



W. Scott Johnson
Ext. 416
sjohnson@hdjn.com

October 25, 2016

The Honorable Siobhan Dunnavant
Senate of Virginia
4600 Cox Road, Suite 100
Glen Allen, VA 23060

The Honorable Scott Garrett
Virginia House of Delegates
2255 Langhorne Road, Suite 4
Lynchburg, VA 24501

By email: district12@senate.virginia.gov

By email: DelSGarrett@house.virginia.gov

Re: **Internet Prescribing – Telemedicine**

Dear Drs. Dunnavant and Garrett:

Pursuant to your request, I am pleased to provide this letter outlining what is believed to be the common interpretation and understanding of federal and state law regarding internet prescribing, telemedicine, and how the federal requirements interplay with state law.

At the outset, it is important to note that “controlled substances” that are regulated by federal law include drugs in Schedules II through V. Schedule VI drugs are not regulated by federal law but are regulated by Virginia law.

Executive Summary

Federal law requires the performance of an in-person examination of the patient for Internet prescribing. An in-person examination of the patient is not required by federal law for telemedicine. Virginia law addresses patient examinations for all prescribing settings, including telemedicine.

Internet Prescribing

From a historical perspective, in 2008 Congress passed legislation that is commonly referred to as "Ryan Haight Online Pharmacy Consumer Protection Act of 2008".

The Ryan Haight Act is set forth in the federal statute and the pertinent portion is found in 21 U.S.C. § 829(d) which provides in part:

- (1) No controlled substance that is a prescription drug may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.

Federal regulations define the terms and phrases that are contained in the statute and gives further clarity. The following three phrases are of import to our understanding:

- (i) The phrase "deliver, distribute, or dispense by means of the Internet" refers respectively "to any delivery, distribution, or dispensing of a controlled substance that is caused or facilitated by means of the Internet;"

- (ii) The phrase "valid prescription" means "a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by (i) a practitioner who has conducted 1 in-person medical evaluation of the patient or (ii) a covering practitioner;" and

- (iii) The phrase "covering practitioner" means "with respect to a patient, a practitioner who conducts a medical evaluation (other than an in-person medical

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evaluation) at the request of a practitioner who: (i) has conducted at least 1 in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine within the previous 24 months and (ii) is temporarily unable to conduct the evaluation of the patient." [Emphasis added.]

An analysis of the above clarifies that an in-person medical evaluation is required in order for a prescriber to meet the requirements of Internet prescribing under the Ryan Haight Act. There is confusion among practitioners as to whether the in-person medical evaluation is a requirement for Internet prescribing or if it is a requirement for telemedicine under federal law. This analysis clarifies that it is for the former, meaning in-person evaluation is required only for Internet prescribing under federal law. If an in-person evaluation is not performed, then the prescriber will need to meet the statutory requirements of telemedicine under federal law.

Telemedicine

The federal requirements for telemedicine are found in 21 U.S.C. 802(54). This code section defines the "practice of telemedicine" and focuses the requirements mainly on two locations and settings where the patient receiving telemedicine services may be located. In order to comply with federal law, one of the two options must be met by the patient.

The first option is for the patient to be located in a DEA registered hospital or clinic. Specifically subsection (A) provides that telemedicine:

(A) is being conducted —

- (i) while the patient is being treated by, and physically located in, a hospital or clinic registered under section 823(f) of this title;

What constitutes a clinic is not defined in regulations. In addition, there are requirements that a practitioner providing the telemedicine services must meet, including acting in the usual course of professional practice, in accordance with state law, and a requirement that the practitioner is a DEA registrant.

The second option is for the patient to be located in the presence of a DEA registered practitioner which includes a DEA registered physician or mid-level provider such as a nurse practitioner or a physician assistant. Paragraph (B) of this statute sets forth this option and states that telemedicine “is being conducted while the patient is being treated by, and in the physical presence of, a practitioner” acting in the usual course of professional practice in accordance with state law and registered under section 823(f) of this title in the state in which the patient is located”

The analysis of these federal requirements clarifies that an in-person medical evaluation of the patient is not required in order to comply with the federal requirements for telemedicine.

Virginia Law

A reminder from the perspective of preemption, Virginia law cannot be in conflict with federal law but may supplement or complement federal law. Note that

federal requirements for telemedicine also require compliance with state laws on prescribing and telemedicine.

