

# THE RYAN HAIGHT ONLINE PHARMACY CONSUMER PROTECTION ACT OF 2008

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Many medical professional are concerned about the impact of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (H.R. 6453) (the “Act”)<sup>1</sup> on their pharmacy’s or medical clinic’s business practices. The Act amends various provisions of the Federal Controlled Substances Act (the “CSA”).<sup>2</sup> The Act was signed into law by President Bush on October 15, 2008. By its terms, the most pertinent provisions of the Act<sup>3</sup> take effect on April 13, 2009 (180 days after the Act’s enactment). Like many similar attempts by the Federal Government to regulate and/or restrict business practices, the scope of the Act can be construed as much broader than what the title of the Act suggests is the intended purpose, while at the same time presenting a few major loopholes in the regulatory scheme, some of which are sure to be closed over time.

The Act’s overall scheme and terminology are quite confusing, and I have tried to reorganize the provisions and analysis below in a manner which makes better sense as to how this Act is supposed to work.

While most medical professionals would assume from the title of the Act that the Act only applies to those “rogue Internet pharmacies” that the Federal government has been complaining about over the past eight years (and certainly the Act was sold on this basis by the Act’s sponsors), the scope of the Act is undoubtedly much broader, affecting the practices of medical professionals who may or may not have incorporated some aspects of telemedicine in their medical practices, yet are not remotely connected to traditional Internet pharmacy. The Act may fundamentally change the way many medical professionals currently do business, intentionally or unintentionally restricting practices and procedures (discussed below) which few health care professionals would find objectionable.

## **New In-Person Medical Evaluation Requirement**

The most fundamental change of the Act is the requirement in most cases that an in-person medical evaluation be performed at some point by the prescribing physician prior to the writing of the first prescription for a controlled substance if the Internet is used (pretty much in any manner). In this regard, the Act provides that:

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<sup>1</sup> Specifically, 21 U.S.C. Sections 802, 823, 827, 829, 841, 843 and 882 of the CSA were amended and Section 831 of the CSA was added. Also, Section 21 U.S.C. 960 of the Controlled Substances Import and Export Act was amended.

<sup>2</sup> Note: This memo does not incorporate changes made in connection with regulations promulgated under the Ryan Haight Act after the date of the drafting of this Memo.

<sup>3</sup> Other than the temporary telemedicine standards described below.

**(1) No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.**

**(2) As used in this subsection:**

**(A) The term “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 at least 1 in-person medical evaluation of the patient; or**

**(ii) a covering practitioner.**

**(B) (i) The term “in-person medical evaluation” means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.**

**(ii) Nothing in clause (i) shall be construed to imply that 1 in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.**

**(C) The term “covering practitioner” means, with respect to a patient, a practitioner who conducts a medical evaluation (other than an in-person medical 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 unavailable to conduct the evaluation of the patient.**

**(3) Nothing in this subsection shall apply to--**

**(A) the delivery, distribution, or dispensing of a controlled substance by a practitioner engaged in the practice of telemedicine; or**

**(B) the dispensing or selling of a controlled substance pursuant to practices as determined by the Attorney General by regulation, which shall be consistent with effective controls against diversion.<sup>4</sup>**

These new additions to the CSA establish a new, heightened national standard for prescribing of controlled substances. Prior to the Act’s enactment, the Federal Government (particularly, the Drug Enforcement Administration) was to a large degree restricted from

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<sup>4</sup> These provisions were newly added to 21 U.S.C. 829 (a/k/a Section 309 of the CSA) as a subsection (e).

promulgating its own detailed prescribing standards for controlled substances or other prescription medication. Instead, the Federal Government's publications to date concerning what constituted appropriate prescribing procedures for Federal law purposes were those procedures deemed acceptable in the particular state in which the medical practitioner practices (or potentially in those states in which the patient resides if the patient's state of residence is different from that where the practitioner is located).

For the first time the Act imposed a face-to-face physical examination requirement by the prescribing doctor (or other prescribing medical practitioner). The face-to-face physical examination needs to be conducted prior to the first prescription. No longer can a physician rely upon another doctor or other medical professional's in-person physical examination in the course of writing a prescription for a controlled substance. Thus, Medical Records Based Prescribing shall become illegal in all fifty states when the Act takes effect.

Intriguingly, Sections 829(e)(2) and 829(e)(3)(A) specifically allow a doctor to treat patients via "the practice of telemedicine" directly or on a consulting doctor basis without violating the Act.

