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HOUSE BILL NO. 1000

Offered January 8, 2020

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A BILL to amend and reenact §§ 54.1-3303, as it is currently effective, 54.1-3408.01, and 54.1-3410 of the Code of Virginia and to repeal the third enactment of Chapter 790 of the Acts of Assembly of 2018, relating to prescription drugs; expedited partner therapy; labels.

Patron—Hope

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3303, as it is currently effective, 54.1-3408.01, and 54.1-3410 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3303. (Effective until July 1, 2020) Prescriptions to be issued and drugs to be dispensed for medical or therapeutic purposes only.

A. A prescription for a controlled substance may be issued only by a practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine who is authorized to prescribe controlled substances, or by a licensed nurse practitioner pursuant to § 54.1-2957.01, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32.

B. A prescription shall be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship or veterinarian-client-patient relationship. *If a practitioner is providing expedited partner therapy consistent with the recommendations of the Centers for Disease Control and Prevention, then a bona fide practitioner-patient relationship shall not be required.*

A bona fide practitioner-patient relationship shall exist if the practitioner has (i) obtained or caused to be obtained a medical or drug history of the patient; (ii) provided information to the patient about the benefits and risks of the drug being prescribed; (iii) performed or caused to be performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; and (iv) initiated additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects. Except in cases involving a medical emergency, the examination required pursuant to clause (iii) shall be performed by the practitioner prescribing the controlled substance, a practitioner who practices in the same group as the practitioner prescribing the controlled substance, or a consulting practitioner. ~~In cases in which the practitioner is an employee of or contracted by the Department of Health or a local health department and is providing expedited partner therapy consistent with the recommendations of the Centers for Disease Control and Prevention, the examination required by clause (iii) shall not be required.~~

A practitioner who has established a bona fide practitioner-patient relationship with a patient in accordance with the provisions of this subsection may prescribe Schedule II through VI controlled substances to that patient, provided that, in cases in which the practitioner has performed the examination required pursuant to clause (iii) by use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically, the prescribing of such Schedule II through V controlled substance is in compliance with federal requirements for the practice of telemedicine.

For the purpose of prescribing a Schedule VI controlled substance to a patient via telemedicine services as defined in § 38.2-3418.16, a prescriber may establish a bona fide practitioner-patient relationship by an examination through face-to-face interactive, two-way, real-time communications services or store-and-forward technologies when all of the following conditions are met: (a) the patient has provided a medical history that is available for review by the prescriber; (b) the prescriber obtains an updated medical history at the time of prescribing; (c) the prescriber makes a diagnosis at the time of prescribing; (d) the prescriber conforms to the standard of care expected of in-person care as appropriate to the patient's age and presenting condition, including when the standard of care requires the use of diagnostic testing and performance of a physical examination, which may be carried out through the use of peripheral devices appropriate to the patient's condition; (e) the prescriber is actively licensed in the Commonwealth and authorized to prescribe; (f) if the patient is a member or enrollee of a health plan or carrier, the prescriber has been credentialed by the health plan or carrier as a participating provider and the diagnosing and prescribing meets the qualifications for reimbursement by the health plan or carrier pursuant to § 38.2-3418.16; and (g) upon request, the prescriber provides patient records in a timely

INTRODUCED

HB1000

59 manner in accordance with the provisions of § 32.1-127.1:03 and all other state and federal laws and
60 regulations. Nothing in this paragraph shall permit a prescriber to establish a bona fide
61 practitioner-patient relationship for the purpose of prescribing a Schedule VI controlled substance when
62 the standard of care dictates that an in-person physical examination is necessary for diagnosis. Nothing
63 in this paragraph shall apply to: (1) a prescriber providing on-call coverage per an agreement with
64 another prescriber or his prescriber's professional entity or employer; (2) a prescriber consulting with
65 another prescriber regarding a patient's care; or (3) orders of prescribers for hospital out-patients or
66 in-patients.

67 For purposes of this section, a bona fide veterinarian-client-patient relationship is one in which a
68 veterinarian, another veterinarian within the group in which he practices, or a veterinarian with whom he
69 is consulting has assumed the responsibility for making medical judgments regarding the health of and
70 providing medical treatment to an animal as defined in § 3.2-6500, other than an equine as defined in
71 § 3.2-6200, a group of agricultural animals as defined in § 3.2-6500, or bees as defined in § 3.2-4400,
72 and a client who is the owner or other caretaker of the animal, group of agricultural animals, or bees
73 has consented to such treatment and agreed to follow the instructions of the veterinarian. Evidence that a
74 veterinarian has assumed responsibility for making medical judgments regarding the health of and
75 providing medical treatment to an animal, group of agricultural animals, or bees shall include evidence
76 that the veterinarian (A) has sufficient knowledge of the animal, group of agricultural animals, or bees
77 to provide a general or preliminary diagnosis of the medical condition of the animal, group of
78 agricultural animals, or bees; (B) has made an examination of the animal, group of agricultural animals,
79 or bees, either physically or by the use of instrumentation and diagnostic equipment through which
80 images and medical records may be transmitted electronically or has become familiar with the care and
81 keeping of that species of animal or bee on the premises of the client, including other premises within
82 the same operation or production system of the client, through medically appropriate and timely visits to
83 the premises at which the animal, group of agricultural animals, or bees are kept; and (C) is available to
84 provide follow-up care.