The primary Virginia statute regarding what constitutes a valid prescription that may be dispensed is found at Va. Code § 54.1-3303. This code section addresses all prescription relationships, whether the patient is seeing a prescriber in person, receiving a written prescription, which may include a prescription transmitted via facsimile or electronically, or prescribing is taking place through telemedicine.

The second paragraph of the statute contains a listing of six requirements that must be satisfied in order to establish a bona fide practitioner-patient-pharmacist relationship in all of the above prescription settings. One of the requirements addresses the issue of “patient examinations”. Specifically, this code section requires that the practitioner:

- (iii) perform or have 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; except for medical emergencies, the examination of the patient shall have been performed by the practitioner himself, within the group in which he practices, or by a consulting practitioner prior to issuing a prescription; [emphasis added.]

Unlike federal law, Virginia does not further flesh out in regulation the patient examination requirements of this code section.

The third paragraph of § 54.1-3303 addresses a specific situation involving the prescribing of Schedule VI drugs via telemedicine services as defined in

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our insurance code, in particular, Va. Code § 38.2-3418.16. That code section defines telemedicine services solely for the requirements of insurance coverage to mean “the use of electronic technology or media, including interactive audio or video, for the purpose of diagnosing and treating a patient or consulting with other health care providers regarding a patient’s diagnosis or treatment.” The terms “interactive audio or video” are not defined in Virginia law and were this section to involve the prescribing of Schedule II – V drugs, would not appear to comply with federal law.

The statute further clarifies that certain services do not constitute telemedicine, and those include “an audio-only telephone, electronic mail message, facsimile transmission, or online questionnaire.”

This paragraph also requires “the prescriber to conform 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”

Conclusion

One of the action items of Dr. Dunnavant’s stakeholder group and one of the action items of Work Group No. 3 of the SJR 47 Commission was to review Virginia laws to make sure that they were not more restrictive than federal laws involving telemedicine and, in particular, services provided through tele-psychiatry. Over the

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summer, Dr. Dunnivant's stakeholder group vetted the idea of amending Va. Code § 54.1-3303 to add a new paragraph to address prescribing by telemedicine. Subsequently, other stakeholders have suggested that for clarity language could be added to the end of the second paragraph in this code section to read: If a practitioner is performing or has performed an appropriate examination either physically or by the use of instrumentation and diagnostic equipment for the purpose of establishing a bona fide practitioner-patient relationship, he may prescribe Schedule II through VI controlled substances, provided the prescribing of Schedule II through V is in compliance with the federal requirements for the practice of telemedicine. I offer this for your review and discussion as Attachment A.

In the work that Dr. Dunnivant's stakeholder group initiated earlier in the summer of 2016, it was identified that the Department of Behavioral Health and Developmental Services would work with the Board of Pharmacy to obtain controlled substance registrations for each of the community services boards. Receiving a controlled substance registration would enable the community services boards to obtain a DEA registration. Obtaining DEA registration would assist the CSBs in complying with the federal law requirements for telemedicine. It is my understanding that the Department will be able to provide an update on October 26, 2016 on how those discussions are evolving. I also understand from Caroline Juran, the Executive Director of the Board of Pharmacy, that legislation is required to clearly authorize the issuance of

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a controlled substance registration to community services boards. Caroline has prepared the attached draft and has shared it with DBDHS (Attachment B). If you agree to advance this as legislation, I would recommend inclusion of an emergency clause as a second enactment.

The Stakeholders have also discussed the fact that when tele-psychiatry services are provided and the need for prescriptions arise, that the current federal and state laws mean the psychiatrist has to contact the primary care provider with recommendations for them to handle the prescribing or with juvenile patients most often a pediatrician or family physician. The family physicians or pediatricians are being advised by the psychiatrists on what they should prescribe in the way of psychiatric medications, the dosages, and quantity. We have heard from some of the family physicians and pediatricians that they are uncomfortable being put in these situations as they are not as well versed in prescribing these medications as are psychiatrists. Given that, you may want to explore what operational changes (i.e. standing referrals, etc), short of legislation, could be recommended to better navigate the legal requirements.

Thank you in advance for allowing me to share these thoughts for educational purposes. I look forward to working with you and all of the stakeholders on this matter. I want to thank the many stakeholders who have been involved in this process, both with Dr. Dunnivant's stakeholder group and with Work Group 3, for their

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input, guidance, and thoughts. They are the ones that deserve the credit, and I am but the scribe.

