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SENATE BILL NO. 560

Offered January 26, 1998

A BILL to amend and reenact §§ 8.01-413, 32.1-127.1:01, 32.1-127.1:03, 42.1-77, 54.1-111, 54.1-2403.2, 54.1-2403.3, 54.1-3401, 54.1-3434, and 54.1-3434.01 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 54.1-3434.02, relating to the practice of pharmacy; penalties.

Patrons—Walker and Schrock; Delegate: Morgan

Referred to the Committee on Education and Health

Be it enacted by the General Assembly of Virginia:

1. That §§ 8.01-413, 32.1-127.1:01, 32.1-127.1:03, 42.1-77, 54.1-111, 54.1-2403.2, 54.1-2403.3, 54.1-3401, 54.1-3434, and 54.1-3434.01 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding a section numbered 54.1-3434.02 as follows:

§ 8.01-413. Certain copies of health care provider's records or papers of patient admissible; right of patient or his attorney to copies of such records or papers; subpoena; damages, costs and attorney's fees.

A. In any case where the hospital, nursing facility, physician's, or other health care provider's original records or papers of any patient in a hospital or institution for the treatment of physical or mental illness are admissible or would be admissible as evidence, any typewritten copy, photograph, photostatted copy, or microphotograph or printout or other hard copy generated from computerized or other electronic storage, microfilm, or other photographic, mechanical, electronic or chemical storage process thereof shall be admissible as evidence in any court of this Commonwealth in like manner as the original, if the printout or hard copy or microphotograph or photograph is properly authenticated by the employees having authority to release or produce the original records.

Any hospital, nursing facility, physician, or other health care provider whose records or papers relating to any such patient are subpoenaed for production under this section or the Rules of the Supreme Court of Virginia may comply with the subpoena by a timely mailing to the clerk issuing the subpoena properly authenticated copies, photographs or microphotographs in lieu of the originals. The court whose clerk issued the subpoena may, after notice to such hospital, nursing facility, physician, or other health care provider, enter an order requiring production of the originals, if available, of any stored records or papers whose copies, photographs or microphotographs are not sufficiently legible. The party requesting the subpoena shall be liable for the reasonable charges of the hospital, nursing facility, physician, or other health care provider for the service of maintaining, retrieving, reviewing, preparing, copying and mailing the items produced. Except for copies of X-ray photographs, however, such charges shall not exceed fifty cents for each page up to fifty pages and twenty-five cents a page thereafter for copies from paper and one dollar per page for copies from microfilm or other micrographic process, plus all postage and shipping costs and a search and handling fee not to exceed ten dollars.

B. Copies of hospital, nursing facility, physician's, or other health care provider's records or papers shall be furnished within fifteen days of such request to the patient or his attorney upon such patient's or attorney's written request, which request shall comply with the requirements of § 32.1-127.1:03. However, copies of a patient's records shall not be furnished to such patient where the patient's treating physician has made a part of the patient's records a written statement that in his opinion the furnishing to or review by the patient of such records would be injurious to the patient's health or well-being, but in any such case such records shall be furnished to the patient's attorney within fifteen days of the date of such request. A reasonable charge may be made for the service of maintaining, retrieving, reviewing and preparing such copies. Except for copies of X-ray photographs, however, such charges shall not exceed fifty cents per page for up to fifty pages and twenty-five cents a page thereafter for copies from paper and one dollar per page for copies from microfilm or other micrographic process, plus all postage and shipping costs and a search and handling fee not to exceed ten dollars. Any hospital, nursing facility, physician, or other health care provider receiving such a request from a patient's attorney shall require a writing signed by the patient confirming the attorney's authority to make the request.

C. Upon the failure of any hospital, nursing facility, physician, or other health care provider to comply with any written request made in accordance with subsection B within the period of time specified in that subsection and within the manner specified in § 32.1-127.1:03, the patient or his attorney may by affidavit filed with the clerk of the circuit court wherein any eventual suit, if any, would be required to be filed, upon payment of the fees required by subdivision (23) of § 14.1-112, and fees for service, request that the clerk subpoena such records or papers. The clerk shall thereupon issue a subpoena, returnable within twenty days of proper service, directing the hospital, nursing facility,

physician, or other health care provider to produce and furnish copies of the reports and papers to him, whereupon, the clerk shall make the same available to the patient or his attorney. If the court finds that a hospital, nursing facility, physician, or other health care provider willfully refused to comply with a written request made in accordance with subsection B, either by willfully or arbitrarily refusing or by imposing a charge in excess of the reasonable expense of making the copies and processing the request for records, the court may award damages for all expenses incurred by the patient to obtain such copies, including court costs and reasonable attorney's fees.