85 C. A prescription shall only be issued for a medicinal or therapeutic purpose in the usual course of
86 treatment or for authorized research. A prescription not issued in the usual course of treatment or for
87 authorized research is not a valid prescription. A practitioner who prescribes any controlled substance
88 with the knowledge that the controlled substance will be used otherwise than for medicinal or
89 therapeutic purposes shall be subject to the criminal penalties provided in § 18.2-248 for violations of
90 the provisions of law relating to the distribution or possession of controlled substances.

91 D. No prescription shall be filled unless a bona fide practitioner-patient-pharmacist relationship exists.
92 A bona fide practitioner-patient-pharmacist relationship shall exist in cases in which a practitioner
93 prescribes, and a pharmacist dispenses, controlled substances in good faith to a patient for a medicinal
94 or therapeutic purpose within the course of his professional practice.

95 In cases in which it is not clear to a pharmacist that a bona fide practitioner-patient relationship
96 exists between a prescriber and a patient, a pharmacist shall contact the prescribing practitioner or his
97 agent and verify the identity of the patient and name and quantity of the drug prescribed.

98 Any person knowingly filling an invalid prescription shall be subject to the criminal penalties
99 provided in § 18.2-248 for violations of the provisions of law relating to the sale, distribution or
100 possession of controlled substances.

101 E. Notwithstanding any provision of law to the contrary and consistent with recommendations of the
102 Centers for Disease Control and Prevention or the Department of Health, a practitioner may prescribe
103 Schedule VI antibiotics and antiviral agents to other persons in close contact with a diagnosed patient
104 when (i) the practitioner meets all requirements of a bona fide practitioner-patient relationship, as
105 defined in subsection B, with the diagnosed patient; *and* (ii) in the practitioner's professional judgment,
106 the practitioner deems there is urgency to begin treatment to prevent the transmission of a communicable
107 disease; ~~(iii) the practitioner has met all requirements of a bona fide practitioner-patient relationship, as~~
108 ~~defined in subsection B, for the close contact except for the physical examination required in clause (iii)~~
109 ~~of subsection B; and (iv) when such emergency treatment is necessary to prevent imminent risk of~~
110 ~~death, life-threatening illness, or serious disability.~~ In cases in which the practitioner is an employee of
111 or contracted by the Department of Health or a local health department, the ~~bona fide~~ bona fide
112 practitioner-patient relationship with the diagnosed patient, as required by clause (i), shall not be
113 required.

114 F. A pharmacist may dispense a controlled substance pursuant to a prescription of an out-of-state
115 practitioner of medicine, osteopathy, podiatry, dentistry, optometry, or veterinary medicine, a nurse
116 practitioner, or a physician assistant authorized to issue such prescription if the prescription complies
117 with the requirements of this chapter and the Drug Control Act (§ 54.1-3400 et seq.).

118 G. A licensed nurse practitioner who is authorized to prescribe controlled substances pursuant to
119 § 54.1-2957.01 may issue prescriptions or provide manufacturers' professional samples for controlled
120 substances and devices as set forth in the Drug Control Act (§ 54.1-3400 et seq.) in good faith to his

patient for a medicinal or therapeutic purpose within the scope of his professional practice.

H. A licensed physician assistant who is authorized to prescribe controlled substances pursuant to § 54.1-2952.1 may issue prescriptions or provide manufacturers' professional samples for controlled substances and devices as set forth in the Drug Control Act (§ 54.1-3400 et seq.) in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.

I. A TPA-certified optometrist who is authorized to prescribe controlled substances pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 may issue prescriptions in good faith or provide manufacturers' professional samples to his patients for medicinal or therapeutic purposes within the scope of his professional practice for the drugs specified on the TPA-Formulary, established pursuant to § 54.1-3223, which shall be limited to (i) analgesics included on Schedule II controlled substances as defined in § 54.1-3448 of the Drug Control Act (§ 54.1-3400 et seq.) consisting of hydrocodone in combination with acetaminophen; (ii) oral analgesics included in Schedules III through VI, as defined in §§ 54.1-3450 and 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.), which are appropriate to relieve ocular pain; (iii) other oral Schedule VI controlled substances, as defined in § 54.1-3455 of the Drug Control Act, appropriate to treat diseases and abnormal conditions of the human eye and its adnexa; (iv) topically applied Schedule VI drugs, as defined in § 54.1-3455 of the Drug Control Act; and (v) intramuscular administration of epinephrine for treatment of emergency cases of anaphylactic shock.

J. The requirement for a bona fide practitioner-patient relationship shall be deemed to be satisfied by a member or committee of a hospital's medical staff when approving a standing order or protocol for the administration of influenza vaccinations and pneumococcal vaccinations in a hospital in compliance with § 32.1-126.4.