Sincerely,



W. Scott Johnson

WSJ/jpr

DM #842908

cc: Tyler S. Cox, Government Affairs Manager
Brittany Olwine, Esquire, Division of Legislative Services
Stakeholders Listed on Dr. Dunnivant' s Email Chain

This letter is intended for educational purposes only and is not legal advice to any person. Any person seeking an opinion or a binding legal interpretation should consult their own counsel.

§ 54.1-3423. Board to issue registration unless inconsistent with public interest; authorization to conduct research; application and fees.

A. The Board shall register an applicant to manufacture or distribute controlled substances included in Schedules I through V unless it determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the Board shall consider the following factors:

1. Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;
2. Compliance with applicable state and local law;
3. Any convictions of the applicant under any federal and state laws relating to any controlled substance;
4. Past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion;
5. Furnishing by the applicant of false or fraudulent material in any application filed under this chapter;
6. Suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law; and
7. Any other factors relevant to and consistent with the public health and safety.

B. Registration under subsection A does not entitle a registrant to manufacture and distribute controlled substances in Schedule I or II other than those specified in the registration.

C. Practitioners must be registered to conduct research with controlled substances in Schedules II through VI. Practitioners registered under federal law to conduct research with Schedule I substances may conduct research with Schedule I substances within this Commonwealth upon furnishing the evidence of that federal registration.

D. The Board may register other persons or entities to possess controlled substances listed on Schedules II through VI upon a determination that (i) there is a documented need, (ii) the issuance of the registration is consistent with the public interest, (iii) the possession and subsequent use of the controlled substances complies with applicable state and federal laws and regulations, and (iv) the subsequent storage, use, and recordkeeping of the controlled substances will be under the general supervision of a licensed pharmacist, practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine as specified in the Board's regulations. The Board shall consider, at a minimum, the factors listed in subsection A of this section in determining whether the registration shall be issued. Notwithstanding the exceptions listed in § 54.1-3422 A, the Board may mandate a controlled substances registration for sites maintaining certain types and quantities of Schedules II through VI controlled substances as it may specify in its regulations. The Board shall promulgate regulations related to requirements or criteria for the issuance of such controlled substances registration, storage, security, supervision, and recordkeeping.

E. The Board may register a public or private animal shelter as defined in § 3.2-6500 to purchase, possess, and administer certain Schedule II-VI controlled substances approved by the State Veterinarian for the purpose of euthanizing injured, sick, homeless, and unwanted domestic pets and animals; and to purchase,

possess, and administer certain Schedule VI controlled substances for the purpose of preventing, controlling, and treating certain communicable diseases that failure to control would result in transmission to the animal population in the shelter. The drugs used for euthanasia shall be administered only in accordance with protocols established by the State Veterinarian and only by persons trained in accordance with instructions by the State Veterinarian. The list of Schedule VI drugs used for treatment and prevention of communicable diseases within the shelter shall be determined by the supervising veterinarian of the shelter and the drugs shall be administered only pursuant to written protocols established or approved by the supervising veterinarian of the shelter and only by persons who have been trained in accordance with instructions established or approved by the supervising veterinarian. The shelter shall maintain a copy of the approved list of drugs, written protocols for administering, and training records of those persons administering drugs on the premises of the shelter.

F. The Board may register a crisis stabilization unit established pursuant to § 37.2-500 or 37.2-601 and licensed by the Department of Behavioral Health and Developmental Services to maintain a stock of Schedule VI controlled substances necessary for immediate treatment of patients admitted to the crisis stabilization unit, which may be accessed and administered by a nurse pursuant to a written or oral order of a prescriber in the absence of a prescriber. Schedule II through Schedule V controlled substances shall only be maintained if so authorized by federal law and Board regulations.

G. Applications for controlled substances registration certificates and renewals thereof shall be made on a form prescribed by the Board and such applications shall be accompanied by a fee in an amount to be determined by the Board.

H. Upon (i) any change in ownership or control of a business, (ii) any change of location of the controlled substances stock, (iii) the termination of authority by or of the person named as the responsible party on a controlled substances registration, or (iv) a change in the supervising practitioner, if applicable, the registrant or responsible party shall immediately surrender the registration. The registrant shall, within 14 days following surrender of a registration, file a new application and, if applicable, name the new responsible party or supervising practitioner.

