COMMONWEALTH OF VIRGINIA
Department of Health Professions

Perimeter Center, 9960 Mayland Drive, Second Floor (804) 367-4456 (Tel)
Henrico, Virginia 23233 (804) 527-4472(Fax)

Tentative Agenda of E-prescribing Workgroup

August 29, 2018

9AM

PAGES

Call to Order: David Brown, DC, Director

- Welcome & Introductions
- Approval of Agenda

Call for Public Comment

Review of Law and Workgroup's Past Actions:

- HB 2165 1-6
- Interim Progress Report, October 12, 2017 7-13

Recommend Legislation to Implement Mandate:

- Issues from Interim Progress Report and Discussion
  - Temporary waivers, exceptions, and other
- Federal legislation 14-27
- Draft legislative proposal 28-30

Next steps

Adjourn

VIRGINIA ACTS OF ASSEMBLY -- 2017 SESSION

CHAPTER 115

An Act to amend and reenact §§ 54.1-3401, 54.1-3408.02, and 54.1-3410 of the Code of Virginia, relating to prescriptions for controlled substances containing opiates; electronic prescription.

[H 2165]

Approved February 21, 2017

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3401, 54.1-3408.02, and 54.1-3410 of the Code of Virginia are amended and reenacted 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, corticosteroids, and dehydroepiandrosterone.

"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.

"Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or any derivative of arsphenamine or any other trivalent organic arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human beings.

"Biosimilar" means a biological product that is highly similar to a specific reference biological product, notwithstanding minor differences in clinically inactive compounds, such that there are no clinically meaningful differences between the reference biological product and the biological product that has been licensed as a biosimilar pursuant to 42 U.S.C. § 262(k) in terms of safety, purity, and potency of the product.

"Board" means the Board of Pharmacy.

"Bulk drug substance" means any substance that is represented for use, and that, when used in the compounding, manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug; however, "bulk drug substance" shall not include intermediates that are used in the synthesis of such substances.

"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 50 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.

"Co-licensed partner" means a person who, with at least one other person, has the right to engage in the manufacturing or marketing of a prescription drug, consistent with state and federal law.

"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in

expectation of receiving a valid prescription based on observed historical patterns of prescribing and dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or chemical analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a manufacturer's product drugs for the purpose of administration to a patient, when performed by a practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person supervised by such practitioner pursuant to subdivision A 6 or 19 of § 54.1-2901, or a person supervised by such practitioner or a licensed nurse practitioner or physician assistant pursuant to subdivision A 4 of § 54.1-2901 shall not be considered compounding.

"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 3.2 or Title 4.1. The term "controlled substance" includes a controlled substance analog that has been placed into Schedule I or II by the Board pursuant to the regulatory authority in subsection D of § 54.1-3443.

"Controlled substance analog" means a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance in Schedule I or II and either (i) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II or (ii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II. "Controlled substance analog" does not include (a) any substance for which there is an approved new drug application as defined under § 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) or that is generally recognized as safe and effective pursuant to §§ 501, 502, and 503 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 351, 352, and 353) and 21 C.F.R. Part 330; (b) with respect to a particular person, any substance for which an exemption is in effect for investigational use for that person under § 505 of the federal Food, Drug, and Cosmetic Act to the extent that the conduct with respect to that substance is pursuant to such exemption; or (c) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

"DEA" means the Drug Enforcement Administration, U.S. 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 care technician" or "dialysis patient care technician" means an individual who is certified by an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.) and who, under the supervision of a licensed physician, nurse practitioner, physician assistant, or a registered nurse, assists in the care of patients undergoing renal dialysis treatments in a Medicare-certified renal dialysis facility.

"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. However, dispensing shall not include the transportation of drugs mixed, diluted, or reconstituted in accordance with this chapter to other sites operated by such practitioner or that practitioner's medical practice for the purpose of administration of such drugs to patients of the practitioner or that practitioner's medical practice at such other sites. For practitioners of medicine or osteopathy, "dispense" shall only include the provision of drugs by a practitioner to patients to take with them away from the practitioner's place of practice.

"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; (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii), or (iii); or (v) a biological product. "Drug"

does not include devices or their components, parts, or accessories.

"Drug product" means a specific drug in dosage form from a known source of manufacture, whether by brand or therapeutically equivalent drug product name.

"Electronic ~~transmission~~ prescription" means ~~any prescription, other than an oral or written prescription or a prescription transmitted by facsimile machine, that is electronically transmitted directly to a pharmacy without interception or intervention from a third party from a practitioner authorized to prescribe or from one pharmacy to another pharmacy~~ *a written prescription that is generated on an electronic application and is transmitted to a pharmacy as an electronic data file; Schedule II through V prescriptions shall be transmitted in accordance with 21 C.F.R. Part 1300.*

"Facsimile (FAX) prescription" means a written prescription or order that is transmitted by an electronic device over telephone lines that sends the exact image to the receiving pharmacy in hard copy form.