D. The provisions of subsections A, B, and C hereof shall apply to any health care provider whose office is located within or without the Commonwealth if the records pertain to any patient who is a party to a cause of action in any court in the Commonwealth of Virginia, and shall apply only to requests made by an attorney, or his client, in anticipation of litigation or in the course of litigation.

E. Health care provider, as used in this section, shall have the same meaning as provided in § 32.1-127.1:03 and shall also include an independent medical copy retrieval service contracted to provide the service of retrieving, reviewing, and preparing such copies for distribution.

F. Notwithstanding the authorization to admit as evidence patient records in the form of microphotographs, prescription dispensing records maintained in or on behalf of any pharmacy registered or permitted in Virginia shall only be stored in compliance with the regulations of the Board of Pharmacy.

§ 32.1-127.1:01. Record storage.

A. Medical records, as defined in § 42.1-77, may be stored by computerized or other electronic process or microfilm, or other photographic, mechanical, or chemical process; however, the stored record shall identify the location of any documents or information that could not be so technologically stored. If the technological storage process creates an unalterable record, the nursing facility, hospital or other licensed health care provider shall not be required to maintain paper copies of medical records that have been stored by computerized or other electronic process, microfilm, or other photographic, mechanical, or chemical process. Upon completing such technological storage, paper copies of medical records may be destroyed in a manner that preserves the patient's confidentiality. However, any documents or information that could not be so technologically stored shall be preserved.

B. Notwithstanding the authority of this section to copy patient records in the form of microfilm, prescription dispensing records maintained in or on behalf of any pharmacy registered or permitted in Virginia shall only be stored in compliance with the regulations of the Board of Pharmacy.

§ 32.1-127.1:03. Patient Health Records Privacy.

A. There is hereby recognized a patient's right of privacy in the content of a patient's medical record. Patient records are the property of the provider maintaining them, and, except when permitted by this section or by another provision of state or federal law, no provider, or other person working in a health care setting, may disclose the records of a patient.

Patient records shall not be removed from the premises where they are maintained without the approval of the provider, except in accordance with a court order or subpoena consistent with § 8.01-413 C or with this section *or in accordance with the regulations relating to change of ownership of patient records promulgated by a health regulatory board established in Title 54.1*.

No third party to whom disclosure of patient records was made by a provider shall redisclose or otherwise reveal the records of a patient, beyond the purpose for which such disclosure was made, without first obtaining the patient's specific consent to such redisclosure. This redisclosure prohibition shall not, however, prevent any provider who receives records from another provider from making subsequent disclosures permitted under this section.

B. As used in this section:

"Agent" means a person who has been appointed as a patient's agent under a power of attorney for health care or an advance directive under the Health Care Decisions Act (§ 54.1-2981 et seq.)

"Guardian" means a court-appointed guardian of the person.

"Health services" includes but is not limited to examination, diagnosis, evaluation, treatment, pharmaceuticals, aftercare, habilitation or rehabilitation and mental health therapy of any kind.

"Parent" means a biological, adoptive or foster parent.

"Patient" means a person who is receiving or has received health services from a provider.

"Provider" shall have the same meaning as set forth in the definition of "Health care provider" in § 8.01-581.1, except that state-operated facilities shall also be considered providers for the purposes of this section. Provider shall also include all individuals who are licensed or certified by any of the health regulatory boards within the Department of Health Professions, except individuals regulated by the Board of Funeral Directors and Embalmers or the Board of Veterinary Medicine.

"Record" means any written, printed or electronically recorded material maintained by a provider in the course of providing health services to a patient concerning the patient and the services provided. "Record" also includes the substance of any communication made by a patient to a provider in confidence during or in connection with the provision of health services to a patient or information

otherwise acquired by the provider about a patient in confidence and in connection with the provision of health services to the patient. *When the "record" is the patient's prescription record, "record" shall mean only the individual subject's data and shall not include the mass of prescription dispensing records maintained in or on behalf of any pharmacy registered or permitted in Virginia.*

C. The provisions of this section shall not apply to any of the following:

1. The status of and release of information governed by §§ 65.2-604 and 65.2-607 of the Virginia Workers Compensation Act; or