I. The Board may register other entities wherein a patient is treated via the use of instrumentation and diagnostic equipment for the purpose of establishing a bona fide practitioner-patient relationship and is prescribed Schedule II through VI controlled substances, when such prescribing is in compliance with federal requirements for the practice of telemedicine, and the patient is not in the physical presence of a practitioner registered with the Drug Enforcement Administration. In determining whether the registration shall be issued, the Board shall consider: (i) the factors listed in subsection A of this section; (ii) whether there is a documented need; and (iii) whether the issuance of the registration is consistent with the public interest.

1 § 54.1-3303. Prescriptions to be issued and drugs to be dispensed
2 for medical or therapeutic purposes only.

3 A. A prescription for a controlled substance may be issued only by a practitioner of medicine,
4 osteopathy, podiatry, dentistry or veterinary medicine who is authorized to prescribe controlled
5 substances, or by a licensed nurse practitioner pursuant to § 54.1-2957.01, a licensed physician
6 assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-
7 3222 et seq.) of Chapter 32. The prescription shall be issued for a medicinal or therapeutic
8 purpose and may be issued only to persons or animals with whom the practitioner has a bona fide
9 practitioner-patient relationship.

10 For purposes of this section, a bona fide practitioner-patient-pharmacist relationship is one in
11 which a practitioner prescribes, and a pharmacist dispenses, controlled substances in good faith
12 to his patient for a medicinal or therapeutic purpose within the course of his professional
13 practice. In addition, a bona fide practitioner-patient relationship means that the practitioner shall
14 (i) ensure that a medical or drug history is obtained; (ii) provide information to the patient about
15 the benefits and risks of the drug being prescribed; (iii) perform or have performed an
16 appropriate examination of the patient, either physically or by the use of instrumentation and
17 diagnostic equipment through which images and medical records may be transmitted
18 electronically; except for medical emergencies, the examination of the patient shall have been
19 performed by the practitioner himself, within the group in which he practices, or by a consulting
20 practitioner, prior to issuing a prescription; and (iv) initiate additional interventions and follow-
21 up care, if necessary, especially if a prescribed drug may have serious side effects. **If a**
22 **practitioner is performing or has performed an appropriate examination, either physically**
23 **or by the use of instrumentation and diagnostic equipment for the purpose of establishing a**
24 **bona fide practitioner-patient relationship, he may prescribe Schedule II through VI**
25 **controlled substances, provided the prescribing of Schedule II through V is in compliance**
26 **with federal requirements for the practice of telemedicine.**

27 For the purpose of prescribing a Schedule VI controlled substance to a patient via telemedicine
28 services as defined in § 38.2-3418.16, a prescriber may establish a bona fide practitioner-patient
29 relationship by an examination through face-to-face interactive, two-way, real-time
30 communications services or store-and-forward technologies when all of the following conditions
31 are met: (a) the patient has provided a medical history that is available for review by the
32 prescriber; (b) the prescriber obtains an updated medical history at the time of prescribing; (c)
33 the prescriber makes a diagnosis at the time of prescribing; (d) the prescriber conforms to the
34 standard of care expected of in-person care as appropriate to the patient's age and presenting
35 condition, including when the standard of care requires the use of diagnostic testing and

36 performance of a physical examination, which may be carried out through the use of peripheral
37 devices appropriate to the patient's condition; (e) the prescriber is actively licensed in the
38 Commonwealth and authorized to prescribe; (f) if the patient is a member or enrollee of a health
39 plan or carrier, the prescriber has been credentialed by the health plan or carrier as a participating
40 provider and the diagnosing and prescribing meets the qualifications for reimbursement by the
41 health plan or carrier pursuant to § ~~38.2-341~~~~3.16~~; and (g) upon request, the prescriber provides
42 patient records in a timely manner in accordance with the provisions of § ~~32.1-127.1:03~~ and all
43 other state and federal laws and regulations. Nothing in this paragraph shall permit a prescriber
44 to establish a bona fide practitioner-patient relationship for the purpose of prescribing a Schedule
45 VI controlled substance when the standard of care dictates that an in-person physical
46 examination is necessary for diagnosis. Nothing in this paragraph shall apply to: (1) a prescriber
47 providing on-call coverage per an agreement with another prescriber or his prescriber's
48 professional entity or employer; (2) a prescriber consulting with another prescriber regarding a
49 patient's care; or (3) orders of prescribers for hospital out-patients or in-patients.

50 Any practitioner who prescribes any controlled substance with the knowledge that the controlled
51 substance will be used otherwise than medicinally or for therapeutic purposes shall be subject to
52 the criminal penalties provided in § ~~18.2-248~~ for violations of the provisions of law relating to
53 the distribution or possession of controlled substances.

