PREScribing CONTROLLED SUBSTANCES VIA TELEMEDICINE

Donna Vanderpool, MBA, JD
Vice President, Risk Management
Professional Risk Management Services, Inc.

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DONNA VANDERPOOL, MBA, JD
TELEMEDICINE

• Treating patients remotely, typically through videoconferencing
  • Physician and patient are in different locations
Only four things are clear...
KEY POINT #1

Treatment is rendered where the patient is physically located.
WHERE ARE TELEMEDICINE SERVICES RENDERED?

From the boards:

• NY: “It is the location of the patient that defines where the care has been delivered and the jurisdiction of applicable regulations”

• SC: “The Board adheres to the view that the practice of medicine occurs where the patient is physically located”
KEY POINT #2

Physicians must comply with all relevant requirements of all relevant states.
FROM THE PENNSYLVANIA MEDICAL BOARD

“Physicians should keep in mind that when they are prescribing across state lines, they are practicing in at least two jurisdictions and they are subject to regulation and discipline in all jurisdictions involved.”
KEY POINT #3

Utilizing telemedicine does not alter the standard of care to which the physician will be held – it is the same standard of care that would apply if the patient was in the physician’s office or facility.
From the Maryland Medical Board – MD Admin. Code §10.32.05.07 **Physician Discipline:**

“The Board shall use the same standards in evaluating and investigating a complaint and disciplining a licensee who practices telemedicine as it would use for a licensee who does not use telemedicine in the licensee’s practice.”
From the Medical Board of California:

“The standard of care is the same whether the patient is seen in-person, through telemedicine or other methods of electronically enabled health care.”

“In summary, the law governs the practice of medicine, and no matter how communication is performed, the standards are no more or less...Physicians practicing via telemedicine are held to the same standard of care, and retain the same responsibilities of providing informed consent, ensuring the privacy of medical information, and any other duties associated with practicing medicine.”

KEY POINT #4

There is no consistency in telemedicine rules – not between the states, and not between state and federal law
STATE LICENSURE REQUIREMENTS

• Varies by state
  › Full license
  › Special purpose / telemedicine license
  › Just registration

• Can be exceptions
TYPICAL TOPICS ADDRESSED IN TELEMEDICINE LAWS

- Informed consent
- Medical records
- Confidentiality and security
- Physician-patient relationship
- Follow-up care
- Verification of patient’s identity
- Etc.
“On the Internet, nobody knows you’re a dog.”
INTERNET PRESCRIBING

• Internet prescribing based solely on online questionnaire
  › *Hageseth* case (150 Cal.App.4th 1399):
    • CO MD pled no contest to **felony** charge of unlawful practice of medicine in CA; sentenced to nine months in jail
    • Civil case against MD was dropped
INTERNET PRESCRIBING

• Internet prescribing based solely on online questionnaire
  › States specifically proscribe
FEDERAL REGULATION OF INTERNET PRESCRIBING

• Controlled Substances Act
  › Amended in 2008 by the Ryan Haight Online Pharmacy Protection Act - 21 USC § 829(e)(3)
Internet prescribing ≠ telemedicine
IN-PERSON EXAMINATION / FACE-TO-FACE REQUIREMENT

• Federal law (Ryan Haight Act)
• State law – no uniformity
  › Some boards do not address it
  › Some boards say in-person exam is not required
  › Some boards say it depends
    • On where patient is located
    • On prescribing
Regulation 10.32.05.05 Patient Evaluation

A. A physician shall perform a patient evaluation to establish diagnoses and identify underlying conditions or contraindications to recommended treatment options before providing treatment or prescribing medication.

B. A Maryland-licensed physician may rely on a patient evaluation performed by another Maryland-licensed physician if one physician is providing coverage for the other physician.

C. If a physician-patient relationship does not include prior in-person, face-to-face interaction with a patient, the physician shall incorporate real-time auditory communications or real-time visual and auditory communications to allow a free exchange of information between the patient and the physician performing the patient evaluation.
Telemedicine

Telemedicine has a place in the practice of medicine. Telemedicine is a tool which should enhance efforts to achieve optimal health outcomes for patients.

Telemedicine is defined very generally as the delivery of healthcare where there is no in-person exchange. Telemedicine, more specifically, is a mode of delivering healthcare services and public health utilizing information and communication technologies to enable the diagnosis, consultation, treatment, education, care management, and self-management of patients at a distance from health care providers.