2. Except where specifically provided herein, the records of minor patients.

D. Providers may disclose the records of a patient:

1. As set forth in subsection E of this section, pursuant to the written consent of the patient or in the case of a minor patient, his custodial parent, guardian or other person authorized to consent to treatment of minors pursuant to § 54.1-2969; also, in emergency cases or situations where it is impractical to obtain the patient's written consent, pursuant to the patient's oral consent for a provider to discuss the patient's records with a third party specified by the patient;

2. In compliance with a subpoena issued in accord with subsection H of this section, pursuant to court order upon good cause shown or in compliance with a subpoena issued pursuant to subsection C of § 8.01-413;

3. In accord with subsection F of § 8.01-399 including, but not limited to, situations where disclosure is reasonably necessary to establish or collect a fee or to defend a provider or the provider's employees or staff against any accusation of wrongful conduct; also as required in the course of an investigation, audit, review or proceedings regarding a provider's conduct by a duly authorized law-enforcement, licensure, accreditation, or professional review entity;

4. In testimony in accordance with §§ 8.01-399 and 8.01-400.2;

5. In compliance with the provisions of § 8.01-413;

6. As required or authorized by any other provision of law including contagious disease, public safety, and suspected child or adult abuse reporting requirements, including but not limited to those contained in §§ 32.1-36, 32.1-36.1, 32.1-40, 32.1-41, 32.1-276.5, 32.1-283, 32.1-283.1, 37.1-98.2, 53.1-40.10, 54.1-2403.3, 54.1-2906, 54.1-2907, 54.1-2966, 54.1-2966.1, 54.1-2967, 54.1-2968, 63.1-55.3 and 63.1-248.11;

7. Where necessary in connection with the care of the patient;

8. In the normal course of business in accordance with accepted standards of practice within the health services setting*; however, the maintenance, storage, and disclosure of the mass of prescription dispensing records maintained in a pharmacy registered or permitted in Virginia shall only be accomplished in compliance with regulations of the Board of Pharmacy*;

9. When the patient has waived his right to the privacy of the medical records;

10. When examination and evaluation of a patient is undertaken pursuant to judicial or administrative law order, but only to the extent as required by such;

11. To the guardian ad litem in the course of a guardianship proceeding of an adult patient authorized under §§ 37.1-128.1, 37.1-128.2 and 37.1-132;

12. To the attorney appointed by the court to represent a patient in a civil commitment proceeding under § 37.1-67.3;

13. To the attorney and/or guardian ad litem of a minor patient who represents such minor in any judicial or administrative proceeding, provided that the court or administrative hearing officer has entered an order granting the attorney or guardian ad litem this right and such attorney or guardian ad litem presents evidence to the provider of such order;

14. With regard to the Court Appointed Special Advocate (CASA) program, a minor's records in accord with § 9-173.12;

15. To an agent appointed under a patient's power of attorney or to an agent or decision maker designated in a patient's advance directive for health care or to any other person consistent with the provisions of the Health Care Decisions Act (§ 54.1-2981 et seq.);

16. To third-party payors and their agents pursuant to the deemed consent provisions of §§ 37.1-226 and 37.1-227 when the patient has requested the provider to submit bills to the third-party payor for payment under a contract or insurance policy;

17. As is necessary to support an application for receipt of health care benefits from a governmental agency or as required by an authorized governmental agency reviewing such application or reviewing benefits already provided;

18. Upon the sale of a medical practice as provided in § 54.1-2405*; or upon a change of ownership or closing of a pharmacy, as defined in § 54.1-3401, pursuant to regulations of the Board of Pharmacy*;

19. In accord with § 54.1-2400.1 B, to communicate a patient's specific and immediate threat to cause serious bodily injury or death of an identified or readily identifiable person;

20. To the patient, except as provided in subsections E and F of this section and subsection B of

§ 8.01-413;

21. In the case of substance abuse records when permitted by and in conformity with requirements of federal law found in 42 U.S.C 290dd-2 and 42 C.F.R. Part 2;

22. In connection with the work of any entity established as set forth in § 8.01-581.16 to evaluate the adequacy or quality of professional services or the competency and qualifications for professional staff privileges; *and*

23. Records of a deceased or mentally incapacitated patient to the personal representative or executor of the deceased patient or the legal guardian or committee of the incompetent or incapacitated patient or if there is no such person appointed, to the following persons in the following order of priority: a spouse, an adult son or daughter, either parent, an adult brother or sister, or any other relative of the deceased patient in order of blood relationship~~; and~~

~~24. Pursuant to a medical temporary detention order as set out in subsection M of § 37.1-134.5~~.