"FDA" means the U.S. Food and Drug Administration.

"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 12 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.

"Interchangeable" means a biosimilar that meets safety standards for determining interchangeability pursuant to 42 U.S.C. § 262(k)(4).

"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, 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 compounding.

"Manufacturer" means every person who manufactures, a manufacturer's co-licensed partner, or a repackager.

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or its 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 12 percent of tetrahydrocannabinol by weight, nor shall marijuana include the mature stalks of such plant, fiber produced from such stalk, or 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. Marijuana shall not include industrial hemp as defined in § 3.2-4112 that is possessed, cultivated, or manufactured by a grower licensed pursuant to § 3.2-4115.

"Medical equipment supplier" means any person, as defined in § 1-230, 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 that are used for the operation and cleaning of medical equipment, solutions for peritoneal dialysis, and sterile water or saline for irrigation.

"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 U.S. 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.), 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.

"Outsourcing facility" means a facility that is engaged in the compounding of sterile drugs and is currently registered as an outsourcing facility with the U.S. Secretary of Health and Human Services and that complies with all applicable requirements of federal and state law, including the Federal Food, Drug, and Cosmetic Act.

"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, 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 the 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 (21 U.S.C. § 353(b)).

"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 that is only advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic, a drug that 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.

"Reference biological product" means the single biological product licensed pursuant to 42 U.S.C. § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food and Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to 42 U.S.C. § 262(k).

"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.

"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book."

"Third-party logistics provider" means a person that provides or coordinates warehousing of or other logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the drug or device but does not take ownership of the product or have responsibility for directing the sale or disposition of the product.

"USP-NF" means the current edition of the United States Pharmacopeia-National Formulary.

"Warehouser" means any person, other than a wholesale distributor, manufacturer, or third-party logistics provider, 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 exemptions set forth in the federal Drug Supply Chain Security Act.

"Wholesale distributor" means any person other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager that engages in wholesale distribution.

The words "drugs" and "devices" as used in Chapter 33 (§ 54.1-3300 et seq.) 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 (§ 54.1-3300 et seq.) unless the context requires a different meaning.

§ 54.1-3408.02. Transmission of prescriptions.

A. Consistent with federal law and in accordance with regulations promulgated by the Board, prescriptions may be transmitted to a pharmacy ~~by~~ *as an* electronic ~~transmission~~ *prescription* or by facsimile machine and shall be treated as valid original prescriptions.

B. Any prescription for a controlled substance that contains an opiate shall be issued as an electronic prescription.

§ 54.1-3410. When pharmacist may sell and dispense drugs.

A. A pharmacist, acting in good faith, may sell and dispense drugs and devices to any person pursuant to a prescription of a prescriber as follows:

1. A drug listed in Schedule II shall be dispensed only upon receipt of a written prescription that is properly executed, dated and signed by the person prescribing on the day when issued and bearing the full name and address of the patient for whom, or of the owner of the animal for which, the drug is dispensed, 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. If the prescription is for an animal, it shall state the species of animal for which the drug is prescribed;

2. In emergency situations, Schedule II drugs may be dispensed pursuant to an oral prescription in accordance with the Board's regulations;

3. Whenever a pharmacist dispenses any drug listed within Schedule II on a prescription issued by a prescriber, he shall affix to the container in which such drug is dispensed, a label showing the prescription serial number or name of the drug; the date of initial filling; his name and address, or the name and address of the pharmacy; the name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal; the name of the prescriber by whom the prescription was written, except for those drugs dispensed to a patient in a hospital pursuant to a chart order; and such directions as may be stated on the prescription.

B. A drug controlled by Schedules III through VI or a device controlled by Schedule VI shall be dispensed upon receipt of a written or oral prescription as follows:

1. If the prescription is written, it shall be properly executed, dated and signed by the person prescribing on the day when issued and bear the full name and address of the patient for whom, or of the owner of the animal for which, the drug is dispensed, and the full name and address of the person prescribing. If the prescription is for an animal, it shall state the species of animal for which the drug is

prescribed.

2. If the prescription is oral, the prescriber shall furnish the pharmacist with the same information as is required by law in the case of a written prescription for drugs and devices, except for the signature of the prescriber.

A pharmacist who dispenses a Schedule III through VI drug or device shall label the drug or device as required in subdivision A 3 of this section.

C. A drug controlled by Schedule VI may be refilled without authorization from the prescriber if, after reasonable effort has been made to contact him, the pharmacist ascertains that he is not available and the patient's health would be in imminent danger without the benefits of the drug. The refill shall be made in compliance with the provisions of § 54.1-3411.

If the written or oral prescription is for a Schedule VI drug or device and does not contain the address or registry number of the prescriber, or the address of the patient, the pharmacist need not reduce such information to writing if such information is readily retrievable within the pharmacy.

