VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 54.1-3401 and 54.1-3408 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 54.1-3410.1, relating to nuclear pharmacy.

[S 679]

Approved

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3401 and 54.1-3408 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding a section numbered 54.1-3410.1 as follows:

§ 54.1-3401. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by (i) a practitioner or by his authorized agent and under his direction or (ii) the patient or research subject at the direction and in the presence of the practitioner.

"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 drugs or devices.

"Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

"Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, and corticosteroids, that promotes muscle growth.

"Animal" means any nonhuman animate being endowed with the power of voluntary action.

"Automated drug dispensing system" means a mechanical or electronic system that performs operations or activities, other than compounding or administration, relating to pharmacy services, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction information, to provide security and accountability for such drugs.

"Board" means the Board of Pharmacy.

"Change of ownership" of an existing entity permitted, registered or licensed by the Board means (i) the sale or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor, the dissolution of a partnership, or change in partnership composition; (iii) the acquisition or disposal of fifty percent or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; (iv) the merger of a corporation owning the entity or of the parent corporation of a wholly-owned subsidiary owning the entity with another business or corporation; or (v) the expiration or forfeiture of a corporation's charter.

"Compound" means the taking of two or more ingredients and fabricating them into a single preparation, usually referred to as a dosage form.

"Controlled substance" means a drug, substance or immediate precursor in Schedules I through VI of this chapter. The term shall not include distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 3.1 or Title 4.1.

"DEA" means the Drug Enforcement Administration, United States Department of Justice, or its successor agency.

"Deliver" or "delivery" means the actual, constructive, or attempted transfer of any item regulated by this chapter, whether or not there exists an agency relationship.

"Device" means instruments, apparatus, and contrivances, including their components, parts and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals or to affect the structure or any function of the body of man or animals.

"Dialysis solution" means either the commercially available, unopened, sterile solutions whose purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal dialysis, or commercially available solutions whose purpose is to be used in the performance of hemodialysis, not to include any solutions administered to the patient intravenously.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling or

compounding necessary to prepare the substance for that delivery.

"Dispenser" means a practitioner who dispenses.

"Distribute" means to deliver other than by administering or dispensing a controlled substance.

"Distributor" means a person who distributes.

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

"Hashish oil" means any oily extract containing one or more cannabinoids, but shall not include any such extract with a tetrahydrocannabinol content of less than twelve percent by weight.

"Immediate precursor" means a substance which the Board of Pharmacy has found to be and by regulation designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

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

"Labeling" means all labels and other written, printed or graphic matter on an article or any of its containers or wrappers, or accompanying such article.

"Manufacture" means the production, preparation, propagation, compounding, conversion or processing of any item regulated by this chapter, either directly or indirectly 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. This term does not include the preparing, compounding, packaging or labeling of a controlled substance by a practitioner as an incident to his administering or dispensing of a controlled substance or marijuana in the course of his professional practice, or by a practitioner, or by his authorized agent under his supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale.

"Manufacturer" means every person who manufactures.

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds or resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless such extract contains less than twelve percent of tetrahydrocannabinol by weight, nor shall marijuana include the mature stalks of such plant, fiber produced from such stalk, oil or cake made from the seeds of such plant, unless such stalks, fiber, oil or cake is combined with other parts of plants of the genus Cannabis.

"Medical equipment supplier" means any person, as defined in § 1-13.19, engaged in the delivery to the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with no medicinal properties which are used for the operation and cleaning of medical equipment and solutions for peritoneal dialysis.

"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, opiates, and any salt, compound, derivative, or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (i), but not including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (iv) coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain cocaine or ecgonine.

"New drug" means: (i) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior

to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or (ii) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

"Nuclear medicine technologist" means an individual who holds a current certification with the American Registry of Radiological Technologists or the Nuclear Medicine Technology Certification Board.

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

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

"Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under Article 4 (§ 54.1-3437 et seq.) of this chapter, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

"Opium poppy" means the plant of the species Papaver somniferum L., except the seeds thereof.

