --** As used in this chapter:

(1) "Adoptee" means a person who was born in this state and who has had an original birth certificate sealed due to an adoption.

(2) "Adoptee vital records file" means a file operated by the division of vital records that maintains adoptees' birth certificates, makes available the contact preference forms, provides adoptees with non-certified copies of their birth certificates.

(3) "Adult adoptee" means an adoptee twenty-five (25) years of age or older.

(4) "Birth parent" is the person, the father or mother of genetic origin of a child, who is legally presumed under the laws of this state to be the father or mother of genetic origin of a child.

(5) "Community of residence" means the city or town within the state of a person's home address at the time of his or her marriage or death, or of his or her mother's home address at the time of his or her birth.

(6) "Contact preference form" means the form prepared and maintained by the division that birth parent(s) of adoptees may file to express his or her preference regarding contact with the adoptee. The contact preference form shall include language informing the birth parent(s) of their ability to provide genetic, social, and health history to the Passive Voluntary Adoption Mutual Consent Registry as defined in chapter 15-7.2.

(7) "Dead body" means a lifeless human body or parts of a lifeless human body or its bones from the state of which it reasonably may be concluded that death recently occurred.

(8) "Division" means the division of vital records as defined in chapter 3 of title 23.

(9) "Fetal death" means death prior to the complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy; the death is indicated by the fact that after the expulsion or extraction the fetus does not breathe or show any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of the voluntary muscles.

(10) "Filing" means the presentation of a certificate, report, or other record provided for in this chapter, of a birth, death, fetal death, adoption, marriage, or divorce for registration by the division of vital records.

(11) "Final disposition" means the burial, interment, cremation, or other disposition of a

dead body or fetus.

(12) "Institution" means any establishment, public or private, which provides in-patient medical, surgical, or diagnostic care or treatment, or nursing, custodial or domiciliary care to two (2) or more unrelated individuals, or to which persons are committed by law.

(13) "Live birth" means the complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy, which, after that expulsion or extraction, breathes or shows any other evidences of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of the voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached.

(14) ~~"Physician"~~ "Practitioner" means a person authorized or licensed to practice medicine pursuant to chapter 37 of title 5, a physician assistant licensed pursuant to chapter 54 of title 5, or an advanced practice registered nurse licensed pursuant to chapter 34 of title 5.

(15) "Registration" means the acceptance by the division of vital records and the incorporation in its official records of certificates, reports, or other records provided for in this chapter, or births, deaths, fetal deaths, adoptions, marriages, or divorces.

(16) "Signing" or "Signature" means the application of either a hand signature to a paper record or an electronic process approved by the state registrar of vital records.

(17) "System of vital records" means the registration, collection, preservation, amendment, and certification of vital statistics records, and activities related to them including the tabulation, analysis, and publication of statistical data derived from those records.

(18) "Vital records" means records of birth, death, fetal death, marriage, divorce, and data related to those records.

**23-3-16. Death registration. --** (a) A death certificate for each death which occurs in this state shall be filed with the state registrar of vital records or as otherwise directed by the state registrar within seven (7) calendar days after death and prior to removal of the body from the state, and shall be registered if it has been completed and filed in accordance with this section; provided:

(1) That if the place of death is unknown, a death certificate shall be filed with the state registrar of vital records or as otherwise directed by the state registrar within seven (7) calendar days after the occurrence; and

(2) That if death occurs in a moving conveyance, a death certificate shall be filed with the state registrar of vital records or as otherwise directed by the state registrar.

(b) The funeral director, his or her duly authorized agent, or person acting as agent, who first assumes custody of a dead body, shall file the death certificate. He or she shall obtain the

personal data from the next of kin or the best qualified person or source available. He or she shall obtain the medical certification of cause of death from the person responsible for certification.

(c) A ~~physician~~ practitioner, after the death of a person whom he or she has attended during his or her last illness, or the ~~physician~~ practitioner declaring that person dead, or if the death occurred in a hospital, a registered hospital medical officer duly appointed by the hospital director or administrator, shall immediately furnish for registration a standard certificate of death to a funeral director or other authorized person or any member of the family of the deceased, stating to the best of his or her knowledge and belief the name of the deceased, the disease of which he or she died, where it was contracted, the duration of the illness from which he or she died, when last seen alive by the ~~physician~~ practitioner, or, if death occurs in a hospital, when last seen alive by a ~~physician~~ practitioner and the date of death.

(d) When death occurred without medical attendance as set forth in subsection (c) or when inquiry is required by chapter 4 of this title, the medical examiner shall investigate the cause of death and shall complete and sign the medical certification within forty-eight (48) hours after taking charge of the case.

**23-3-17. Fetal death registration. --** (a) A fetal death certificate for each fetal death which occurs in this state after a gestation period of twenty (20) completed weeks or more shall be filed with the state registrar of vital records or as otherwise directed by the state registrar within seven (7) calendar days after the delivery and prior to removal of the fetus from the state, and shall be registered if it has been completed and filed in accordance with this section; provided:

(1) That if the place of fetal death is unknown, a fetal death certificate shall be filed with the state registrar of vital records or as otherwise directed by the state registrar within seven (7) calendar days after the occurrence; and

(2) That if a fetal death occurs on a moving conveyance, a fetal death certificate shall be filed with the state registrar of vital records or as otherwise directed by the state registrar.

(b) All other fetal deaths, irrespective of the number of weeks uterogestation, shall be reported directly to the state department of health within seven (7) calendar days after delivery.

(c) The funeral director, his or her duly authorized agent, or another person acting as agent, who first assumes custody of a fetus, shall file the fetal death certificate. In the absence of a funeral director or agent, the physician or another person in attendance at or after delivery shall file the certificate of fetal death. He or she shall obtain the personal data from the next of kin or the best qualified person or source available. He or she shall obtain the medical certification of cause of death from the person responsible for the certification.

(d) The medical certification shall be completed and signed within forty-eight (48) hours after delivery by the ~~physician~~ practitioner in attendance at or after delivery except when inquiry is required by chapter 4 of this title.

(e) When a fetal death occurs without medical attendance upon the mother at or after the delivery or when inquiry is required by chapter 4 of this title, the medical examiner shall investigate the cause of fetal death and shall complete and sign the medical certification within forty-eight (48) hours after taking charge of the case.

(f) Each funeral director shall, on or before the tenth (10th) day of the following month, file a report with the state registrar of vital records listing funerals and/or decedents serviced following deaths or fetal deaths within the month. Failure to file these reports or any of the certificates required under § 23-3-16 and this section within the prescribed time limits shall be grounds for disciplinary action, including revocation of license by the state board of examiners in embalming.

SECTION 5. This act shall take effect upon passage.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

A N  A C T

RELATING TO BUSINESSES AND PROFESSIONS

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This act would increase the composition of the Board of Licensure for physician assistants, and also clarify the definition, standards, and scope of practice for physician assistants.

This act would take effect upon passage.

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LC000916
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