D. Pursuant to authorization of the prescriber, an agent of the prescriber on his behalf may orally transmit a prescription for a drug classified in Schedules III through VI if, in such cases, the written record of the prescription required by this subsection specifies the full name of the agent of the prescriber transmitting the prescription.

E. No pharmacist shall dispense a controlled substance that contains an opiate unless the prescription for such controlled substance is issued as an electronic prescription.

2. That the provisions of the first enactment of this act shall become effective on July 1, 2020.

3. That the Secretary of Health and Human Resources shall convene a work group of interested stakeholders, including the Medical Society of Virginia, the Virginia Hospital and Healthcare Association, the Virginia Dental Association, the Virginia Association of Health Plans, and the Virginia Pharmacy Association to review actions necessary for the implementation of the provisions of this act and shall make an interim progress report to the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2017 and shall make a final report to such Chairmen by November 1, 2018. In addition, the work group shall evaluate hardships on prescribers, the inability of prescribers to comply with the deadline for electronic prescribing and make recommendations to the General Assembly for any extension or exemption processes relative to compliance or disruptions due to natural or manmade disasters or technology gaps, failures or interruptions of services.

COMMONWEALTH of VIRGINIA

Office of the Governor

William A. Hazel, Jr., MD
Secretary of Health and Human Resources

October 12, 2017

The Honorable Robert D. Orrock, Sr.
Chairman
House Committee on Health, Welfare, and Institutions

The Honorable Stephen D. Newman
Chairman
Senate Committee on Education and Health

Re: Interim Progress Report, E-Prescribing Workgroup (HB2165)

Dear Chairmen:

Pursuant to HB2165, passed during the 2017 General Assembly Session, a workgroup was convened on August 2, 2017 and on August 29, 2017 to review actions necessary for implementation of the mandatory issuance of electronic prescriptions for controlled substances containing an opiate, effective July 1, 2020. Transmitting prescriptions for opiates electronically can potentially reduce medication errors, prescription theft, and forgery, assist prescribers and pharmacists in obtaining electronic prior authorizations when necessary, and integrate prescription records directly into a patient's electronic health record. The workgroup evaluated hardships on prescribers and the inability of prescribers to comply with the deadline for electronic prescribing. Additionally, it developed recommendations to the General Assembly for any extension or exemption processes relative to compliance or disruptions due to natural or manmade disasters or technology gaps, failures, or interruptions of services. The workgroup was comprised of representatives from the Board of Pharmacy; Virginia Pharmacists Association; Virginia Council of Nurse Practitioners; National Association of Chain Drug Stores; Medical Society of Virginia; Virginia Hospital and Health Care Association; Surescripts; Virginia Dental Association; Virginia Veterinary Medical Association; Drug Enforcement Administration; and, the Virginia Association of Health Plans. A complete listing of the workgroup members is enclosed. David Brown, DC, Director of the Department of Health Professions (DHP) chaired the workgroup meetings.

Data was provided by Surescripts to the members. Surescripts self-reports that it operates the nation's largest clinical health information network, serving providers in all 50 states and D.C. The company's network connects to over 98 percent of all retail pharmacies, most mail order pharmacies, and over one million U.S. providers. The Surescripts data represented two types of prescribers: Active E-prescribers (prescribers who have sent e-prescriptions to pharmacies using Surescripts network in the last 30 days using the EHR software applications)

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and Active E-Prescribers EPCS Enabled (prescribers who use an EHR software that is Electronic Prescriptions for Controlled Substances certified and audit approved). As of June 2017, 56.8% of Virginia prescribers are active E-prescribers with 6.3% EPCS enabled. Nationally, 17.1% of prescribers are EPCS enabled. Additionally, 97.5% of Virginia pharmacies are active eRx pharmacies (pharmacies that are ready and processing e-prescriptions from prescribers' applications) and that 90.3% are EPCS enabled pharmacies (pharmacies with certified and audit approved software ready to receive EPCS transactions from prescribers). The percentage of EPCS enabled pharmacies for Virginia reflects favorably with the national number of 90.5%. During the workgroup discussions, a member noted that there are hundreds of EPCS enabled physicians practicing within healthcare systems that do not utilize Surescripts, e.g. Kaiser Permanente, that are not included in the Surescripts data. Additionally, it should be noted that the Surescripts data regarding EPCS enabled prescribers does not include most dentists.

The workgroup briefly reviewed federal requirements passed in 2010 authorizing electronic prescriptions for controlled substances in Schedules II-V and the Board of Pharmacy regulation authorizing electronic prescriptions for controlled substances in Schedules II-VI, and discussed similar mandates implemented in other states, particularly New York. The workgroup was informed that seven other states have passed legislation requiring electronic prescriptions for certain types of controlled substances. New York was the first state to mandate electronic prescriptions, effective March 2016, for all controlled and non-controlled substances.