E. Requests for copies of medical records shall (i) be in writing, dated and signed by the requester; (ii) identify the nature of the information requested; and (iii) include evidence of the authority of the requester to receive such copies and identification of the person to whom the information is to be disclosed. Within fifteen days of receipt of a request for copies of medical records, the provider shall do one of the following: (i) furnish such copies to any requester authorized to receive them; (ii) inform the requester if the information does not exist or cannot be found; (iii) if the provider does not maintain a record of the information, so inform the requester and provide the name and address, if known, of the provider who maintains the record; or (iv) deny the request (a) under subsection F, (b) on the grounds that the requester has not established his authority to receive such records or proof of his identity, or (c) as otherwise provided by law. Procedures set forth in this section shall apply only to requests for records not specifically governed by other provisions of this Code or of federal law.

F. Except as provided in subsection B of § 8.01-413, copies of a patient's records shall not be furnished to such patient or anyone authorized to act on the patient's behalf where the patient's attending physician or the patient's clinical psychologist has made a part of the patient's record a written statement that, in his opinion, the furnishing to or review by the patient of such records would be injurious to the patient's health or well-being. If any custodian of medical records denies a request for copies of records based on such statement, the custodian shall permit examination and copying of the medical record by another such physician or clinical psychologist selected by the patient, whose licensure, training and experience relative to the patient's condition is at least equivalent to that of the physician or clinical psychologist upon whose opinion the denial is based. The person or entity denying the request shall inform the patient of the patient's right to select another reviewing physician or clinical psychologist under this subsection who shall make a judgment as to whether to make the record available to the patient. Any record copied for review by the physician or clinical psychologist selected by the patient shall be accompanied by a statement from the custodian of the record that the patient's attending physician or clinical psychologist determined that the patient's review of his record would be injurious to the patient's health or well-being.

G. A written consent to allow release of patient records may, but need not, be in the following form:

CONSENT TO RELEASE OF CONFIDENTIAL HEALTH CARE INFORMATION

Patient Name.....

Provider Name.....

Person, agency or provider to whom

disclosure is to be made.....

Information or Records to be disclosed.....

As the person signing this consent, I understand that I am giving my

permission to the above-named provider or other named third party for

disclosure of confidential health care records. I also understand that

I have the right to revoke this consent, but that my revocation is not

effective until delivered in writing to the person who is in possession

of my records. A copy of this consent and a notation concerning the persons or agencies to whom disclosure was made shall be included with my original records. The person who receives the records to which this consent pertains may not redisclose them to anyone else without my separate written consent unless such recipient is a provider who makes a disclosure permitted by law.

This consent expires on (date).....

Signature of Patient ..... Date .....

H. 1. No party to an action shall request the issuance of a subpoena duces tecum for an opposing party's medical records unless a copy of the request for the subpoena is provided to opposing counsel or the opposing party if they are pro se, simultaneously with filing the request. No party to an action shall request the issuance of a subpoena duces tecum for the medical records of a nonparty witness unless a copy of the request for the subpoena is provided to the nonparty witness simultaneously with filing the request.

In instances where medical records being subpoenaed are those of a pro se party or nonparty witness, the party requesting the issuance of the subpoena shall deliver to the pro se party or nonparty witness together with the copy of the request for subpoena, a statement informing them of their rights and remedies. The statement shall include the following language and the heading shall be in boldface capital letters:

NOTICE TO PATIENT

The attached Request for Subpoena means that (insert name of party requesting subpoena) has asked the court to issue a subpoena to your doctor or other health care providers (names of health care providers inserted here) requiring them to produce your medical records. Your doctor or other health care provider is required to respond by providing a copy of your medical records. If you believe your records should not be disclosed and object to their disclosure, you have the right to file a motion with the clerk of the court to quash the subpoena. You may contact the clerk's office to determine the requirements that must be satisfied when filing a motion to quash and you may elect to contact an attorney to represent your interest. If you elect to file a motion to quash, it must be filed as soon as possible before the provider sends out the records in response to the subpoena. If you elect to file a motion to quash, you must notify your doctor or other health care provider(s) that you are filing the motion so that the provider knows to send the records to the clerk of court in a sealed envelope or package for safekeeping while your motion is decided.