K. Notwithstanding any other provision of law, a prescriber may authorize a registered nurse or licensed practical nurse to approve additional refills of a prescribed drug for no more than 90 consecutive days, provided that (i) the drug is classified as a Schedule VI drug; (ii) there are no changes in the prescribed drug, strength, or dosage; (iii) the prescriber has a current written protocol, accessible by the nurse, that identifies the conditions under which the nurse may approve additional refills; and (iv) the nurse documents in the patient's chart any refills authorized for a specific patient pursuant to the protocol and the additional refills are transmitted to a pharmacist in accordance with the allowances for an authorized agent to transmit a prescription orally or by facsimile pursuant to subsection C of § 54.1-3408.01 and regulations of the Board.

§ 54.1-3408.01. Requirements for prescriptions.

A. The written prescription referred to in § 54.1-3408 shall be written with ink or individually typed or printed. The prescription shall contain the name, address, and telephone number of the prescriber. A prescription for a controlled substance other than one controlled in Schedule VI shall also contain the federal controlled substances registration number assigned to the prescriber. The prescriber's information shall be either preprinted upon the prescription blank, electronically printed, typewritten, rubber stamped, or printed by hand.

The written prescription shall contain the first and last name of the patient for whom the drug is prescribed. The address of the patient shall either be placed upon the written prescription by the prescriber or his agent, or by the dispenser of the prescription. *If the prescriber is providing expedited partner therapy pursuant to § 54.1-3303 and the contact patient's name and address are unavailable, then "Expedited Partner Therapy" or "EPT" shall be affixed on the written prescription, in lieu of the contact patient's name and address.* If not otherwise prohibited by law, the dispenser may record the address of the patient in an electronic prescription dispensing record for that patient in lieu of recording it on the prescription. Each written prescription shall be dated as of, and signed by the prescriber on, the day when issued. The prescription may be prepared by an agent for the prescriber's signature.

This section shall not prohibit a prescriber from using preprinted prescriptions for drugs classified in Schedule VI if all requirements concerning dates, signatures, and other information specified above are otherwise fulfilled.

No written prescription order form shall include more than one prescription. However, this provision shall not apply (i) to prescriptions written as chart orders for patients in hospitals and long-term-care facilities, patients receiving home infusion services or hospice patients, or (ii) to a prescription ordered through a pharmacy operated by or for the Department of Corrections or the Department of Juvenile Justice, the central pharmacy of the Department of Health, or the central outpatient pharmacy operated by the Department of Behavioral Health and Developmental Services; or (iii) to prescriptions written for patients residing in adult and juvenile detention centers, local or regional jails, or work release centers operated by the Department of Corrections.

B. Prescribers' orders, whether written as chart orders or prescriptions, for Schedules II, III, IV, and V controlled drugs to be administered to (i) patients or residents of long-term care facilities served by a Virginia pharmacy from a remote location or (ii) patients receiving parenteral, intravenous,

intramuscular, subcutaneous or intraspinal infusion therapy and served by a home infusion pharmacy from a remote location, may be transmitted to that remote pharmacy by an electronic communications device over telephone lines which send the exact image to the receiver in hard copy form, and such facsimile copy shall be treated as a valid original prescription order. If the order is for a radiopharmaceutical, a physician authorized by state or federal law to possess and administer medical radioactive materials may authorize a nuclear medicine technologist to transmit a prescriber's verbal or written orders for radiopharmaceuticals.

C. The oral prescription referred to in § 54.1-3408 shall be transmitted to the pharmacy of the patient's choice by the prescriber or his authorized agent. For the purposes of this section, an authorized agent of the prescriber shall be an employee of the prescriber who is under his immediate and personal supervision, or if not an employee, an individual who holds a valid license allowing the administration or dispensing of drugs and who is specifically directed by the prescriber.

§ 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. *If the prescription is for expedited partner therapy pursuant to § 54.1-3303 and the contact patient's name and address are unavailable, the prescription shall state "Expedited Partner Therapy" or "EPT" in lieu of the full name and address of the contact patient.*

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. *However, if the pharmacist dispenses a Schedule III through VI drug or device for expedited partner therapy pursuant to § 54.1-3303 and the contact patient's name and address are unavailable, the prescription shall state "Expedited Partner Therapy" or "EPT" in lieu of the full name and address of the contact patient.*

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. *If the prescription is for a Schedule VI drug or device for expedited partner therapy pursuant to § 54.1-3303 and the contact patient's name and address are unavailable, then labeling the name and address of the contact patient is not required.*

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) A dispenser who receives a non-electronic prescription for a controlled

244 substance containing an opioid is not required to verify that one of the exceptions set forth in
245 § 54.1-3408.02 applies and may dispense such controlled substance pursuant to such prescription and
246 applicable law.
247 **2. That the third enactment of Chapter 790 of the Acts of Assembly of 2018 is repealed.**

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HB1000