While there was no expressed direct opposition to the mandate, there was general consensus among the workgroup members that exceptions to the mandate were needed. A review of passed legislation from other states revealed that most states have identified in Code various exceptions to the mandate, with one state authoring the promulgation of regulation on the subject. Therefore, the workgroup recommends a legislative amendment to identify exceptions to the mandate that prescriptions for controlled substances containing an opiate must be issued as an electronic prescription, which could include: a prescriber who dispenses the opiate directly to the patient or patient's agent; a prescriber who orders a controlled substance to be administered in a hospital, nursing home, hospice facility, outpatient dialysis facility, or residential healthcare facility; a prescriber who experiences temporary technological or electrical failure or other temporary extenuating circumstance that prevents the prescription from being transmitted electronically, provided the prescriber documents the reason for this exception in the patient's medical record; a prescriber who writes a prescription to be dispensed by a pharmacy located on federal property or out-of-state, provided the prescriber documents the reason for this exception in the patient's medical record; prescriptions issued by a veterinarian; prescriptions with complicated directions; prescriptions with directions longer than 140 characters or for compounded drugs containing two or more drugs if the software application cannot accommodate the required number of characters (Note: it is purported that these two issues may be addressed in an upcoming NCPDP version and therefore, may no longer require exemption from the mandate.); prescriptions containing attachments required by the Food and Drug Administration; approved protocols authorized in law; and, prescriptions that cannot be issued in a timely manner and the patient's condition is at risk.

Because various exceptions to the mandate were deemed necessary by the workgroup, there was general consensus that pharmacists would not be able to readily determine if an

otherwise valid prescription was transmitted in compliance with an exception. New York and North Carolina, along with federal bill HR3528 introduced July 28, 2017, support and have acknowledged this understanding. Therefore, the workgroup recommends a legislative amendment to strike in §54.1-3410 E, "No pharmacist shall dispense a controlled substance that contains an opiate unless the prescription for such controlled substance is issued as an electronic prescription." and insert "A dispenser is not required to verify that a prescriber properly falls under one of the exceptions specified in Code prior to dispensing a controlled substance containing an opiate. A dispenser may continue to dispense controlled substances from valid written, oral, or facsimile prescriptions that are otherwise consistent with applicable laws."

There was additional discussion regarding whether an allowance for prescribers to apply for a temporary waiver should also be implemented. New York has such a provision wherein prescribers may apply annually for a temporary waiver of the mandate due to economic hardship, technological limitations that are not reasonably within the control of the prescriber, or other exceptional circumstance demonstrated by the prescriber. During the first year of implementation, New York granted approximately 6,200 waivers for approximately 19,000 prescribers. The following year, the number of approved waivers reduced to approximately 3,120. The most commonly approved waiver in the first year were for institutions and large group practices that were in the process of upgrading their software applications to comply with the mandate. North Carolina did not include a waiver provision in its 2017 legislation mandating electronic prescribing of "targeted controlled substances", i.e., Schedule II drugs containing opiates. The workgroup did not determine that it is necessary to create a process for approving temporary waivers, but acknowledge that additional review may be necessary.

New York also exempts prescribers from the mandate if they certify that they do not issue more than twenty-five prescriptions during a twelve-month period. Prescriptions in both oral and written form are included in determining whether the prescriber will reach the limit of twenty-five prescriptions. Approximately 1,000 New York prescribers have certified that they will not issue more than twenty-five prescriptions during a twelve-month period. The workgroup discussed the need for allowing a certification process for low volume prescribers. There was discussion regarding how best to define "low volume". While New York defines the term as a specified number of prescriptions per year, there was concern that even a few prescriptions written for large quantities could be problematic. It was suggested that "low volume" be defined as a maximum number of prescriptions per year with a restriction for the allowable maximum day supply for each prescription. The workgroup concluded that an exception for low volume prescribers should be included in the aforementioned legislative amendment to create a list of exceptions to the mandate and that a definition for low volume will need to be defined.

Other identified challenges included costs for procuring or upgrading a software application that may transmit electronic prescriptions compliant with federal requirements. Cost will vary greatly depending on the chosen application and actions necessary to enable proper functions. It was stated that many providers utilize an application capable of electronically transmitting opioid prescriptions in compliance with federal rules, but have not activated the function for various reasons. Surescripts estimates that 95% of the active e-prescribers in Virginia use systems that are certified and approved for EPCS, and therefore, further estimates

that 54% of all Virginia prescribers could become enabled to transmit EPCSs in a relatively short period of time by working with their application vendor to download and/or install the EPCS functionality in their EHR. Additionally, during staff's research, a New York colleague indicated the purchasing of an electronic health record is not required for electronically transmitting prescriptions and that lesser expensive stand-alone applications exist which enable e-prescribing. Professional associations could potentially assist providers in identifying the best and most affordable software applications to meet the providers' needs. The workgroup recommends exploring the possibility of using Hi-tech grant funding to assist prescribers and pharmacists in obtaining a software application capable of electronically transmitting controlled substances in compliance with federal and state requirements.