What Healthcare Providers Should Do

Evaluation of the Patient

Evaluating a patient via Telemedicine or in-person is a dynamic, interactive experience which should conclude with a customized care plan for the patient relevant to the chief complaint. A documented patient evaluation, including history and physical evaluation adequate to establish diagnoses and identify underlying conditions and/or contra-indications to the treatment recommended and/or provided, must be obtained prior to providing treatment, including issuing prescriptions, electronically or otherwise. Physical evaluation means using the tools and resources available utilizing telemedicine and the internet appropriately to come to a reasonable diagnostic conclusion. It is understood that a physical evaluation done via Telemedicine or the internet is inherently different than in the traditional in-person encounter.

Treatment

Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in face-to-face settings. Treatment, including issuing a prescription, based solely on an online questionnaire without an appropriate evaluation does not constitute an acceptable standard of care and is considered unprofessional conduct. The BMLD specifically highlights that prescribing controlled substances without an established in-person physician-patient relationship is prohibited. (Exception* a covering physician may prescribe a controlled substance if an established coverage agreement is in place and the quantity reflects the prescription is for a short duration)
329:1-d Teledicine.—

I. "Teledicine" means the use of audio, video, or other electronic media for the purpose of diagnosis, consultation, or treatment. "Teledicine" shall not include the use of audio-only telephone or facsimile.

II. An out-of-state physician providing services by means of teledicine shall be deemed to be in the practice of medicine and shall be required to be licensed under this chapter. This paragraph shall not apply to out-of-state physicians who provide consultation services pursuant to RSA 329:21, II.

III. It shall be unlawful for any person to prescribe by means of teledicine a controlled drug classified in schedule II through IV.

IV. (a) The prescribing of a non-opioid controlled drug classified in schedule II through IV by means of teledicine shall be limited to prescribers as defined in RSA 329:1-d, I and RSA 326-B:2, XII(a), who are treating patients at a state designated community mental health center pursuant to RSA 135-C or at a Substance Abuse and Mental Health Services Administration (SAMHSA)-certified state opioid treatment program, and shall require an initial in-person exam by a practitioner licensed to prescribe the drug. Subsequent in-person exams shall be by a practitioner licensed to prescribe the drug at intervals appropriate for the patient, medical condition, and drug, but not less than annually.

(b) The prescribing of an opioid controlled drug classified in schedule II through IV by means of teledicine shall be limited to prescribers as defined in RSA 329:1-d, I and RSA 326-B:2, XII(a), who are treating patients at a SAMHSA-certified state opioid treatment program. Such prescription authority shall require an initial in-person exam by a practitioner licensed to prescribe the drug and subsequent in-person exams shall be by a practitioner licensed to prescribe the drug at intervals appropriate for the patient, medical condition, and opioid, but not less than annually.

V. A physician providing services by means of teledicine directly to a patient shall:
   (a) Use the same standard of care as used in an in-person encounter;
   (b) Maintain a medical record; and
   (c) Subject to the patient's consent, forward the medical record to the patient's primary care or treating provider, if appropriate.

VI. Under this section, Medicaid coverage for telehealth services shall comply with the provisions of 42 C.F.R. section 410.78 and RSA 167:4-d.
Prescribing Controlled Substances via Telemedicine
Determining compliance with all state and federal laws to prescribe controlled substances in telepsychiatry

Are both of the following statements true?
- You have a license to practice medicine in your state and in patient's state (if different) AND
- The prescription is being issued for a legitimate medical purpose in your usual course of professional practice.

Yes

Does your state and the patient's state (if different) allow controlled substances to be prescribed via telemedicine?

Yes

Have you seen patient in-person at least once? *

Yes

Have you either:
- Met all state requirements for your state and patient's state (if different) such as state controlled substance license, PMP registration, etc.
- Determined there are no state requirements?

Yes

Will the patient be seen in the presence of patient's treater with federal DEA registration?

Yes

Do any other exceptions to in-person visit apply?
- Indian Health Service
- Public Health Emergency
- Special Registration**
- Medical Emergency
- Or other circumstances per AG or Secretary?

No

Do you have federal DEA registration in patient's state?

Yes

Okay to prescribe controlled substances

No

Is patient in a facility with a federal DEA registration?

Yes

Okay to prescribe controlled substances

No

You cannot prescribe controlled substances - but laws can change

No

Check with licensing and pharmacy boards

Notes:
1. *: or covering for another provider- see CSA for specific requirements
2. **: Special Registration doesn't currently exist; to be addressed by DEA in 2017
3. This is a risk management resource- it is not legal advice.
4. There can always be exceptions to these rules, especially if practicing within VA or IHS.
5. You should check with licensing boards in your state, and patient state’s (if different) for specific requirements and prohibitions.
Prescribing Controlled Substances via Telepsychiatry: Compliance with State and Federal Law
Compliance with State Prescribing Law
Is prescribing controlled substances via telemedicine allowed by prescriber’s state and patient’s state (if different)?
PREScribing controlled substances via telemedicine

• No uniformity
  ‣ Some boards do not address it
  ‣ Some boards say yes
  ‣ Some boards say no
  ‣ Some boards say no, then yes in some cases!
New Connecticut Law Allows Telemedicine Prescribing of Controlled Substances

Connecticut has taken another step towards expanding the meaningful use of telemedicine in connection with treatment of mental health and
64B8-9.0141 Standards for Telemedicine Practice.