#### **Meaning of Terms: "Covering Practitioner" and "Practice of Telemedicine"**

Again, the Act defines the term "covering practitioner" as follows:

**(C) The term "covering practitioner" means, with respect to a patient, a practitioner who conducts a medical evaluation (other than an in-person medical 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 unavailable to conduct the evaluation of the patient.**

The Act creates an exception for a prescription written by a "covering practitioner" who need not conduct an in-person physical examination of the patient in the course of prescribing a controlled substance for that patient. The Act provides that the covering practitioner needs to be invited by the patient's doctor (the "**Treating Doctor**") to treat the patient. The Treating Doctor must have initially conducted an in-person medical evaluation "*or an evaluation of the patient through the practice of telemedicine within the previous 24 months.*" While this might appear to be a major loophole to the face to face requirement, the definition of the term "telemedicine" in the Act is quite narrow and is different than what is ordinarily meant by such term.

It would appear that the "covering practitioner" rules, the statement in the Act that "Nothing in this subsection shall apply to-- (A) the delivery, distribution, or dispensing of a controlled substance by a practitioner engaged in the practice of telemedicine..." and the interim telemedicine rules discussed below indicate that no in-person medical evaluation is required for physicians who prescribe controlled substances in accordance with the "practice of telemedicine" as defined in the Act. This conclusion is not really all that clear from the Act, but this would be a reasonable reading of the Act.

The Act defines "practice of telemedicine" as follows:

**Section 802(a)(54) The term “practice of telemedicine” means ... the practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1834(m) of the Social Security Act,<sup>5</sup> which practice--**

**(A) is being conducted--**

**(i) while the patient is being treated by, and physically located in, a hospital or clinic registered under section 303(f);<sup>6</sup> and**

**(ii) by a practitioner--**

**(I) acting in the usual course of professional practice;**

**(II) acting in accordance with applicable State law; and**

**(III) registered under section 303(f) in the State in which the patient is located, unless the practitioner--**

**(aa) is exempted from such registration in all States under section 302(d);<sup>7</sup> or**

**(bb) is--**

**(AA) an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract; and**

**(BB) registered under section 303(f) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);**

**(B) is being conducted while the patient is being treated by, and in the physical presence of, a practitioner--**

**(i) acting in the usual course of professional practice;**

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<sup>5</sup> This Section of the Social Security Act relates to reimbursement for telehealth services by the Federal Government for Medicare enrollees receiving remote medical treatment from their medical practitioner. The section does describe in any real degree particular types of telecommunications technology or systems.

<sup>6</sup> Section 303(f) of the CSA (a/ka 21 U.S.C. 823(f)) refers to DEA licensing of practitioners and pharmacies to dispense controlled substances.

<sup>7</sup> Section 302(d) of the CSA (a/ka 21 U.S.C. 822(d)) refers to manufacturers, distributors, or dispensers that the U.S. Attorney General determines by regulation do not need to obtain a DEA license after a finding that such lack of registration is consistent with the public health and safety.

**(ii) acting in accordance with applicable State law; and**

**(iii) registered under section 303(f) in the State in which the patient is located, unless the practitioner--**

**(I) is exempted from such registration in all States under section 302(d); or**

**(II) is--**

**(aa) an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract; and**

**(bb) registered under section 303(f) in any State or is using the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);**

**(C) is being conducted by a practitioner--**

**(i) who is an employee or contractor of the Indian Health Service, or is working for an Indian tribe or tribal organization under its contract or compact with the Indian Health Service under the Indian Self-Determination and Education Assistance Act;**

**(ii) acting within the scope of the employment, contract, or compact described in clause (i); and**

**(iii) who is designated as an Internet Eligible Controlled Substances Provider by the Secretary under section 311(g)(2);**

**(D) (i) is being conducted during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act; and**

**(ii) involves patients located in such areas, and such controlled substances, as the Secretary, with the concurrence of the Attorney General, designates, provided that such designation shall not be subject to the procedures prescribed by subchapter II of chapter 5 of title 5, United States Code;**

**(E) is being conducted by a practitioner who has obtained from the Attorney General a special registration under section 311(h);**

**(F) is being conducted--**

**(i) in a medical emergency situation--**

**(I) that prevents the patient from being in the physical presence of a practitioner registered under section 303(f) who is an employee or contractor of the Veterans Health Administration acting in the usual course of business and employment and within the scope of the official duties or contract of that employee or contractor;**

**(II) that prevents the patient from being physically present at a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);**

