Congressional Research Service
Informing the legislative debate since 1914

The Special Registration for Telemedicine: In Brief

Updated November 28, 2018

Congressional Research Service
https://crsreports.congress.gov
R45240

CRS REPORT
Prepared for Members and
Committees of Congress

Contents

Tables

Contacts

Introduction

According to the Association of American Medical Colleges (AAMC), "[t]he United States is suffering from a dramatic shortage of psychiatrists and other mental health providers."[1] There were an estimated 111 million people living in areas that have a limited number of mental health providers, as of September 2017.[2] The shortage of mental health providers is of concern because an estimated 50% of all Americans are diagnosed with a mental illness or disorder at some point in their lives, according to the Centers for Disease Control and Prevention (CDC) of the Department of Health and Human Services (HHS).[3] To increase patients' access to mental health care, mental health care providers can provide the care through a *telemedicine* platform. Telemedicine is the electronic delivery of a clinical health care service via a technological method.[4] Examples of telemedicine platforms that mental health providers can use to deliver mental health care services include telepsychiatry and telepsychology.[5]

In response to the concerns about the opioid epidemic, the Trump Administration proposed "[expanding] access to telemedicine services, including services involving remote prescribing of medicine commonly used for substance abuse or mental health treatment," as an intervention to address the opioid crisis.[6] Section 311(h)(1) of the Controlled Substance Act (CSA),[7] which was added by Section 3 of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act; P.L. 110-425), authorized the special registration for telemedicine with the goal of increasing patients' access to *practitioners* that can prescribe controlled substances via telemedicine in limited circumstances.[8] Section 802(21) of Title 21, U.S.C. defines a practitioner as

> a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with

[1] Stacy Weiner, "Addressing the Escalating Psychiatrist Shortage," *Association of American Medical Colleges (AAMC) NEWS*, February 13, 2018, https://news.aamc.org/patient-care/article/addressing-escalating-psychiatrist-shortage/.

[2] U.S. Congress, House Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, *Statement by Dr. Luis Padilla, Associate Administrator, Bureau of Health Workforce, Health Resources and Services Administration, of HHS*, 115th Cong., April 12, 2018, p. 2, https://docs.house.gov/meetings/AP/AP07/20180412/108104/HHRG-115-AP07-Wstate-PadillaL-20180412.pdf.

[3] The Centers for Disease Control and Prevention (CDC) of the Department of Health and Human Services (HHS) is the federal agency charged developing and supporting community-based and population-wide programs and systems to promote quality of life and prevent the leading causes of disease, injury, disability, and death. See CDC, *Mental Health: Data and Publications*, https://www.cdc.gov/mentalhealth/data_publications/index.htm; and CRS Report R44916, *Public Health Service Agencies: Overview and Funding (FY2016-FY2018)*.

[4] HHS, *Report to Congress: E-health and Telemedicine*, August 12, 2016, pp. 4-5, https://aspe.hhs.gov/system/files/pdf/206751/TelemedicineE-HealthReport.pdf.

[5] American Psychiatric Association, *What is Telepsychiatry?*, https://www.psychiatry.org/patients-families/what-is-telepsychiatry; and American Psychological Association, *What are Telehealth and Telepsychology?*, http://www.apa.org/pi/disability/resources/publications/telepsychology.aspx.

[6] U.S. President (Trump), "President Donald J. Trump is Taking Action on Drug Addiction and the Opioid Crisis," 115th Cong., October 26, 2017.

[7] The primary federal law governing the manufacture, distribution, and use of prescription and illicit opioids is the CSA, a statute that the Drug Enforcement Agency (DEA) is principally responsible for administering and enforcing. See CRS Report R45164, *Legal Authorities Under the Controlled Substances Act to Combat the Opioid Crisis*.

[8] Letter from Senator Claire McCaskill, Senator Lisa Murkowski, and Senator Dan Sullivan to Robert W. Patterson, Acting Administrator, Drug Enforcement Administration (DEA), January 30, 2018, https://www.hsgac.senate.gov/imo/media/doc/2018-01-30%20CMC%20Murkowski%20Sullivan%20ltr%20to%20DEA%20re%20telemedicine.pdf.

> respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

The registration would enable a practitioner to deliver, distribute, dispense, or prescribe via telemedicine a controlled substance to a patient who has not been medically examined in-person by the prescribing practitioner.[9] For example in the event of an opioid overdose, a patient might need a prescription for an opioid antagonist such as naloxone from a provider who has never examined the patient in-person prior to the telemedicine encounter.[10]

While the CSA authorizes the special registration for telemedicine, practitioners have not been able to apply for this special registration. The Drug Enforcement Administration (DEA), of the Department of Justice (DOJ), has yet to finalize a rule on the registration's application process and procedures and the limited circumstances that warrant it.[11] (On April 6, 2009, the DEA stated in an interim final rule that the agency would issue a separate rule regarding the special registration for telemedicine.[12]) According to the Fall 2018 Unified Agenda of the Office of Management and Budget (OMB), the DEA plans to publish in the *Federal Register* a proposed rule on the special registration.[13]

Legislative Activities

On October 24, 2018, the President signed into law the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (P.L. 115-271; the SUPPORT for Patients and Communities Act, or the SUPPORT Act).[14] Section 3232 of the SUPPORT Act amends CSA Section 311(h)(2) to require that not later than one year after enactment, the Attorney General, in consultation with the HHS Secretary, promulgate final regulations specifying the limited circumstances in which a special registration for telemedicine may be issued and the procedure for obtaining the registration. The amendment replaces the provision found in CSA Section 311(h)(2) with new language, as follows (with italics indicating new language and strike-throughs indicating deleted language):

> (2) Regulations
>
> ~~The Attorney General shall, with the concurrence of the Secretary, promulgate regulations specifying the limited circumstances in which a special registration under this subsection may be issued and the procedures for obtaining such a special registration.~~

[9] 21 U.S.C. §831(h); and 21 U.S.C. §829(e).