(1) “Telemedicine” means the practice of medicine by a licensed Florida physician or physician assistant where patient care, treatment, or services are provided through the use of medical information exchanged from one site to another via electronic communications. Telemedicine shall not include the provision of health care services only through an audio only telephone, email messages, text messages, facsimile transmission, U.S. Mail or other parcel service, or any combination thereof.

(2) The standard of care, as defined in Section 456.50(1)(c), F.S., shall remain the same regardless of whether a Florida licensed physician or physician assistant provides health care services in person or by telemedicine.

(3) Florida licensed physicians and physician assistants providing health care services by telemedicine are responsible for the quality of the equipment and technology employed and are responsible for their safe use. Telemedicine equipment and technology must be able to provide, at a minimum, the same information to the physician and physician assistant which will enable them to meet or exceed the prevailing standard of care for the practice of medicine.

(4) Controlled substances shall not be prescribed through the use of telemedicine.

(5) The practice of medicine by telemedicine does not alter any obligation of the physician or the physician assistant regarding patient confidentiality or recordkeeping.

(6) A physician-patient relationship may be established through telemedicine.

(7)(a) No images, parts or Florida patients.

(b) This rule does not apply to emergency medical services provided by emergency physicians, emergency medical technicians (EMTs), paramedics, and emergency dispatchers. Emergency medical services are those activities or services to prevent or treat a sudden critical illness or injury and to provide emergency medical care and prehospital emergency medical transportation to sick, injured, or otherwise incapacitated persons in this state.

(c) The provisions of this rule shall not apply where a physician or physician assistant is treating a patient with an emergency medical condition that requires immediate medical care. An emergency medical condition is a medical condition manifesting itself by acute symptoms of sufficient severity that the absence of immediate medical attention will result in serious jeopardy to patient health, serious impairment to bodily functions, or serious dysfunction of a body organ or part.

Rulemaking Authority 458.331(1)(v) FS. Law Implemented 458.331(1)(v) FS. History—New 3-12-14.
Controlled substances shall not be prescribed through the use of telemedicine except for the treatment of psychiatric disorders.
Florida Board of Medicine
Rules/Legislative Committee Meeting

Regency Hyatt
9801 International Drive
Orlando, FL 32819
(800) 233-1234

February 4, 2016

MEETING REPORT

Roll call 5:34 p.m.

Members Present:
Zachariah P. Zachariah, M.D., Chair
James W. Orr, Jr., M.D., Vice Chair
Enrique Ginzburg, M.D.
Steven Rosenberg, M.D.
Brigitte Goersch, Consumer Member
Seela Ramesh, M.D.
Bernardo Fernandez, M.D.

Members Absent:
Sarvam TerKonda, M.D.
Jorge Lopez, M.D.

Staff Present:
Adrienne Rodgers, J.D., Interim Executive Director
Edward Tellechea, Esquire, Board Counsel
Donna McNulty, Esquire, Board Counsel
Nancy Murphy, Certified Paralegal
Crystal A. Sanford, CPM, Program Operations Administrator

Others Present:
American Court Reporting
Suzette Bragg
425 Old Magnolia Road
Crawfordville, FL 32327
(850) 421-0058

Rules Discussion:
Rule 64B8-9.0141, F.A.C. - Standards for Telemedicine Practice

The Board amended this rule at the last meeting to allow the prescribing of controlled substances for the treatment of psychiatric disorders. Mr. Tellechea discussed the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 as it relates to the Board’s telemedicine rule. He explained the Act’s definition of “valid prescription” involves an in-person medical evaluation with the patient and physician physically present together. He informed the board that questions had been raised whether the Board’s rule was inconsistent with the Act. Mr. Tellechea opined that the Board’s rule is not inconsistent because physicians are required to comply with federal regulations and the Board’s rule does not contravene that law. He asked Ms. Rodgers if Board staff could publish information on the Board’s website about this matter. He recommended not changing the rule.

The Board members did not any changes to the rule at this time.

Ms. Murphy advised the rule would be adopted right after this meeting.
Telemedicine

“Telemedicine” is the practice of medicine using electronic communication, information technology or other means between a licensee in one location and a patient in another location with or without an intervening health care provider.