"Original package" means the unbroken container or wrapping in which any drug or medicine is enclosed together with label and labeling, put up by or for the manufacturer, wholesaler, or distributor for use in the delivery or display of such article.

"Person" means both the plural and singular, as the case demands, and includes an individual, partnership, corporation, association, governmental agency, trust, or other institution or entity.

"Pharmacist-in-charge" means the person who, being licensed as a pharmacist, signs the application for a pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in a manner complying with the laws and regulations for the practice of pharmacy and the sale and dispensing of controlled substances; the "pharmacist-in-charge" shall personally supervise the pharmacy and the pharmacy's personnel as required by § 54.1-3432.

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

"Practitioner" means a physician, dentist, licensed nurse practitioner pursuant to § 54.1-2957.01, licensed physician assistant pursuant to § 54.1-2952.1, pharmacist pursuant to § 54.1-3300, TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 of this title, veterinarian, scientific investigator, or other person licensed, registered or otherwise permitted to distribute, dispense, prescribe and administer, or conduct research with respect to, a controlled substance in the course of professional practice or research in this Commonwealth.

"Prescriber" means a practitioner who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription.

"Prescription" means an order for drugs or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph or other means of communication to a pharmacist by a duly licensed physician, dentist, veterinarian or other practitioner, authorized by law to prescribe and administer such drugs or medical supplies.

"Prescription drug" means any drug required by federal law or regulation to be dispensed only pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503 (b) of the federal Food, Drug, and Cosmetic Act.

"Production" or "produce" includes the manufacture, planting, cultivation, growing or harvesting of a controlled substance or marijuana.

"Proprietary medicine" means a completely compounded nonprescription drug in its unbroken, original package which does not contain any controlled substance or marijuana as defined in this chapter and is not in itself poisonous, and which is sold, offered, promoted or advertised directly to the general public by or under the authority of the manufacturer or primary distributor, under a trademark, trade name or other trade symbol privately owned, and the labeling of which conforms to the requirements of this chapter and applicable federal law. However, this definition shall not include a drug which is only advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic, a drug which may be dispensed only upon prescription or the label of which bears substantially the statement "Warning - may be habit-forming," or a drug intended for injection.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei

with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as an individual, proprietor, agent, servant or employee.

"Warehouser" means any person, other than a wholesale distributor, engaged in the business of selling or otherwise distributing prescription drugs or devices to any person who is not the ultimate user or consumer. No person shall be subject to any state or local tax by reason of this definition.

"Wholesale distribution" means distribution of prescription drugs to persons other than consumers or patients, subject to the exceptions set forth in § 54.1-3401.1.

"Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses conducting wholesale distributions, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies conducting wholesale distributions. No person shall be subject to any state or local tax as a wholesale merchant by reason of this definition.

The words "drugs" and " devices" as used in Chapter 33 (§ 54.1-3300 et seq.) of this title and in this chapter shall not include surgical or dental instruments, physical therapy equipment, X-ray apparatus or glasses or lenses for the eyes.

The terms "pharmacist," "pharmacy" and "practice of pharmacy" as used in this chapter shall be defined as provided in Chapter 33 of this title unless the context requires a different meaning.

§ 54.1-3408. Professional use by practitioners.

A. A practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine or a licensed nurse practitioner pursuant to § 54.1-2957.01, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 of this title shall only prescribe, dispense, or administer controlled substances in good faith for medicinal or therapeutic purposes within the course of his professional practice.

The prescribing practitioner's order may be on a written prescription or pursuant to an oral prescription as authorized by this chapter. The prescriber may administer drugs and devices, or he may cause them to be administered by a nurse, physician assistant or intern under his direction and supervision, or he may prescribe and cause drugs and devices to be administered to patients in state-owned or state-operated hospitals or facilities licensed as hospitals by the Board of Health or psychiatric hospitals licensed by the State Mental Health, Mental Retardation and Substance Abuse Services Board by other persons who have been trained properly to administer drugs and who administer drugs only under the control and supervision of the prescriber or a pharmacist or a prescriber may cause drugs and devices to be administered to patients by emergency medical services personnel who have been certified and authorized to administer such drugs and devices pursuant to Board of Health regulations governing emergency medical services and who are acting within the scope of such certification. A prescriber may authorize a certified respiratory therapy practitioner as defined in § 54.1-2954 to administer by inhalation controlled substances used in inhalation or respiratory therapy.