**(III) during which the primary care practitioner of the patient or a practitioner otherwise practicing telemedicine within the meaning of this paragraph is unable to provide care or consultation; and**

**(IV) that requires immediate intervention by a health care practitioner using controlled substances to prevent what the practitioner reasonably believes in good faith will be imminent and serious clinical consequences, such as further injury or death; and**

**(ii) by a practitioner that--**

**(I) is an employee or contractor of the Veterans Health Administration acting within the scope of that employment or contract;**

**(II) is registered under section 303(f) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f); and**

**(III) issues a controlled substance prescription in this emergency context that is limited to a maximum of a 5-day supply which may not be extended or refilled; or**

**(G) is being conducted under any other circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.**

What this all means is that pursuant to subpart A above, “telemedicine” means remote treatment of a patient *while the patient is physically present at a DEA registered clinic or hospital facility*, by a practitioner with a DEA license, acting in full compliance with state law, *and with a DEA registered office in the state in which the patient is then located*. An exception to the requirement that the practitioner have in place an in-state DEA registered office exists for practitioners working through the VA. This definition of the practice of telemedicine would allow a physician to remotely treat patients within the physician’s own state (or another state in which the physician maintains a second DEA registered office) so long as the patient was at the time physically present in a hospital, rural clinic or the like.

Pursuant to subpart B above, “telemedicine” also means remote treatment of a patient occurring *while the patient is physically present with the practitioner*, when such practitioner has a DEA license, is acting in full compliance with state law, *and has a DEA registered office in the state in which the patient is then located*. Again, an exception to the requirement that the practitioner have in place an in-state DEA registered office exists for practitioners working through the VA. Presumably this definition would apply to situations in which a local practitioner uses telemedicine in connection with a remote expert’s assessment of the patient. Alternatively, in states in which a physician’s assistant or other health care professional can prescribe controlled substances and obtain a DEA license, the PA could consult in real time with a supervising physician while the patient was with the PA to obtain a prescription (perhaps for more powerful narcotics than the PA could prescribe).

Pursuant to subpart C above, “telemedicine” also means remote treatment of a patient by practitioners while under the employ of the Indian Health Service acting within the scope of such employment and holding a special certification from the Federal Government.

Pursuant to subpart D above, “telemedicine” also means remote treatment of a patient during a public emergency declared by the Federal Government involving patients within the emergency areas.

Pursuant to subpart E above, “telemedicine” also means remote treatment of a patient by a practitioner who has been registered as a telemedicine practitioner by the U.S. Attorney General. This registration process is a new one created by the Act. It entails the practitioner only treating patients within the same state in which the practitioner has a DEA registered office and showing a special need for telemedicine treatment. An exemption exists from the in-state office requirement for VA practitioners. This exception could be utilized, for example, by a physician who regularly treats a widely dispersed group of rural patients, or a specialist treating patients throughout the state who do not have access to a local physician with the same skills.

Pursuant to subpart F above, “telemedicine” also means remote treatment of a patient by a practitioner in a medical emergency situation that prevents the practitioner from being in the physical presence of the patient. This exception is limited to VA employed/contractors and their patients in such programs.

Pursuant to subpart G above, the U.S. Attorney General and the Secretary can jointly decide to exempt additional activities by regulation.

For most medical professionals, subparts A and B provide the only exemptions with which they might be able to work. Subparts A and B allow for a variety of telemedicine arrangements, with the common denominator being real time, coordinated treatment of a patient while either in the physical presence of at least one DEA licensed practitioner or while the patient is physically present at a DEA registered hospital or clinic being treated remotely by a DEA registered practitioner. Staggering the treatment time-wise (as is the case with Medical Records Based Prescribing) does not work to meet these exemptions.

It is important to note that the “telemedicine” definitions apply in the context of a “consulting practitioner” to the requirement that a physical examination be performed within the prior 24-month period by or under the telemedicine-based supervision of the Treating Doctor. In this respect, subpart A might be used for a Miami Treating Doctor to treat a patient in Tallahassee who has been examined at a local clinic in the patient’s neighborhood by a physician’s assistant

with a supervisory relationship with the Treating Doctor. This should qualify under subpart A as the appropriate practice of telemedicine.

However, the referral of the Treating Doctor to the consulting practitioner is limited by the Act to situations in which the Treating Doctor is “*temporarily unavailable to conduct the evaluation of the patient.*” The use of the terms “temporarily unavailable” indicates that a routine practice of using Treating Doctors to conduct the initial in-person examination, followed thereafter by a referral of the patient by the Treating Doctor to the consulting doctor and continuous treatment of the patient by the consulting physician (with periodic bi-annual patient evaluations by the Treating Doctor) would be unlawful. The Treating Doctor could not reasonably be characterized as “temporarily unavailable to conduct the evaluation of the patient.”