The Board recognizes that technological advances have
The Ohio Medical Board just last week adopted new rules for telemedicine prescribing of drugs and controlled substances, allowing providers to prescribe drugs via telemedicine without conducting an in-person examination. Effective
If prescribing controlled substances via telemedicine allowed by prescriber’s state and patient’s state (if different), under what conditions?
STANDARD RULES FOR PRESCRIBING CONTROLLED SUBSTANCES
(For in-person and telemedicine)

- Compliance with state law
  - State law requirements could include:
    - License to practice in state where patient is seen (patient’s state)
      - Some type of license or registration is required in all states
    - State controlled substance registration in prescriber’s state
    - State controlled substance registration in patient’s state, if different from prescriber’s state
      - Resource: [http://www.nasca.org/stateprofiles.htm](http://www.nasca.org/stateprofiles.htm); if it indicates no state registration is required, contact state pharmacy board (contact info in same resource) to confirm accuracy
    - Registration with PMP in patient’s state
      - Same resource as above will have this information
    - Other requirements
      - Ex: DE requires CME on prescribing controlled substances
If by telemedicine, some states specifically prohibit prescribing controlled substances via telemedicine

- Some states only allow it in certain circumstances
  - Ex: In FL, controlled substances shall not be prescribed through the use of telemedicine except for the treatment of psychiatric disorders
- Confirm with both states’ boards, if patient is in a different state
State Controlled Substances Authorities:
Texas Department of State Health Services
State Prescription Drug Monitoring Program: Texas Department of Public Safety

Contact Information: Controlled Substances Authority
Karen Tannert, R.Ph., M.P.H.
Chief Pharmacist
Texas Department of State Health Services
Drugs and Medical Devices Group
P.O. Box 149347, Mail Code 1987
Austin, TX 78714-9347
Phone: (512) 834-6755
Fax: (512) 834-6759
Email Address: karen.tannert@dshs.state.tx.us

Prescription Drug Monitoring Program
Sherry Wright
Assistant Manager
Compliance and Enforcement
Narcotics Regulatory Program
Texas Department of Public Safety
5805 H. Lamar Blvd.
P.O. Box 4087
Austin, TX 78773-0439
Phone: (512) 424-7568
Email Address: Sherry.Wright@txcps.state.tx.us

Brief Agency Descriptions:
Texas Department of State Health Services: Mission is to improve health and well-being in Texas. The Department provides a broad range of health-related services and also licenses and regulates a number of health-related professions. The Drugs and Medical Devices Group is part of the Division for Regulatory Services within the Department. Our mission is to protect the citizens of Texas from adulterated, misbranded, and otherwise unsafe drugs and medical devices. The Drugs and Medical Devices Group endeavors to perform this function through effective enforcement of Texas drug and medical device laws and regulations. The Drugs and Medical Devices Group also serves as the Commissioner of Health’s designee for establishment and modification of the Schedules of Controlled Substances.

Texas Department of Public Safety: An agency created to provide public safety services to those people in the state of Texas by enforcing laws, administering regulatory programs, managing records, educating the public and managing emergencies, both directly and through interaction with other agencies. The Texas Prescription Program seeks to control misuse of controlled substances by following those substances to the point of ultimate use. The online Prescription Access in Texas system can be used by practitioners and pharmacists to verify their own records and inquire about patients. In addition, the program can be used to generate and disseminate information regarding prescription trends.

Controlled Substances Statute(s): Texas Controlled Substances Act, Health and Safety Code, Title 6, Subtitle C, Chapter 481 - http://www.statutes.legis.state.tx.us/Docs/HS/htm/HS.481.htm


Issuance of State Controlled Substances Registration(s): Yes
Anyone who manufactures, distributes, prescribes, possesses, analyzes, or dispenses a controlled substance is required to register with the Texas Department of Public Safety. Examples include but are not limited to drug distributors, pharmacies, and practitioners.

Schedules of Controlled Substances:
http://dshs.texas.gov/drugs/controlled-substances.aspx

Controlled Substances Registration:
http://www.txdps.state.tx.us/rsd/ControlledSubstances/index.htm

Prescription Monitoring Program: Yes
Prescription Monitoring Program Website:
http://www.txdps.state.tx.us/rsd/PrescriptionProgram/index.htm

Prescription Access in Texas web link: https://www.texaspadx.com
R4-23-501. Controlled Substances Prescription Monitoring (CSPMP) Program Registration and Database Access

A. Under A.R.S. § 36-2606, a medical practitioner who is issued a license under A.R.S. Title 32, Chapter 7, 11, 13, 14, 15, 16, 17, 21, 25, or 29 and possesses a current DEA registration under the Federal Controlled Substances Act shall have a current CSPMP registration issued by the Board.

B. Application.

1. An applicant for CSPMP registration shall:
   a. Submit a completed application for CSPMP registration electronically or manually on a form furnished by the Board, and
   b. Submit with the application form the documents specified in the application form.