The workgroup discussed the need for prescribers, who are not currently complying with federal requirements for transmitting electronic prescriptions, to obtain a two-factor credential and complete identity proofing in order to electronically sign a prescription. It appears a prescriber may incur a cost for this process, unless the employer subsidizes the cost. Additionally, there appeared to be concern for educating prescribers, particularly those working in solo or small practices, on how to complete the process. The workgroup recommends that the relevant professional associations and related boards could assist providers in educating them on how to obtain a two-factor credential.

The appropriateness of the effective date for the mandate, July 1, 2020, was discussed. While some members thought the deadline could be moved up to an earlier date, others thought 2020 provided the necessary amount of time to potentially obtain funding and software.

The appropriateness of the mandate exclusively addressing controlled substances containing an opiate was briefly discussed by the workgroup. One member supported a potential expansion of the mandate to other abuseable drugs given the addiction crisis. Others thought a possible expansion to other drug classifications would likely impact a greater number of prescribers and could complicate the implementation process for meeting the 2020 effective date.

Subsequent to the workgroup's meetings, Board of Pharmacy staff was reminded of the following pharmacist observations with current utilization of e-prescribing which may need to be addressed prior to implementation of the mandate: prescribers practicing within a large healthcare system, wherein the prescriber may practice in multiple offices, often use a default address or telephone number for the healthcare system on the e-prescription, instead of the address number and telephone number associated with the site from which the prescription was issued, which creates challenges for the pharmacist contacting the prescriber with questions or concerns related to the dispensing of the prescription; occasionally prescribers will choose the default directions in the e-prescribing system, but then enter different directions in a text field thus creating opportunities for medication errors and confusion regarding the intended use of the drug; coupons or rebate opportunities associated with the cost of the drug will occasionally be included on the e-prescription which obscures the pharmacist's ability to read important prescribing information for dispensing the drug; and, while DEA allows the "forwarding" of an unfilled electronically transmitted prescription to another pharmacy should the patient choose to have the prescription filled at another pharmacy or if the prescriber transmits the prescription to

the wrong pharmacy, it has not provided information on how a pharmacist completes this process and the current NCPDP does not allow for such a transaction.

No additional meetings of the workgroup are scheduled at this time. A final report shall be submitted to you by November 1, 2018. Please feel free to contact Caroline Juran at (804) 367-4456, or Dr. David Brown at (804) 367-4450, should you have any questions.

Respectfully,

William A. Hazel, Jr., MD

Enclosure

HHR/DHP E-Prescribing Workgroup

Member List – August 29, 2017

William A. Hazel Jr., MD
Secretary of Health & Human Resources

David Brown, DC
Department of Health Professions, Director

Caroline Juran
Board of Pharmacy, Executive Director

Omar Abubaker, DMD, Ph.D.
Virginia Dental Association

Barbara Brown, Ph.D.
Virginia Hospital & Healthcare Association

Ruth A. Carter
Drug Enforcement Administration

Tyler Cox
Medical Society of Virginia and HCA Hospitals

Carol Forster, MD
Kaiser Permanente

Kelly Gottschalk, DVM
Virginia Veterinary Medical Association

Richard Grossman
Virginia Council of Nurse Practitioners

Stephanie Lynch
Virginia Association of Health Plans

Rusty Maney
Virginia Association of Chain Drug Stores

Jodi Manz, MSW
Policy Advisor, Office of the Secretary of Health & Human Resources

Johnny Moore
Virginia Pharmacists Association

Ken Whittemore, Jr., R.Ph., MBA
Surescripts, LLC

ALTERNATES:

Lauren Bates-Rowe
Medical Society of Virginia

B. Ellen Byrne, R.Ph., D.D.S., Ph.D.
Virginia Dental Association

Shelley Craft
Virginia Association of Chain Drug Stores (Kroger Pharmacy)

Chuck Duvall
Virginia Dental Association

Sara Heisler
Virginia Hospital & Healthcare Association

Ralston King
Medical Society of Virginia

R. Brent Rawlings
Virginia Hospital & Healthcare Association

STAFF:

Laura Z. Rothrock
Department of Health Professions, Executive Assistant to Director Brown

Sylvia Tamayo-Suijk
Board of Pharmacy, Executive Assistant

Union Calendar No. 582

115TH CONGRESS
2D SESSION

H. R. 3528

[Report No. 115–748, Part I]

To amend title XVIII of the Social Security Act to require e-prescribing for coverage under part D of the Medicare program of prescription drugs that are controlled substances.