2. Any party filing a request for a subpoena duces tecum for a patient's medical records shall include a Notice to Providers in the same part of the request where the provider is directed where and when to return the records. Such notice shall be in boldface capital letters and shall include the following language:

NOTICE TO PROVIDERS

IF YOU RECEIVE NOTICE THAT YOUR PATIENT HAS FILED A MOTION TO QUASH (OBJECTING TO) THIS SUBPOENA, OR IF YOU FILE A MOTION TO QUASH THIS SUBPOENA, SEND THE RECORDS ONLY TO THE CLERK OF THE COURT WHICH ISSUED THE SUBPOENA USING THE FOLLOWING PROCEDURE: PLACE THE RECORDS IN A SEALED ENVELOPE AND ATTACH TO THE SEALED ENVELOPE A COVER LETTER TO THE CLERK OF COURT WHICH STATES THAT CONFIDENTIAL HEALTH CARE RECORDS ARE ENCLOSED AND ARE TO BE HELD UNDER SEAL PENDING THE COURT'S RULING ON THE MOTION TO QUASH THE SUBPOENA. THE SEALED ENVELOPE AND THE COVER LETTER SHALL BE PLACED IN AN OUTER ENVELOPE OR PACKAGE FOR TRANSMITTAL TO THE COURT.

3. Health care providers shall provide a copy of all records as required by a subpoena duces tecum or court order for such medical records. If the health care provider has, however, actual receipt of notice that a motion to quash the subpoena has been filed or if the health care provider files a motion to quash the subpoena for medical records, then the health care provider shall produce the records to the clerk of

the court issuing the subpoena, where the court shall place the records under seal until a determination is made regarding the motion to quash. The securely sealed envelope shall only be opened on order of the judge. In the event the court grants the motion to quash, the records shall be returned to the health care provider in the same sealed envelope in which they were delivered to the court. In the event that a judge orders the sealed envelope to be opened to review the records in camera, a copy of the judge's order shall accompany any records returned to the provider. The records returned to the provider shall be in a securely sealed envelope.

4. It is the duty of any party requesting a subpoena duces tecum for medical records to determine whether the patient whose records are sought is pro se or a nonparty. Any request for a subpoena duces tecum for the medical records of a nonparty or of a pro se party shall direct the provider (in boldface type) not to produce the records until ten days after the date on which the provider is served with the subpoena duces tecum and shall be produced no later than twenty days after the date of such service.

In the event that the individual whose records are being sought files a motion to quash the subpoena, the court shall decide whether good cause has been shown by the discovering party to compel disclosure of the patient's private records over the patient's objections. In determining whether good cause has been shown, the court shall consider (i) the particular purpose for which the information was collected; (ii) the degree to which the disclosure of the records would embarrass, injure, or invade the privacy of the individual; (iii) the effect of the disclosure on the individual's future health care; (iv) the importance of the information to the lawsuit or proceeding; and (v) any other relevant factor.

The provisions of this subsection have no application to subpoenas for medical records requested under § 8.01-413, or issued by a duly authorized administrative agency conducting an investigation, audit, review or proceedings regarding a provider's conduct. The provisions of this subsection apply to the medical records of both minors and adults.

A subpoena for substance abuse records must conform to the requirements of federal law found in 42 C.F.R. Part 2, Subpart E.

Providers may testify about the medical records of a patient in compliance with §§ 8.01-399 and 8.01-400.2.

§ 42.1-77. Definitions.

As used in this chapter:

"Agency" means all boards, commissions, departments, divisions, institutions, authorities, or parts thereof, of the Commonwealth or its political subdivisions and includes the offices of constitutional officers.

"Archival quality" means a quality of reproduction consistent with established standards specified by state and national agencies and organizations responsible for establishing such standards, such as the Association for Information and Image Management, the American Standards Association, and the National Bureau of Standards.

"Board" means the State Library Board.

"Council" means the State Public Records Advisory Council.

"Custodian" means the public official in charge of an office having public records.

"Data" means symbols, or representations, of facts or ideas that can be communicated, interpreted, or processed by manual or automated means.

"Database" means a set of data, consisting of one file or a group of integrated files, maintained as an information system managed by a database management system.

"Database management system" means a set of software programs that controls the organization, storage and retrieval of data in a database. It also controls the security and integrity of the database.

"Electronic record" means any information that is recorded in machine readable form.

"Electronic records system" means any information system that produces, processes, or stores records by using a computer, and is also called an automated information system.