2. The Board office shall deem an application form received on the date the Board office electronically or manually date-stamps the form.

C. Registration. Within seven business days of receipt of a completed application specified in subsection (B), the Board office shall determine whether an application is complete. If the application is complete, the Board office shall issue a registration number and provide a current registration certificate to the applicant by mail or electronic transmission. If the application is incomplete, the Board office shall issue a written notice of incompleteness. An applicant with an incomplete application shall comply with the requirements of R4-23-202(F).

D. Registration renewal. As specified in A.R.S. § 36-2606(C), the Board shall automatically suspend the registration of any registrant that fails to renew the registration on or before May 1 of the year in which the renewal is due. The Board shall vacate a suspension if the registrant submits a renewal application. A suspended registrant with CSPMP database access credentials is prohibited from accessing information in the prescription monitoring program database.

E. CSPMP database access.

1. A medical practitioner that chooses to use the CSPMP database shall request access from the CSPMP Director by completing an access user registration form electronically. Upon receipt of the access user registration form, the CSPMP Director or designee shall issue access credentials provided the medical practitioner is in compliance with the registration requirements of this Section.

2. A pharmacist that chooses to use the CSPMP database shall request access from the CSPMP Director by completing an access user registration form electronically. Upon receipt of the access user registration form, the CSPMP Director or designee shall issue access credentials provided the pharmacist has a current active pharmacist license.

3. A medical practitioner or pharmacist who is not licensed in Arizona may request access from the CSPMP Director by:
   a. Completing an access user registration form electronically;
   b. Printing the access user registration form;
   c. Having the access user registration form signed and notarized; and
   d. Mailing the notarized access user form along with a current copy of the applicant's nonresident state license and driver's license. Upon receipt of the notarized access user registration form and other required documents, the CSPMP Director or designee shall issue access credentials provided the nonresident licensed medical practitioner or pharmacist credentials show an current active license in another state.

Historical Note
Uniform Controlled Substances Act Regulations

3.0 Requirements

3.1 Registration shall be on a biennial basis upon forms supplied by the Division of Professional Regulation and/or Secretary of State for that purpose. A separate registration is required at each principal place of business or professional practice where controlled substances are manufactured, distributed, dispensed, or kept for research analysis. Out-of-State registrants who dispense or distribute controlled substances to patients or facilities in Delaware are required to obtain a registration.

3.1.1 All practitioners registered under Title 16, Chapter 47 as of July 1, 2013, must attest to completion of a one hour education course on Delaware law, regulation and programs, acceptable to the Secretary, pertaining to the prescribing and distribution of controlled substances on or before June 30, 2015 in order to qualify for continued registration.

3.1.2 All practitioners who obtain new registration under Title 16, Chapter 47 after July 1, 2013 must attest to completion of a one hour education course on Delaware law, regulation and programs, acceptable to the Secretary, pertaining to the prescribing and distribution of controlled substances within the first year of obtaining registration in order to qualify for continued registration.

3.1.3 All practitioners must attest to completion of two hours of continuing education biennially in the areas of controlled substance prescribing practices, treatment of chronic pain, or other topics related to the prescribing of controlled substances.
Compliance with Federal Controlled Substances Act
To: Donna Vanderpool, VP-Risk Management, PRMS

From: Matthew Lee, Bill Hake, Vince D’Angelo, Mary Jean Geroulo, Sabrina M. Ly, and Kristin Invanco

Date: April 12, 2016

Subject: Drug Enforcement Agency Registration in each State

File No.: 01592.00091

With the ever increasing proliferation of multiple state healthcare practices, providers must be aware of the need for separate DEA licenses in each state in which they practice.

**CIVIL PENALTIES**

In *U.S. v. Butterbaugh*, the government sued Dr. Barton Butterbaugh (“Butterbaugh”) for presenting controlled substances without a Drug Enforcement Administration (“DEA”) registration in Washington State.¹ Butterbaugh was both an Arizona licensed physician and DEA registrant.² Through his employment with a Florida based company, eClinicMD, Butterbaugh volunteered to temporarily service patients in Washington after its Washington provider relocated to California.³ Between October 2010 and November 2012, Butterbaugh treated and prescribed medications to approximately 80 individuals in Washington.⁴ Prior to treating patients in Washington, Butterbaugh applied for and received a Washington medical license.⁵ However, he did not register with the DEA to dispense, administer, or distribute controlled substances in the state of Washington. During the 2 year period, Butterbaugh wrote over 1300 prescriptions for controlled substances for over 200 people.⁶
FEDERAL REGULATION