IN THE HOUSE OF REPRESENTATIVES

JULY 28, 2017

Ms. CLARK of Massachusetts (for herself and Mr. MULLIN) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

JUNE 12, 2018

Additional sponsors: Mr. HIGGINS of New York, Ms. ESTY of Connecticut, Mr. HIMES, Mr. KENNEDY, Mr. KELLY of Pennsylvania, Mr. TONKO, Mr. PANETTA, Mr. DONOVAN, Mr. KING of New York, Mr. BUDD, Mr. KATKO, Mr. LONG, Mr. THOMPSON of Pennsylvania, Ms. STEFANIK, Mr. COLLINS of New York, Mr. MACARTHUR, Ms. SHEA-PORTER, Ms. SLAUGHTER, Mrs. WALORSKI, Mr. NORCROSS, Mr. MOULTON, Mr. JENKINS of West Virginia, Mr. KRISHNAMOORTHI, Mr. FLORES, Mr. RYAN of Ohio, Ms. JENKINS of Kansas, Mr. PAYNE, Ms. HANABUSA, Mr. KNIGHT, Mr. SCHNEIDER, Mr. SCHWEIKERT, Ms. TITUS, Mr. FASO, Ms. KUSTER of New Hampshire, Ms. DEGETTE, Mr. YARMUTH, Mr. POCAN, Ms. WASSERMAN SCHULTZ, Ms. BONAMICI, Mr. COHEN, Mr. O'HALLERAN, Mr. RENACCI, Mr. HASTINGS, Mrs. BLACKBURN, Mr. POLIQUIN, Mrs. HANDEL, Mr. WALDEN, Mr. FITZPATRICK, Mr. CRAMER, and Mr. BROOKS of Alabama

JUNE 12, 2018
Reported from the Committee on Energy and Commerce with an amendment
[Strike out all after the enacting clause and insert the part printed in italic]

JUNE 12, 2018
The Committee on Ways and Means discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed
[For text of introduced bill, see copy of bill as introduced on July 28, 2017]

A BILL

To amend title XVIII of the Social Security Act to require e-prescribing for coverage under part D of the Medicare program of prescription drugs that are controlled substances.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Every Prescription Conveyed Securely Act".

SEC. 2. REQUIRING E-PRESCRIBING FOR COVERAGE OF COVERED PART D CONTROLLED SUBSTANCES.

(a) IN GENERAL.—Section 1860D–4(e) of the Social Security Act (42 U.S.C. 1395w–104(e)) is amended by adding at the end the following:

"(7) REQUIREMENT OF E-PRESCRIBING FOR CONTROLLED SUBSTANCES.—

"(A) IN GENERAL.—Subject to subparagraph (B), a prescription for a covered part D drug under a prescription drug plan (or under an MA–PD plan) for a schedule II, III, IV, or V controlled substance shall be transmitted by a health care practitioner electronically in accordance with an electronic prescription drug program that meets the requirements of paragraph (2).

"(B) EXCEPTION FOR CERTAIN CIRCUMSTANCES.—The Secretary shall, pursuant to rulemaking, specify circumstances with respect

to which the Secretary may waive the requirement under subparagraph (A), with respect to a covered part D drug, including in the case of—

"(i) a prescription issued when the practitioner and dispenser are the same entity;

"(ii) a prescription issued that cannot be transmitted electronically under the most recently implemented version of the National Council for Prescription Drug Programs SCRIPT Standard;

"(iii) a prescription issued by a practitioner who has received a waiver or a renewal thereof for a specified period determined by the Secretary, not to exceed one year, from the requirement to use electronic prescribing, pursuant to a process established by regulation by the Secretary, due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner;

"(iv) a prescription issued by a practitioner under circumstances in which, not-

withstanding the practitioner's ability to submit a prescription electronically as required by this subsection, such practitioner reasonably determines that it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual's medical condition involved;

"(v) a prescription issued by a practitioner allowing for the dispensing of a non-patient specific prescription pursuant to a standing order, approved protocol for drug therapy, collaborative drug management, or comprehensive medication management, in response to a public health emergency, or other circumstances where the practitioner may issue a non-patient specific prescription;

"(vi) a prescription issued by a practitioner prescribing a drug under a research protocol;

"(vii) a prescription issued by a practitioner for a drug for which the Food and Drug Administration requires a prescrip-

tion to contain elements that are not able to be included in electronic prescribing, such as a drug with risk evaluation and mitigation strategies that include elements to assure safe use; and

"(viii) a prescription issued by a practitioner for an individual who—

"(I) receives hospice care under this title; or

"(II) is a resident of a skilled nursing facility (as defined in section 1819(a)), or a medical institution or nursing facility for which payment is made for an institutionalized individual under section 1902(q)(1)(B), for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy, as determined by the Secretary in accordance with this paragraph.

"(C) DISPENSING.—Nothing in this paragraph shall be construed as requiring a sponsor of a prescription drug plan under this part, MA organization offering an MA–PD plan under part C, or a pharmacist to verify that a practi-

tioner, with respect to a prescription for a covered part D drug, has a waiver (or is otherwise exempt) under subparagraph (B) from the requirement under subparagraph (A). Nothing in this paragraph shall be construed as affecting the ability of the plan to cover or the pharmacists' ability to continue to dispense covered part D drugs from otherwise valid written, oral or fax prescriptions that are consistent with laws and regulations. Nothing in this paragraph shall be construed as affecting the ability of the beneficiary involved to designate a particular pharmacy to dispense a prescribed drug to the extent consistent with the requirements under subsection (b)(1) and under this paragraph.