The Act does not provide an exception for the Treating Doctor’s requirement that he perform at least one in-person medical evaluation of the patient (at least when a consulting doctor later writes a prescription based upon a referral from the Treating Doctor). Notably, there is no 24 month expiration date on such physical examination/medical evaluation if the Treating Doctor is writing the prescription rather than the covering physician.

This “temporarily unavailable” focus means that it is likely unlawful to engage a consulting physician with special expertise to treat a patient’s condition if the consulting physician is expected to write prescriptions for controlled substances for the patient as part of the treatment regimen (although the Treating Doctor could instead write the prescriptions without running afoul of the Act). Also, the use of PAs and ANPs to conduct a physical examination of the patient outside of the supervising doctor’s presence would also be unlawful.

Doctors at this point might exclaim: “But such practices clearly are not ‘Online Pharmacy’ -- such conduct clearly is not covered by an Act which is designed to combat those ‘Rogue Internet Pharmacy’ operators!” Nevertheless, prohibition of such specialist referrals and such use of PAs and ANPs appears to soon become the law of the land.

### **Dispensing by means of the Internet**

Again, Section 829(e)(1) of the CSA has been amended by the Act to provide that:

**(1) No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.**

Section 802(a) of the CSA has been amended by the Act to provide as follows:

**(50) The term ‘Internet’ means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected worldwide network of networks that employ the Transmission Control Protocol/Internet Protocol, or any predecessor or successor protocol to such protocol, to communicate information of all kinds by wire or radio.**

The question has arisen as to what this means. The short answer is that in addition the general understanding of Internet use (*i.e.*, searching the wide world web to locate and interact with websites), the Act’s use of the term picks up a much broader range of activities, including e-

mail transmissions and Blackberry and other PDA technologies that utilize the “Transmission Control Protocol/Internet Protocol.”

Thus surprisingly, any time that a physician utilizes e-mail or other electronic data transfer in connection with the filling or dispensing of a prescription, including billing for the prescription using this manner of communication or transmitting prescription data from the physician to the pharmacy for dispensing of a controlled substance, the Act is brought into play. The definition is not limited to use of a website to market pharmacy or medical services to patients (note that a doctor’s use of a website to advertise in a general manner his clinic could bring the Act into play) or e-mailed or web camera communications between the physician and patient.

A major loophole to the Act’s coverage exists with respect to Medical Records Based Prescribing which avoids entirely the use of the Internet or e-mail and instead relies upon telephonic consults and faxed transmission of prescriptions and medical records and/or transmission of such paperwork via the mail. While it might be difficult to totally cut out modern technology from a doctor’s prescribing practices, some physicians and pharmacies might decide that it still makes sense to do so in order to continue serving existing patient groups via telemedicine means.

#### **Expansive Coverage of Act to Website Operators and Indirect Players**

There are a variety of sponsors of Internet websites who prey upon pharmacies and physicians who are unfamiliar with Federal and local prescribing laws, knowing that in the past the regulators found it easy to prosecute or discipline the medical professionals but struggled with legal theories to employ against the promoters of these illegal prescribing schemes. The Act now provides a direct path for Federal prosecutors to hold such website operators personally responsible for illegal prescribing activities. For example, Section 802(a) of the CSA has been amended by the Act to provide that:

**(51) The term “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.**

**(52) The term “online pharmacy”—**

**(A) means a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet...**

Under these two definitions (particularly use of the term “facilitated”), not only the doctors, pharmacists and pharmacies, but also website operators, merchant account processors, wholesalers, computer software vendors, physicians assistants and other participants in a controlled substance distribution network would likely be swept into a prosecution for illegal Internet pharmacy activity as defined in the Act.

#### **Online Pharmacies**

Various outfits, individuals and activities are excluded from the definition of “online pharmacies” (meaning that they do not need to register with the Federal Government as such in

accordance with the Act), including DEA registered drug wholesalers (under most circumstances), non-pharmacy DEA registered medical practitioners, hospitals and medical facilities operated by the U.S. Government, health care facilities operated by Indian tribes, mere advertisements that do not attempt to facilitate the delivery, distribution or dispensing of a controlled substance via the Internet, and persons or entities located outside the U.S. who do not dispense, etc. controlled substances via the Internet to any person in the U.S.