• Controlled Substances Act
  › Amended in 2008 by the Ryan Haight Online Pharmacy Protection Act - 21 USC § 829(e)(3)
• Controlled Substances Act (as amended by the Ryan Haight Act)
  • “No controlled substance that is a prescription drug...may be delivered, distributed or dispensed by means of the Internet without a valid prescription.”
    › Note: “dispense” is defined in §802(10) to include prescribing
FEDERAL REGULATION

• Controlled Substances Act (as amended by the Ryan Haight Act)
  • “Valid prescription means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by –
    ‣ A practitioner who has conducted at least 1 in-person medical evaluation of the patient, or a covering practitioner
      • In-person medical evaluation means a medical evaluation that is conducted with the patient in the physical presence of the practitioner
FEDERAL REGULATION

• Controlled Substances Act (as amended by the Ryan Haight Act)
  • Exception to the in-person visit requirement is “telemedicine”
  › *But as defined by the CSA*
FEDERAL REGULATION

- Controlled Substances Act (as amended by the Ryan Haight Act)
  - 7 definitions of telemedicine / 7 exceptions to in-person visit
    1. Patient in facility with federal DEA registration
    2. Patient in presence of a treater with DEA registration in patient’s state
    3. Indian Health Service
    4. Public health emergency
    5. Special registration from Attorney General
Title: Special Registration to Engage in the Practice of Telemedicine

Abstract:
The Ryan Haight Online Pharmacy Consumer Protection Act of 2000 (the Act) (Pub. L. 110-425) was enacted on October 15, 2000, and amended the Controlled Substances Act by adding various provisions to prevent the illegal distribution and dispensing of controlled substances by means of the Internet. Among other things, the Act required an in-person medical evaluation as a prerequisite to prescribing or otherwise dispensing controlled substances by means of the Internet, except in the case of practitioners engaged in the practice of telematics. The definition of the “practice of telemedicine” includes seven distinct categories that involve circumstances in which the prescribing practitioner might be unable to satisfy the Act’s in-person medical evaluation requirement yet nonetheless has sufficient medical information to prescribe a controlled substance for a legitimate medical purpose in the usual course of professional practice. One specific category within the Act’s definition of the “practice of telemedicine” includes “a practitioner who has obtained from the [DEA Administrator] a special registration under [21 U.S.C. 831(h)].” 21 U.S.C. 802(54)(E). The Act also specifies certain criteria that DEA must consider when evaluating an application for such a registration. However, the Act contemplates that DEA must issue regulations to effectuate this special registration provision. The DEA proposes to amend the registration requirements to permit such a special registration.

Agency: Department of Justice (DOJ)
RIN Status: First time published in the Unified Agenda
Major: No
EO 13771 Designation:
CFR Citation: 21 CFR 1301
Legal Authority: 21 U.S.C. 831(h) 21 U.S.C. 802(54)
Legal Deadline: None

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Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Included in the Regulatory Plan: No
RIN Data Printed in the FR: No
DOJ/DEA
RIN: 1117-AB40

Title: Special Registration to Engage in the Practice of Telemedicine

Abstract:
The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (the Act) (Pub. L. 110-425) was enacted on October 15, 2008, and amended the Controlled Substances Act by adding various provisions to prevent the illegal distribution and dispensing of controlled substances by means of the Internet. Among other things, the Act required an in-person medical evaluation as a prerequisite to prescribing or otherwise dispensing controlled substances by means of the Internet, except in the case of practitioners engaged in the practice of telemedicine. The definition of the “practice of telemedicine” includes seven distinct categories that involve circumstances in which the prescribing practitioner might be unable to satisfy the Act's in-person medical evaluation requirement yet nonetheless has sufficient medical information to prescribe a controlled substance for a legitimate medical purpose in the usual course of professional practice. One specific category within the Act's definition of the “practice of telemedicine” includes “a practitioner who has obtained from the [DEA Administrator] a special registration under [21 U.S.C. 831(h)].” 21 U.S.C. 802(54)(E). The Act also specifies certain criteria that DEA must consider when evaluating an application for such a registration. However, the Act contemplates that DEA must issue regulations to effectuate this special registration provision. The DEA proposes to amend the registration requirements to permit such a special registration.