"(D) ENFORCEMENT.—The Secretary shall, pursuant to rulemaking, have authority to enforce and specify appropriate penalties for noncompliance with the requirement under subparagraph (A).".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to coverage of drugs prescribed on or after January 1, 2021.

Union Calendar No. 582

115TH CONGRESS
2D SESSION

H. R. 3528

[Report No. 115–748, Part I]

A BILL

To amend title XVIII of the Social Security Act to require e-prescribing for coverage under part D of the Medicare program of prescription drugs that are controlled substances.

JUNE 12, 2018

Reported from the Committee on Energy and Commerce with an amendment

JUNE 12, 2018

The Committee on Ways and Means discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

II

115TH CONGRESS
2D SESSION

S. 2460

To amend title XVIII of the Social Security Act to require e-prescribing for coverage under part D of the Medicare program of prescription drugs that are controlled substances.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 27, 2018

Mr. BENNET (for himself, Mr. HELLER, Ms. WARREN, and Mr. TOOMEY) introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To amend title XVIII of the Social Security Act to require e-prescribing for coverage under part D of the Medicare program of prescription drugs that are controlled substances.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Every Prescription Conveyed Securely Act".

SEC. 2. REQUIRING E-PRESCRIBING FOR COVERAGE OF COVERED PART D CONTROLLED SUBSTANCES.

(a) IN GENERAL.—Section 1860D–4(e) of the Social Security Act (42 U.S.C. 1395w–104(e)) is amended by adding at the end the following:

"(7) REQUIREMENT OF E-PRESCRIBING FOR CONTROLLED SUBSTANCES.—

"(A) IN GENERAL.—Subject to subparagraph (B), a prescription for a covered part D drug under a prescription drug plan (or under an MA–PD plan) for a schedule II, III, IV, or V controlled substance shall be transmitted by a health care practitioner electronically in accordance with an electronic prescription drug program that meets the requirements of paragraph (2).

"(B) EXCEPTION FOR CERTAIN CIRCUMSTANCES.—The Secretary shall, pursuant to rulemaking, specify circumstances with respect to which the Secretary may waive the requirement under subparagraph (A), with respect to a covered part D drug, including in the case of—

"(i) a prescription issued when the prescriber and dispenser are the same entity;

"(ii) a prescription issued that cannot be transmitted electronically due to the constraints of the most recently implemented version of the National Council for Prescription Drug Programs SCRIPT Standard;

"(iii) a prescription issued by a practitioner who has received a waiver or a renewal thereof for a specified period determined by the Secretary, not to exceed one year, from the requirement to use electronic prescribing, pursuant to a process established by regulation by the Secretary, due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner;

"(iv) a prescription issued by a practitioner under circumstances in which, notwithstanding the practitioner's ability to make an electronic prescription as required

by this subsection, such practitioner reasonably determines that it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual's medical condition involved;

"(v) a prescription issued by a practitioner allowing for the dispensing of a non-patient specific prescription pursuant to a standing order, approved protocol for drug therapy, collaborative drug management, or comprehensive medication management, in response to a public health emergency, or other circumstances where the practitioner may issue a non-patient specific prescription;

"(vi) a prescription issued by a practitioner prescribing a drug under a research protocol;

"(vii) a prescription issued by a practitioner for a drug for which the Food and Drug Administration requires the prescription to contain certain elements that are not able to be accomplished with electronic

prescribing such as, a drug with risk evaluation and mitigation strategies that include elements to assure safe use; and

"(viii) a prescription issued by a practitioner for an individual who—

"(I) receives hospice care under this title; or

"(II) is a resident of a long-term care facility, of a facility described in section 1905(d), or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy.

"(C) DISPENSING.—(i) Nothing in this paragraph shall be construed as requiring a sponsor of a prescription drug plan under this part, MA organization offering an MA–PD plan under part C, or a pharmacist to verify that a practitioner, with respect to a prescription for a covered part D drug, has a waiver (or is otherwise exempt) under subparagraph (B) from the requirement under subparagraph (A).

"(ii) Nothing in this paragraph shall be construed as affecting the ability of the plan to cover or the pharmacists' ability to continue to

dispense covered part D drugs from otherwise valid written, oral or fax prescriptions that are consistent with laws and regulations.

"(iii) Nothing in this paragraph shall be construed as affecting the ability of an individual who is being prescribed a covered part D drug to designate a particular pharmacy to dispense the covered part D drug to the extent consistent with the requirements under subsection (b)(1) and under this paragraph.

"(D) ENFORCEMENT.—The Secretary shall, pursuant to rulemaking, have authority to enforce and specify appropriate penalties for noncompliance with the requirement under subparagraph (A).".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to coverage of drugs prescribed on or after January 1, 2020.