"Information system" means the organized collection, processing, transmission, and dissemination of information in accordance with defined procedures, whether automated or manual.

"State Librarian" means the State Librarian or his designated representative.

"Public official" means all persons holding any office created by the Constitution of Virginia or by any act of the General Assembly, the Governor and all other officers of the executive branch of the state government, and all other officers, heads, presidents or chairmen of boards, commissions, departments, and agencies of the state government or its political subdivisions.

"Public record" means recorded information that documents a transaction or activity by or with any public officer, agency or employee of the state government or its political subdivisions. Regardless of physical form or characteristic, the recorded information is a public record if it is produced, collected, received or retained in pursuance of law or in connection with the transaction of public business.

The medium on which such information is recorded may be, but is not limited to paper, film, magnetic, optical or solid state devices which can store electronic signals, tapes, mylar, linen, silk or vellum. The general types of records may be, but are not limited to books, papers, letters, documents,

printouts, photographs, films, tapes, microfiche, microfilm, photostats, sound recordings, maps, drawings, and any representations held in computer memory.

Nonrecord materials, meaning reference books and exhibit materials made or acquired and preserved solely for reference use or exhibition purposes, extra copies of documents preserved only for convenience or reference, and stocks of publications, shall not be included within the definition of public records as used in this chapter.

"Archival records" means all noncurrent records of continuing and enduring value useful to the citizens of the Commonwealth and necessary to the administrative functions of public agencies in the conduct of services and activities mandated by law. In appraisal of public records deemed archival, the terms "administrative," "legal," "fiscal," and "historical" shall be defined as:

1. "Administrative value" : Records shall be deemed of administrative value if they have continuing utility in the operation of an agency.

2. "Legal value" : Records shall be deemed of legal value when they document actions taken in the protection and proving of legal or civil rights and obligations of individuals and agencies.

3. "Fiscal value" : Records shall be deemed of fiscal value so long as they are needed to document and verify financial authorizations, obligations and transactions.

4. "Historical value" : Records shall be deemed of historical value when they contain unique information, regardless of age, which provides understanding of some aspect of the government and promotes the development of an informed and enlightened citizenry.

"Medical records" means the documentation of health care services, whether physical or mental, rendered by direct or indirect patient-provider interaction which is used as a mechanism for tracking the patient's health care status. Medical records may be technologically stored by computerized or other electronic process, or through microfilm or other similar photographic form or chemical process. *Notwithstanding the authority provided by this definition to store medical records on microfilm or other similar photographic form or chemical process, prescription dispensing records maintained in or on behalf of any pharmacy registered or permitted in Virginia shall only be stored in compliance with the regulations of the Board of Pharmacy.*

"Official records" means public records.

"Persons under a disability" means persons so defined under subsection A of § 8.01-229.

"Preservation" means maintaining archival records in their original physical form by stabilizing them chemically or strengthening them physically to ensure their survival as long as possible in their original form. It also means the reformatting of written, printed, electronic or visual archival information to extend the life of the information.

"Retention and disposition schedule" means an approved timetable stating the retention time period and disposition action of records series.

"Software programs" means the written specifications used to operate an electronic records system as well as the documentation describing implementation strategies.

§ 54.1-111. Unlawful acts; prosecution; proceedings in equity.

A. It shall be unlawful for any person, partnership, corporation or other entity to engage in any of the following acts:

1. Practicing a profession or occupation without holding a valid license as required by statute or regulation.

2. Making use of any designation provided by statute or regulation to denote a standard of professional or occupational competence without being duly certified or licensed.

3. Making use of any titles, words, letters or abbreviations which may reasonably be confused with a designation provided by statute or regulation to denote a standard of professional or occupational competence without being duly certified or licensed.

4. Performing any act or function which is restricted by statute or regulation to persons holding a professional or occupational license or certification, without being duly certified or licensed.

5. Failing to register as a practitioner of a profession or occupation as required by statute or regulation.

6. Materially misrepresenting facts in an application for licensure, certification or registration.

7. Willfully refusing to furnish a regulatory board information or records required or requested pursuant to statute or regulation.

8. Violating any statute or regulation governing the practice of any profession or occupation regulated pursuant to this title.

9. Withholding patient records or prescription dispensing records after the closing of a business or professional practice or the transfer or ownership of a business or professional practice when such records have previously been maintained or stored in the course of doing business or conducting a health profession regulated pursuant to this title by a health regulatory board.