Agency: Department of Justice (DOJ)
RIN Status: Previously published in the Unified Agenda
Major: No
EO 13771 Designation:
CFR Citation: 21 CFR 1304
Legal Authority: 21 U.S.C. 831(h) 21 U.S.C. 802(54)
Legal Deadline: None
Timetable:

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Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Included in the Regulatory Plan: No
RIN Data Printed in the FR: No

Publication ID: Fall 2015
DOJ/DEA
Title: Special Registration to Engage in the Practice of Telemedicine

Abstract:
The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (the Act) (Pub. L. 110-425) was enacted on October 15, 2008, and amended the Controlled Substances Act by adding various provisions to prevent the illegal distribution and dispensing of controlled substances by means of the Internet. Among other things, the Act required an in-person medical evaluation as a prerequisite to prescribing or otherwise dispensing controlled substances by means of the Internet, except in the case of practitioners engaged in the practice of telemedicine. The definition of the “practice of telemedicine” includes seven distinct categories that involve circumstances in which the prescribing practitioner might be unable to satisfy the Act's in-person medical evaluation requirement yet nonetheless has sufficient medical information to prescribe a controlled substance for a legitimate medical purpose in the usual course of professional practice. One specific category within the Act's definition of the “practice of telemedicine” includes ‘a practitioner who has obtained from the [DEA Administrator] a special registration under [21 U.S.C. 831(h)]’ 21 U.S.C. 802(54)(E). The Act also specifies certain criteria that DEA must consider when evaluating an application for such a registration. However, the Act contemplates that DEA must issue regulations to effectuate this special registration provision.

Agency: Department of Justice (DOJ)
RIN Status: Previously published in the Unified Agenda
Major: No
EO 13771 Designation: 
CFR Citation: 21 CFR 1301
Legal Authority: 21 U.S.C. 831(h), 21 U.S.C. 802(54)
Legal Deadline: None

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Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Included in the Regulatory Plan: No
RIN Data Printed in the FR: No

Publication ID: Spring 2016
DOJ/DEA
Title: Special Registration to Engage in the Practice of Telemedicine

Abstract:
The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (the Act) (Pub. L. 110-425) was enacted on October 15, 2008, and established the Controlled Substances Act by adding various provisions to prevent the illegal distribution and dispensing of controlled substances by means of the Internet. Among other things, the Act required an in-person medical evaluation as a prerequisite to prescribing or otherwise dispensing controlled substances by means of the Internet, except in the case of practitioners engaged in the practice of telemedicine. The definition of the "practice of telemedicine" includes seven distinct categories that involve circumstances in which the prescribing practitioner might be unable to satisfy the Act's in-person medical evaluation requirement yet nonetheless has sufficient medical information to prescribe a controlled substance for a legitimate medical purpose in the usual course of professional practice. One specific category within the Act's definition of the "practice of telemedicine" includes "a practitioner who has obtained from the [DEA Administrator] a special registration under [21 U.S.C. 831(h)]." 21 U.S.C. 802(54)(E). The Act also specifies certain criteria that DEA must consider when evaluating an application for such a registration. However, the Act contemplates that DEA must issue regulations to effectuate this special registration provision. The DEA proposes to amend the registration requirements to permit such a special registration.

Agency: Department of Justice (DOJ)
RIN Status: Previously published in the Unified Agenda
Major: No
EO 13771 Designation:
CFR Citation: 21 CFR 1304
Legal Authority: 21 U.S.C. 831(h) 21 U.S.C. 802(54)
Legal Deadline: None

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Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Included in the Regulatory Plan: No
RIN Data Printed in the FR: No
DOJ/DEA
RIN: 1117-AB40
Publication ID: Spring 2017

Title: Special Registration to Engage in the Practice of Telemedicine

Abstract:

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (the Act) (Pub. L. 110-425) was enacted on October 15, 2008, and amended the Controlled Substances Act by adding various provisions to prevent the illegal distribution and dispensing of controlled substances by means of the Internet. Among other things, the Act required an in-person medical evaluation as a prerequisite to prescribing or otherwise dispensing controlled substances by means of the Internet, except in the case of practitioners engaged in the practice of telemedicine. The definition of the “practice of telemedicine” includes seven distinct categories that involve circumstances in which the prescribing practitioner might be unable to satisfy the Act’s in-person medical evaluation requirement yet nonetheless has sufficient medical information to prescribe a controlled substance for a legitimate medical purpose in the usual course of professional practice. One specific category within the Act’s definition of the “practice of telemedicine” includes “a practitioner who has obtained from the [DEA Administrator] a special registration under [21 U.S.C. 831(h)],” 21 U.S.C. 802(54)(E). The Act also specifies certain criteria that DEA must consider when evaluating an application for such a registration. However, the Act contemplates that DEA must issue regulations to effectuate this special registration provision. The DEA proposes to amend the registration requirements to permit such a special registration.