Furthermore, an exclusion from the definition of “online pharmacy” exists for those pharmacies registered with the DEA whose dispensing of controlled substances via the Internet consists solely of: (a) refilling prescriptions for Schedules III through V controlled substances or (b) filling new prescriptions for Schedules III through V controlled substances. Under this exemption, a pharmacy can take in electronic prescriptions via the Internet, but might not be allowed to enter into special arrangements with doctors to fill prescriptions using telemedicine prescribing procedures or send or receive patients’ medical records via e-mail or other Internet means. The meaning of this exemption nevertheless seems unclear.

Section 802(a) of the CSA has been amended by the Act to clarify this pharmacy exemption from the “online pharmacy” disclosure requirements by providing that:

**(55) The term “refilling prescriptions for controlled substances in schedule III, IV, or V”—**

**(A) means the dispensing of a controlled substance in schedule III, IV, or V in accordance with refill instructions issued by a practitioner as part of a valid prescription that meets the requirements of subsections (b) and (c) of section 309,<sup>8</sup> as appropriate; and**

**(B) does not include the issuance of a new prescription to an individual for a controlled substance that individual was previously prescribed.**

**(56) The term “filling new prescriptions for controlled substances in schedule III, IV, or V” means filling a prescription for an individual for a controlled substance in schedule III, IV, or V, if—**

**(A) the pharmacy dispensing that prescription has previously dispensed to the patient a controlled substance other than by means of the Internet and pursuant to the valid prescription of a practitioner that meets the applicable requirements of subsections (b) and (c) of section 309<sup>9</sup> (in this paragraph referred to as the “original prescription”);**

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<sup>8</sup> Section 829(b) and (c) discussed above.

<sup>9</sup> This Section is also known as 21 U.S.C. 829 of the CSA (entitled “Prescriptions”), other provisions of which were amended by the Act as discussed above. Subsections (b) and (c) thereof, which were not amended by the Act, provide as follows:

Schedule III and IV substances

(b) Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug

**(B) the pharmacy contacts the practitioner who issued the original prescription at the request of that individual to determine whether the practitioner will authorize the issuance of a new prescription for that individual for the controlled substance described in subparagraph (A); and**

**(C) the practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription.**

As a rule of construction, the Act provides that:

**Nothing in this Act or the amendments made by this Act shall be construed as authorizing, prohibiting, or limiting the use of electronic prescriptions for controlled substances.**

Thus the use of electronic prescriptions for controlled substances will not standing alone cause the Act to become applicable.

Online pharmacies as defined in the Act are required to post on the online pharmacy's website's homepage (and/or a direct link thereto) the following:

- A statement that the pharmacy complies with Section 831 of the CSA.
- The name and address of the pharmacy as it appears on the pharmacy's DEA certificate of registration.
- The pharmacy's telephone number and email address.
- The name, professional degree, and States of licensure of the pharmacist-in-charge, and a telephone number at which the pharmacist-in-charge can be contacted.
- A list of the States in which the pharmacy is licensed to dispense controlled substances.
- A certification that the pharmacy is registered under this part to deliver, distribute, or dispense by means of the Internet controlled substances.

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as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

Schedule V substances

(c) No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

- The name, address, telephone number, professional degree, and States of licensure of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the website or at the request of the owner or operator of the website, or any employee or agent thereof.
- The following statement, unless revised by the Attorney General by regulation: “This online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation or medical evaluation via telemedicine in accordance with applicable requirements of section 309.”<sup>10</sup>

A violation by the pharmacy of a state law is deemed a violation of the CSA.<sup>11</sup>

Online pharmacies are required to notify the U.S. Attorney General’s office at least 30 days prior to offering a controlled substance for sale or delivery, etc. and notify in advance the state boards of pharmacy in all states in which the pharmacy intends to deliver controlled substances.<sup>12</sup>

Furthermore, online pharmacies are required to report monthly sales of controlled substances to the U.S. Attorney General’s office, provided that no such reporting need occur unless such monthly sales equate to either 100 or more prescriptions per month or 5,000 dosage units of all controlled substances combined.<sup>13</sup>

It is very unclear when pharmacies will be deemed to have crossed the line between having a web presence and accepting electronic prescriptions for initial filling or refilling, and conducting additional “Internet related activities” which place the pharmacy in the category of the highly regulated “online pharmacies.”