54 B. In order to determine whether a prescription that appears questionable to the pharmacist
55 results from a bona fide practitioner-patient relationship, the pharmacist shall contact the
56 prescribing practitioner or his agent and verify the identity of the patient and name and quantity
57 of the drug prescribed. The person knowingly filling an invalid prescription shall be subject to
58 the criminal penalties provided in § ~~18.2-248~~ for violations of the provisions of law relating to
59 the sale, distribution or possession of controlled substances.

60 No prescription shall be filled unless there is a bona fide practitioner-patient-pharmacist
61 relationship. A prescription not issued in the usual course of treatment or for authorized research
62 is not a valid prescription.

63 C. Notwithstanding any provision of law to the contrary and consistent with recommendations of
64 the Centers for Disease Control and Prevention or the Department of Health, a practitioner may
65 prescribe Schedule VI antibiotics and antiviral agents to other persons in close contact with a
66 diagnosed patient when (i) the practitioner meets all requirements of a bona fide practitioner-
67 patient relationship, as defined in subsection A, with the diagnosed patient; (ii) in the
68 practitioner's professional judgment, the practitioner deems there is urgency to begin treatment to
69 prevent the transmission of a communicable disease; (iii) the practitioner has met all
70 requirements of a bona fide practitioner-patient relationship, as defined in subsection A, for the

71 close contact except for the physical examination required in clause (iii) of subsection A; and
72 (iv) when such emergency treatment is necessary to prevent imminent risk of death, life-
73 threatening illness, or serious disability.

74 D. A pharmacist may dispense a controlled substance pursuant to a prescription of an out-of-state
75 practitioner of medicine, osteopathy, podiatry, dentistry, ~~or~~ veterinary medicine, optometrist,
76 nurse practitioner, or physician assistant authorized to issue such prescription if the
77 prescription complies with the requirements of this chapter and the Drug Control Act (§ ~~34.1-~~
78 ~~3400~~ et seq.).

79 E. A licensed nurse practitioner who is authorized to prescribe controlled substances pursuant to
80 § ~~54.1-2957.01~~ may issue prescriptions or provide manufacturers' professional samples for
81 controlled substances and devices as set forth in the Drug Control Act (§ ~~54.1-3400~~ et seq.) in
82 good faith to his patient for a medicinal or therapeutic purpose within the scope of his
83 professional practice.

84 F. A licensed physician assistant who is authorized to prescribe controlled substances pursuant to
85 § ~~54.1-2952.1~~ may issue prescriptions or provide manufacturers' professional samples for
86 controlled substances and devices as set forth in the Drug Control Act (§ ~~54.1-3400~~ et seq.) in
87 good faith to his patient for a medicinal or therapeutic purpose within the scope of his
88 professional practice.

89 G. A TPA-certified optometrist who is authorized to prescribe controlled substances pursuant to
90 Article 5 (§ ~~54.1-3222~~ et seq.) of Chapter 32 may issue prescriptions in good faith or provide
91 manufacturers' professional samples to his patients for medicinal or therapeutic purposes within
92 the scope of his professional practice for the drugs specified on the TPA-Formulary, established
93 pursuant to § ~~54.1-3223~~, which shall be limited to (i) analgesics included on Schedule II
94 controlled substances as defined in § ~~54.1-3448~~ of the Drug Control Act (§ ~~54.1-3400~~ et seq.)
95 consisting of hydrocodone in combination with acetaminophen; (ii) oral analgesics included in
96 Schedules III through VI, as defined in §§ ~~54.1-3450~~ and ~~54.1-3455~~ of the Drug Control Act (§
97 ~~54.1-3400~~ et seq.), which are appropriate to relieve ocular pain; (iii) other oral Schedule VI
98 controlled substances, as defined in § ~~54.1-3455~~ of the Drug Control Act, appropriate to treat
99 diseases and abnormal conditions of the human eye and its adnexa; (iv) topically applied
100 Schedule VI drugs, as defined in § ~~54.1-3455~~ of the Drug Control Act; and (v) intramuscular
101 administration of epinephrine for treatment of emergency cases of anaphylactic shock.

102 H. The requirement for a bona fide practitioner-patient relationship shall be deemed to be
103 satisfied by a member or committee of a hospital's medical staff when approving a standing order

104 or protocol for the administration of influenza vaccinations and pneumococcal vaccinations in a
105 hospital in compliance with § 32.1-126.4.

106 DM # 827249