Any person who willfully engages in any unlawful act enumerated in this section shall be guilty of a

Class 1 misdemeanor. The third or any subsequent conviction for violating this section during a thirty-six-month period shall constitute a Class 6 felony.

B. In addition to the criminal penalties provided for in subsection A of this section, the Department of Professional and Occupational Regulation or the Department of Health Professions, without compliance with the Administrative Process Act (§ 9-6.14:1 et seq.), shall have the authority to enforce the provisions of subsection A of this section and may institute proceedings in equity to enjoin any person, partnership, corporation or any other entity from engaging in any unlawful act enumerated in this section. Such proceedings shall be brought in the name of the Commonwealth by the appropriate Department in the circuit court of the city or county in which the unlawful act occurred or in which the defendant resides.

C. In addition to the penalties and proceedings authorized above, the Department of Health Professions may petition the circuit court for the jurisdiction in which any permitted pharmacy is located for the appointment of a receiver whenever such pharmacy has engaged in one of the acts listed in subsection A of this section, and the Director has provided the owner of the pharmacy with notice of such violation and the violation presents a continuing threat to the health of any patients. Any receiver appointed pursuant to this subsection shall be a pharmacist licensed in the Commonwealth of Virginia.

§ 54.1-2403.2. Record storage.

A. Medical records, as defined in § 42.1-77, may be stored by computerized or other electronic process or microfilm, or other photographic, mechanical, or chemical process; however, the stored record shall identify the location of any documents or information that could not be so technologically stored. If the technological storage process creates an unalterable record, a health care provider licensed, certified or registered by a health regulatory board within the Department shall not be required to maintain paper copies of medical records that have been stored by computerized or other electronic process, microfilm, or other photographic, mechanical, or chemical process. Upon completing such technological storage, paper copies of medical records may be destroyed in a manner that preserves the patient's confidentiality. However, any documents or information that could not be so technologically stored shall be preserved.

B. Notwithstanding the authority given in this section to store patient records in the form of microfilm, prescription dispensing records maintained in or on behalf of any pharmacy registered or permitted in Virginia shall only be stored in compliance with the regulations of the Board of Pharmacy.

§ 54.1-2403.3. Medical records; ownership; provision of copies.

A. Medical records maintained by any health care provider as defined in § 32.1-127.1:03 shall be the property of such health care provider. Such health care provider shall release copies of any such medical records in compliance with § 32.1-127.1:03 or § 8.01-413, if the request is made for purposes of litigation, or as otherwise provided by state or federal law.

B. The owner of a business engaging in health care and employing health care providers who are regulated by a board within the Department of Health Professions shall not, under any circumstances, be the owner of any health records. The pharmacist-in-charge, or other supervising professional in situations other than a pharmacy, shall be the owner of such records. The mass of prescription dispensing records maintained in a pharmacy registered or permitted in Virginia shall only be transferred, disclosed or released in compliance with regulations of the Board of Pharmacy.

§ 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.

"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.

"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.

"Board" means the Board of Pharmacy.

"Change of ownership" means, regardless of the legal mechanism for such change, any acquisition by or shift in control to another person or entity of an existing permitted, registered or licensed facility or of any corporation under which the facility is directly or indirectly organized.

"Closing of a pharmacy" means the cessation or interruption of the practice of pharmacy at a permitted location during its normal hours of operation as reported to the Board.

"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, or the mature stalks of such plant, fiber produced from such stalk, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture or preparation of such mature stalks, fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

"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.

"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.

"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~~ *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.

"Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as 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.

§ 54.1-3434. Permit to conduct pharmacy.

No person shall conduct a pharmacy without first obtaining a permit from the Board.

The application for such permit shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the pharmacy and who will be fully engaged in the practice of pharmacy at the location designated on the application.

The application shall *(i)* show the corporate name and trade name ~~and shall~~, *(ii)* list any pharmacist in addition to the pharmacist-in-charge practicing at the location indicated on the application, *and (iii) list the hours during which the pharmacy will be open to provide pharmacy services. Any change in the hours of operation shall be reported to the Board in writing and posted, at least fourteen days prior to the anticipated change, in a conspicuous place to provide notice to the public. The Board may promulgate regulations to provide exceptions to this prior notification.*

If the owner is other than the pharmacist making the application, the type of ownership shall be indicated and shall list any partner or partners, and, if a corporation, then the corporate officers and directors. Further, if the owner is not a pharmacist, he shall not abridge the authority of the pharmacist-in-charge to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations.