### **Increased Criminal Penalties, Criminal Violations and Other Government Remedies**

The Act further amended the CSA by increasing the criminal penalties for selling Schedule III controlled substances from five to not more than 10 years imprisonment (15 years if the drug causes death or serious bodily injury). Fines for the same were increased to up to \$500,000 for individuals and \$2,500,000 for entities. Second offence penalties were also increased substantially.<sup>14</sup>

The Act criminalizes the following behaviors:

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<sup>10</sup> 21 U.S.C. Section 839(a) and (c).

<sup>11</sup> 21 U.S.C. Section 839(b).

<sup>12</sup> 21 U.S.C. Section 839(d).

<sup>13</sup> 21 U.S.C. Section 802(c)(2).

<sup>14</sup> 21 U.S.C. Section 831(e)(1)(E).

To ...**(1)...knowingly or intentionally--**

**(A) deliver, distribute, or dispense a controlled substance by means of the Internet, except as authorized by this title; or**

**(B) aid or abet (as such terms are used in section 2 of title 18, United States Code) any activity described in subparagraph (A) that is not authorized by this title.**

**(2) EXAMPLES- Examples of activities that violate paragraph (1) include, but are not limited to, knowingly or intentionally--**

**(A) delivering, distributing, or dispensing a controlled substance by means of the Internet by an online pharmacy that is not validly registered with a modification authorizing such activity as required by section 303(f)<sup>15</sup> (unless exempt from such registration);**

**(B) writing a prescription for a controlled substance for the purpose of delivery, distribution, or dispensation by means of the Internet in violation of section 309(e);<sup>16</sup>**

**(C) serving as an agent, intermediary, or other entity that causes the Internet to be used to bring together a buyer and seller to engage in the dispensing of a controlled substance in a manner not authorized by sections 303(f) or 309(e);**

**(D) offering to fill a prescription for a controlled substance based solely on a consumer's completion of an online medical questionnaire; and**

**(E) making a material false, fictitious, or fraudulent statement or representation in a notification or declaration under subsection (d) or (e), respectively, of section 311.<sup>17</sup>**

The Act further provides that:

**(2) (A) It shall be unlawful for any person to knowingly or intentionally use the Internet, or cause the Internet to be used, to advertise the sale of, or to offer to sell, distribute, or dispense, a controlled substance where such sale, distribution, or dispensing is not authorized by this title or by the Controlled Substances Import and Export Act.**

**(B) Examples of activities that violate subparagraph (A) include, but are not limited to, knowingly or intentionally causing the placement on the Internet of an advertisement that refers to or directs prospective buyers to Internet sellers of**

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<sup>15</sup> 21 U.S.C. Section 823(f) refers to DEA licensing of practitioners and pharmacies to dispense controlled substances (irrespective of the use of the Internet or other aspects of Internet pharmacy).

<sup>16</sup> 21 U.S.C. Section 829 (which addresses the in-person medical evaluation requirements discussed above).

<sup>17</sup> 21 U.S.C. Section 831 (containing the online pharmacy notice and disclosure requirements discussed above).

**controlled substances who are not registered with a modification under section 303(f).**

**(C) Subparagraph (A) does not apply to material that either--**

**(i) merely advertises the distribution of controlled substances by nonpractitioners to the extent authorized by their registration under this title; or**

**(ii) merely advocates the use of a controlled substance or includes pricing information without attempting to facilitate an actual transaction involving a controlled substance**

The Act provides that individual states can bring action against and enjoin the activities of those persons or entities violating the CSA's provisions with respect to activities harming the residents of their states.<sup>18</sup> Venue lies in any jurisdiction in which the individual or entity conducts business.

### **Conclusions**

The Act, while widely perceived as stamping out the use of telemedicine in the course of prescribing controlled substances, still leaves open a few avenues worth considering – namely, avoiding use of the Internet, structuring the physical examination to comply with the Act's long-term version of the "practice of telemedicine" rules and/or continuing to use Medical Records Based Prescribing methods during the interim "practice of telemedicine" rules, although using heightened telecommunications technology during this period.

Compliance with the Act's provisions as indicated in the preceding paragraph might immunize telemedicine prescribing businesses beyond the status quo immediately prior to the effective date of the Act.

An argument could be made that the comprehensive regulation of prescribing standards by the Federal Government preempts inconsistent State laws relating to prescribing standards. Time will tell if this is determined to be the case. If so, the Act could inadvertently expand telemedicine based prescribing (both with respect to controlled substances and non-controlled) far beyond what is allowable under the current state and Federal regulatory scheme.

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<sup>18</sup> 21 U.S.C. Section 882(c).