Pursuant to an oral or written order or standing protocol, the prescriber, who is authorized by state or federal law to possess and administer radiopharmaceuticals in the scope of his practice, may authorize a nuclear medicine technologist to administer, under his supervision, radiopharmaceuticals used in the diagnosis or treatment of disease.

Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered nurses and licensed practical nurses to possess (i) epinephrine for administration in treatment of emergency medical conditions and (ii) heparin and sterile normal saline to use for the maintenance of intravenous access lines.

Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize, with the consent of the parents as defined in § 22.1-1, an employee of a school board who is trained in the administration of insulin and glucagon to assist with the adminstration of insulin or administer glucagon to a student diagnosed as having diabetes and who requires insulin injections during the school day or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, nurse practitioner, physician or physician assistant is not present to perform the administration of the medication.

A prescriber may authorize, pursuant to a protocol approved by the Board of Nursing, the administration of vaccines to adults for immunization, when a practitioner with prescriptive authority is not physically present, (i) by licensed pharmacists, (ii) by registered nurses or (iii) licensed practical

nurses under the immediate and direct supervision of a registered nurse. A prescriber acting on behalf of and in accordance with established protocols of the Department of Health may authorize the administration of vaccines to any person by a pharmacist or nurse when the prescriber is not physically present.

A dentist may cause Schedule VI topical drugs to be administered under his direction and supervision by either a dental hygienist or by an authorized agent of the dentist.

No written prescription order form shall include more than one prescription. This provision shall not apply, however, to the entry of any order on a patient's chart in any hospital or any long-term care facility, as defined in Board regulations, in Virginia or to a prescription ordered through the pharmacy operated by the Department of Corrections, the central pharmacy of the Department of Health, or the central outpatient pharmacy operated by the Department of Mental Health, Mental Retardation and Substance Abuse Services.

Such a prescription shall be written, dated, and signed by the person prescribing on the day when issued, and shall bear the full name and address of the patient for whom the drug is prescribed, and the full name, address, and registry number under the federal laws of the person prescribing, if he is required by those laws to be so registered.

This section shall not prevent the administration of drugs by a person who has satisfactorily completed a training program for this purpose approved by the Board of Nursing and who administers such drugs in accordance with a physician's instructions pertaining to dosage, frequency, and manner of administration, and in accordance with regulations promulgated by the Board of Pharmacy relating to security and record keeping, when the drugs administered would be normally self-administered by (i) a resident of a facility licensed or certified by the State Mental Health, Mental Retardation and Substance Abuse Services Board; (ii) a resident of any adult care residence which is licensed by the Department of Social Services; (iii) a resident of the Virginia Rehabilitation Center for the Blind and Visually Impaired; (iv) a resident of a facility approved by the Board or Department of Juvenile Justice for the placement of children in need of services or delinquent or alleged delinquent youth; (v) a program participant of an adult day-care center licensed by the Department of Social Services; or (vi) a resident of any facility authorized or operated by a state or local government whose primary purpose is not to provide health care services.

Nothing in this title shall prohibit the administration of normally self-administered oral or topical drugs by unlicensed individuals to a person in his private residence.

This section shall not interfere with any prescriber issuing prescriptions in compliance with his authority and scope of practice and the provisions of this section to a Board agent for use pursuant to subsection G of § 18.2-258.1. Such prescriptions issued by such prescriber shall be deemed to be valid prescriptions. This section shall not prohibit a prescriber from using preprinted prescriptions for drugs classified in Schedule VI if all requirements concerning dates, signatures, and other information specified above are otherwise fulfilled.