The permit shall be issued only to the pharmacist who signs the application as the pharmacist-in-charge and as such assumes the full responsibilities for the legal operation of the pharmacy. This permit and responsibilities shall not be construed to negate any responsibility of any pharmacist or other person.

Upon termination of practice by the pharmacist-in-charge, or upon any change ~~in partnership composition, or upon the acquisition of the existing corporation by another person~~ *of ownership or closing of a pharmacy, as defined in § 54.1-3401,* the permit previously issued shall be immediately surrendered to the Board by the pharmacist-in-charge to whom it was issued, or by his legal representative, and an application for a new permit may be made in accordance with the requirements of this chapter.

The Board shall promulgate regulations providing *for the transfer and integrity of the pharmacy's prescription dispensing records, regardless of where located, and* a reasonable time period for designation of a new pharmacist-in-charge. At the conclusion of ~~such~~*the* time period *for designation of a new pharmacist-in-charge,* a pharmacy which has failed to designate a new pharmacist-in-charge shall not operate as a pharmacy nor maintain a stock of prescription drugs on the premises. The Director shall immediately notify the owner of record that the pharmacy no longer holds a valid permit and that the owner shall make provision for the proper disposition of all Schedule II through VI drugs and devices on the premises within fifteen days of receipt of this notice. At the conclusion of the fifteen-day period, the Director or his authorized agent shall seize and indefinitely secure all Schedule II through VI drugs

and devices still on the premises, and notify the owner of such seizure. The Director may properly dispose of the seized drugs and devices after six months from the date of the notice of seizure if the owner has not claimed and provided for the proper disposition of the property. The Board shall assess a fee of not less than the cost of storage of said drugs upon the owner for reclaiming seized property.

The succeeding pharmacist-in-charge shall cause an inventory to be made of all Schedule I, II, III, IV and V drugs on hand. Such inventory shall be completed as of the date he becomes pharmacist-in-charge and prior to opening for business on that date.

The pharmacist to whom such permit is issued shall provide safeguards against diversion of all controlled substances.

An application for a pharmacy permit shall be accompanied by a fee determined by the Board. All permits shall expire on December 31 of each year.

Every pharmacy must be equipped so that prescriptions can be properly filled. The Board of Pharmacy shall prescribe the minimum of such professional and technical equipment, which a pharmacy shall at all times possess, and such list shall include as reference the latest revision of the United States Pharmacopoeia Dispensing Information. No permit shall be issued or continued for the conduct of a pharmacy until or unless there is compliance with the provisions of this chapter and regulations promulgated by the Board.

Each day during which a person is in violation of this section shall constitute a separate offense.

§ 54.1-3434.01. Notice of pharmacy closing; change of ownership*; penalty*.

A. Prior to the closing of a pharmacy for more than one week, the ~~pharmacist-in-charge~~*owner* shall either (i) post a conspicuous notice at least thirty days prior to the anticipated closing or (ii) mail a notice, at least ~~14~~ *fourteen* days prior to the anticipated closing, to every current pharmacy customer having refill authority. Each notice posted or mailed pursuant to this section shall indicate the date of such closing, if available, and the name of the pharmacy to which prescriptions *and other required prescription dispensing records and individual patient records* will be transferred unless patients indicate their preference to the contrary. The Board of Pharmacy shall promulgate regulations providing exceptions to this requirement.

B. In the event the pharmacy is to be temporarily closed during reported business hours for more than one day, the owner of the pharmacy shall transfer a patient's individual record upon a patient's request if the request is in accordance with applicable law.

C. Upon any change of ownership of a pharmacy, regardless of how such change may be effectuated, the prescription dispensing records and other patient records for at least two years immediately prior, shall be transferred to the new owner in a manner to ensure continuity of pharmacy services at substantially the same level as that offered by the previous owner.

Failure to transfer the prescription dispensing records and other patient records in accordance with law shall constitute a closing and the requirements of this section shall apply. Such failure may constitute a violation of § 54.1-111 A 9, depending on the circumstances.

§ 54.1-3434.02. Registration of certain site of prescription dispensing records.

A. The owner of any pharmacy which maintains or stores the mass of its prescription dispensing records in a database residing at a location other than the permitted pharmacy, shall register the location of such database with the Board.

B. The application for such registration shall be made on a form provided by the Board and accompanied by a fee set by the Board. The Board shall promulgate regulations related to the security, confidentiality, accessibility, and maintenance of such database.