○

DRAFT Legislation

2019 Session of the General Assembly

A BILL to amend the *Code of Virginia* by amending §§ 54.1-3408.02 and 54.1-3410 of the Code of Virginia relating to electronic prescribing of a controlled substance containing an opiate.

Be it enacted by the General Assembly of Virginia:

1. **That § 54.1-3408.02 and 54.1-3410 of the *Code of Virginia* are amended and reenacted as follows:**

§ 54.1-3408.02. (Effective July 1, 2020) Transmission of prescriptions.

A. Consistent with federal law and in accordance with regulations promulgated by the Board, prescriptions may be transmitted to a pharmacy as an electronic prescription or by facsimile machine and shall be treated as valid original prescriptions.

B. Any prescription for a controlled substance that contains an opiate shall be issued as an electronic prescription with the following exceptions:

1. A prescriber who dispenses the opiate directly to the patient or patient's agent;

2. A prescriber who orders a controlled substance to be administered in a hospital, nursing home, hospice facility, outpatient dialysis facility, or residential healthcare facility;

3. A prescriber who experiences temporary technological or electrical failure or other temporary extenuating circumstance that prevents the prescription from being transmitted electronically, provided the prescriber documents the reason for this exception in the patient's medical record;

4. A prescriber who writes a prescription to be dispensed by a pharmacy located on federal property or out-of-state, provided the prescriber documents the reason for this exception in the patient's medical record;

5. A prescriber who writes a low volume of prescriptions, defined as less than twenty-five prescriptions during a twelve-month period with a maximum of a 7-day supply for each prescription;

6. A prescription issued by a veterinarian;

7. A prescription containing attachments required by the Food and Drug Administration;

8. Approved protocols authorized in law; and

9. A prescription that cannot be issued electronically in a timely manner and the patient's condition is at risk.

§ 54.1-3410. When pharmacist may sell and dispense drugs.

A. A pharmacist, acting in good faith, may sell and dispense drugs and devices to any person pursuant to a prescription of a prescriber as follows:

1. A drug listed in Schedule II shall be dispensed only upon receipt of a written prescription that is properly executed, dated and signed by the person prescribing on the day when issued and bearing the full name and address of the patient for whom, or of the owner of the animal for which, the drug is dispensed, 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. If the prescription is for an animal, it shall state the species of animal for which the drug is prescribed;

2. In emergency situations, Schedule II drugs may be dispensed pursuant to an oral prescription in accordance with the Board's regulations;

3. Whenever a pharmacist dispenses any drug listed within Schedule II on a prescription issued by a prescriber, he shall affix to the container in which such drug is dispensed, a label showing the prescription serial number or name of the drug; the date of initial filling; his name and address, or the name and address of the pharmacy; the name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal; the name of the prescriber by whom the prescription was written, except for those drugs dispensed to a patient in a hospital pursuant to a chart order; and such directions as may be stated on the prescription.

B. A drug controlled by Schedules III through VI or a device controlled by Schedule VI shall be dispensed upon receipt of a written or oral prescription as follows:

1. If the prescription is written, it shall be properly executed, dated and signed by the person prescribing on the day when issued and bear the full name and address of the patient for whom, or of the owner of the animal for which, the drug is dispensed, and the full name and address of the person prescribing. If the prescription is for an animal, it shall state the species of animal for which the drug is prescribed.

2. If the prescription is oral, the prescriber shall furnish the pharmacist with the same information as is required by law in the case of a written prescription for drugs and devices, except for the signature of the prescriber.

A pharmacist who dispenses a Schedule III through VI drug or device shall label the drug or device as required in subdivision A 3 of this section.

C. A drug controlled by Schedule VI may be refilled without authorization from the prescriber if, after reasonable effort has been made to contact him, the pharmacist ascertains that he is not available and the patient's health would be in imminent danger without the benefits of the drug. The refill shall be made in compliance with the provisions of § 54.1-3411.

If the written or oral prescription is for a Schedule VI drug or device and does not contain the address or registry number of the prescriber, or the address of the patient, the pharmacist need not reduce such information to writing if such information is readily retrievable within the pharmacy.

D. Pursuant to authorization of the prescriber, an agent of the prescriber on his behalf may orally transmit a prescription for a drug classified in Schedules III through VI if, in such cases, the written record of the prescription required by this subsection specifies the full name of the agent of the prescriber transmitting the prescription.

E. (Effective July 1, 2020) ~~No pharmacist shall dispense a controlled substance that contains an opiate unless the prescription for such controlled substance is issued as an electronic prescription.~~ A dispenser is not required to verify that a prescriber properly falls under one of the exceptions specified in § 54.1-3408.02 for electronic prescribing prior to dispensing a controlled substance containing an opiate. A dispenser may continue to dispense a controlled substance containing an opiate from valid written, oral, or facsimile prescriptions that are otherwise consistent with applicable laws.