B. The written prescription referred to in subsection A of this section shall be written with ink or individually typed and each prescription shall be manually signed by the prescriber. The prescription may be prepared by an agent for his signature. The prescription shall contain the name, address, telephone number, and federal controlled substances registration number assigned to the prescriber. The prescriber's information shall be either preprinted upon the prescription blank, typewritten, rubber stamped, or printed by hand.

The oral prescription referred to in subsection A of this section shall be transmitted to the pharmacy of the patient's choice by the prescriber or his authorized agent. For the purposes of this section, an authorized agent of the prescriber shall be an employee of the prescriber who is under his immediate and personal supervision, or if not an employee, an individual who holds a valid license allowing the administration or dispensing of drugs and who is specifically directed by the prescriber.

C. Pursuant to § 32.1-87, the prescription form shall include two boxes, one labelled "Voluntary Formulary Permitted" and the other labelled "Dispense As Written." A prescriber may indicate his permission for the dispensing of a drug product included in the Formulary upon signing a prescription form and marking the box labelled "Voluntary Formulary Permitted." A Voluntary Formulary product shall be dispensed if the prescriber fails to indicate his preference. Whenever a pharmacist dispenses a Voluntary Formulary product when a prescription is written for a brand name product, the pharmacist shall label the drug with the generic name followed by the words "generic for" followed by the brand name of the drug for which the prescription is written. If no Voluntary Formulary product is immediately available, or if the patient objects to the dispensing of a generic drug, the pharmacist may dispense a brand name drug. On and after July 1, 1993, printed prescription forms shall provide:

" [ ] Dispense As Written

[ ] Voluntary Formulary Permitted

.....

Signature of prescriber

If neither box is marked, a Voluntary Formulary

product must be dispensed."

D. Prescribers' orders, whether written as chart orders or prescriptions, for Schedules II, III, IV and V controlled drugs to be administered to (i) patients or residents of long-term care facilities served by a Virginia pharmacy from a remote location or (ii) patients receiving parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion therapy and served by a home infusion pharmacy from a remote location, may be transmitted to that remote pharmacy by an electronic communications device over telephone lines which send the exact image to the receiver in hard-copy form, and such facsimile copy shall be treated as a valid, original prescription order. *If the order is for a radiopharmaceutical, a physician authorized by state or federal law to possess and administer medical radioactive materials may authorize a nuclear medicine technologist to transmit a prescriber's verbal or written orders for radiopharmaceuticals.*

§ 54.1-3410.1. Requirements for radiopharmaceuticals.

A. A pharmacist who is authorized by the Board and acting in good faith, may sell and dispense radiopharmaceuticals pursuant to the order of a physician who is authorized by state or federal law to possess and administer radiopharmaceuticals for the treatment or diagnosis of disease.

B. When an authorized nuclear pharmacist dispenses a radioactive medical material, he shall assure that the outer container (shield) of the radiopharmaceutical shall bear the following information:

1. The name and address of the nuclear pharmacy;

2. The name of the prescriber (authorized user);

3. The date of dispensing;

4. The serial number assigned to the radiopharmaceutical order;

5. The standard radiation symbol;

6. The name of the diagnostic procedure;

7. The words "Caution: Radioactive Material";

8. The name of the radionuclide;

9. The amount of radioactivity and the calibration date and time;

10. The expiration date and time;

11. In the case of a diagnostic radiopharmaceutical, the patient's name or the words "Per Physician's Order"; and

12. In the case of a therapeutic radiopharmaceutical, the patient's name.

C. Orders for radiopharmaceuticals, whether written or verbal, shall include at least the following information:

1. The name of the institution or facility and the name of the person transmitting the order;

2. The date that the radiopharmaceutical will be needed and the calibration time;

3. The name or generally recognized and accepted abbreviation of the radiopharmaceutical;

4. The dose or activity of the radiopharmaceutical at the time of calibration; and

5. In the case of a therapeutic radiopharmaceutical or a radiopharmaceutical blood product, the name of the patient shall be obtained prior to dispensing.