Agency: Department of Justice (DOJ)
RIN Status: Previously published in the Unified Agenda
Major: No
EO 13771 Designation:
CFR Citation: 21 CFR 1301
Legal Authority: 21 U.S.C. 831(h) 21 U.S.C. 802(54)
Legal Deadline: None
Timetable:

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Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Included in the Regulatory Plan: No
RIN Data Printed in the FR: No

Priority: Other Significant
Agenda Stage of Rulemaking: Long-Term Actions
Unfunded Mandates: No

Federalism: None
DOJ/DEA
RIN: 1117-AB40

Title: Special Registration to Engage in the Practice of Telemedicine

Abstract:
The Ryan Haight Online Pharmacy Consumer Protection Act of 2006 (the Act) (Pub. L. 110-425) was enacted on October 15, 2006, and amended the Controlled Substances Act by adding various provisions to prevent the illegal distribution and dispensing of controlled substances by means of the Internet. Among other things, the Act required an in-person medical evaluation as a prerequisite to prescribing or otherwise dispensing controlled substances by means of the Internet, except in the case of practitioners engaged in the practice of telemedicine. The definition of the “practice of telemedicine” includes seven distinct categories that involve circumstances in which the prescribing practitioner might be unable to satisfy the Act’s in-person medical evaluation requirement yet nonetheless has sufficient medical information to prescribe a controlled substance for a legitimate medical purpose in the usual course of professional practice. One specific category within the Act’s definition of the “practice of telemedicine” includes “a practitioner who has obtained from the [DEA Administrator] a special registration under [21 U.S.C. 831(h)].” 21 U.S.C. 802(54)(E). The Act also specifies certain criteria that DEA must consider when evaluating an application for such a registration. However, the Act contemplates that DEA must issue regulations to effectuate this special registration provision. The DEA proposes to amend the registration requirements to permit such a special registration.

Agency: Department of Justice (DOJ)
RIN Status: Previously published in the Unified Agenda
Major: No
EO 13771 Designation: Not subject to, not significant
CFR Citation: 21 CFR 1301
Legal Authority: 21 U.S.C. 831(i), 21 U.S.C. 802(E)
Legal Deadline: None

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Regulatory Flexibility Analysis Required: No
Federalism: No
Included in the Regulatory Plan: No
RIN Data Printed in the FR: No

Publication ID: Fall 2017
H.R.5483 - Special Registration for Telemedicine Clarification Act of 2018

115th Congress (2017-2018) | Get alerts


Committees: House - Energy and Commerce; Judiciary

Latest Action: House - 04/12/2018 Referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, 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. (All Actions)

Tracker: Introduced -> Passed House -> Passed Senate -> To President -> Became Law


Short Titles

Short Titles - House of Representatives

Short Title as Introduced
Congress has taken another step forward to require the federal Drug Enforcement Administration (DEA) to activate a special
FEDERAL REGULATION

- Controlled Substances Act (as amended by the Ryan Haight Act)
  - 7 definitions of telemedicine / 7 exceptions to in-person visit
    - Medical emergency
    - Other circumstances, as deemed by Attorney
    - General and Secretary
Telemedicine and Prescribing Buprenorphine for the Treatment of Opioid Use Disorder

September 2018

THE UNITED STATES is in the midst of an unprecedented crisis of prescription and illicit opioid misuse, addiction, and overdose. To combat the epidemic HHS is working to prevent more people from becoming addicted while also expanding access to treatment and recovery support services for those with opioid use disorder. Improving access to medication-assisted treatment (MAT) for opioid use disorder, which combines the use of medications (methadone, buprenorphine, and naltrexone) with psychosocial and other behavioral health support services, is a critical component of the HHS Opioid Strategy.

Despite the well-documented effectiveness of MAT, the majority of Americans with opioid use disorder do not receive this life-saving treatment. This is particularly true in some rural and remote areas of the country where there are few clinicians available to provide MAT and patients often have to travel long distances to receive care or go without care. One particular barrier to MAT access is the limited number of practitioners with a Drug Addiction Treatment Act of 2000 (“DATA 2000”) waiver, which allows qualified practitioners to prescribe buprenorphine, for the treatment of opioid use disorder in settings other than a federally regulated opioid treatment program.

Use of Telemedicine While Providing Medication Assisted Treatment (MAT)

Under the Ryan Haight Act of 2008, where controlled substances are prescribed by means of the Internet, the general requirement is that the prescribing Practitioner must have conducted at least one in-person medical evaluation of the patient. U.S.C. § 829(e). However, the Act provides an exception to this requirement. 21 USC § 829 (e)(3)(A). Specifically, a DEA-registered Practitioner acting within the United States is exempt from the requirement of an in-person medical evaluation as a prerequisite to prescribing or otherwise dispensing controlled substances by means of the Internet if the Practitioner is engaged in the practice of telemedicine and is acting in accordance with the requirements of 21 U.S.C. § 802(54).

Under 21 U.S.C. § 802(54)(A),(B), for most (DEA-registered) Practitioners in the United States, including Qualifying Practitioners and Qualifying Other Practitioners (“Medication Assisted Treatment Providers”), who are using FDA approved Schedule III-V controlled substances to treat opioid addiction, the term “practice of telemedicine” means the practice of medicine in