[10] Naloxone is an emergency overdose reversal medication. See National Institute on Drug Abuse, within the National Institutes of Health, *Opioid Overdose Reversal with Naloxone (Narcan, Evzio)*, April 2018, https://www.drugabuse.gov/related-topics/opioid-overdose-reversal-naloxone-narcan-evzio; and Letter from Claire McCaskill, U.S. Senator, Lisa Murkowski, U.S. Senator, and Dan Sullivan, U.S. Senator, to Robert W. Patterson, Acting Administrator of the Drug Enforcement Administration, January 30, 2018, https://www.hsgac.senate.gov/imo/media/doc/2018-01-30%20CMC%20Murkowski%20Sullivan%20ltr%20to%20DEA%20re%20telemedicine.pdf.

[11] 21 U.S.C. §831(h)(2).

[12] DEA, "Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008," 74 *Federal Register* 15603, April 6, 2009.

[13] Office of Management and Budget (OMB), *Unified Agenda: Special Registration to Engage in the Practice of Telemedicine*, RIN: 1117-AB40, 2018, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201810&RIN=1117-AB40.

[14] CRS Report R45405, *The SUPPORT for Patients and Communities Act (P.L. 115-271): Food and Drug Administration and Controlled Substance Provisions*.

> *Not later than 1 year after the date of enactment of the SUPPORT for Patients and Communities Act, in consultation with the Secretary, the Attorney General shall promulgate final regulations specifying—*
>
> > *(A) the limited circumstances in which a special registration under this subsection may be issued; and*
> >
> > *B) the procedure for obtaining a special registration under this subsection.*[15]

The language in Section 3232 of the SUPPORT Act that requires the DEA to promulgate a rule on the special registration not later than one year after enactment originates from the Special Registration for Telemedicine Clarification Act of 2018 (H.R. 5483). This bill is included in the SUPPORT Act.[16] H.R. 5483 would not have, however, replaced the language that is found in CSA Section 311(h)(2). The bill would have amended CSA Section 311(h)(2) as follows (with italics indicating new language and strikethroughs indicating deleted language):

> (2) Regulations
>
> ~~The Attorney General shall, with the concurrence of the Secretary, promulgate regulations~~ *Not later than 1 year after the date of enactment of the Special Registration for Telemedicine Clarification Act of 2018, the Attorney General shall, with the concurrence of the Secretary, promulgate interim final regulations* specifying the limited circumstances in which a special registration under this subsection may be issued and the procedures for obtaining such a special registration.

On June 12, 2018, the House passed H.R. 5483 through a motion to suspend the rules and pass the bill, as amended and agreed to by voice vote.[17] On June 13, 2018 (the same day that the House introduced the SUPPORT Act), the Senate received H.R. 5483, read it twice, and referred it to its Committee on Health, Education, Labor, and Pensions (HELP).[18]

The Congressional Budget Office (CBO) provided a cost estimate for H.R. 5483,[19] which estimated that implementing the bill would cost less than $500,000 over the 2019-2023 period. It can be assumed that this cost estimate is the same for that of Section 3232 of the SUPPORT Act since Congress chose to fold H.R. 5483 into the act.

Special Registration Requirements

Under Sections 823 and 831(h)(1) of Title 21 of the *U.S. Code*, Congress established three general requirements that practitioners must meet while using the special registration to deliver, distribute, dispense, or prescribe controlled substances via telehealth. First, the practitioners must

---

[15] This new language is not viewable online at the official U.S. Code website because the online version is only current up to October 16, 2018. See Office of the Law Revision Counsel, *United States Code: Currency and Updating*, http://uscode.house.gov/currency/currency.shtml;jsessionid=319C0F3879943F4E4C4C2AAD88F967AC. Accessed on November 19, 2018.

[16] Congress.gov, *H.R. 6 - SUPPORT for Patients and Communities Act*, Related Bills, https://www.congress.gov/bill/115th-congress/house-bill/6/related-bills.

[17] Representative John J. Faso (Speaker pro tempore), "Special Registration for Telemedicine Clarification Act of 2018," House debate, *Congressional Record*, vol. 164, part 97 (June 12, 2018), p. H5060.

[18] Congress.gov, H.R. 5483 - *Special Registration for Telemedicine Clarification Act of 2018*, All Actions, https://www.congress.gov/bill/115th-congress/house-bill/5483/all-actions.

[19] Congressional Budget Office (CBO), *Cost Estimate: Opioid Legislation*, June 6, 2018, pp. 17 and 21, https://www.cbo.gov/system/files?file=115th-congress-2017-2018/costestimate/53949-opioid.pdf. According to CBO, the agency's estimate of H.R. 5483 derives from information that DOJ provided to the agency.

demonstrate a legitimate need for the special registration.[20] Second, the practitioners must be registered to deliver, distribute, dispense, or prescribe controlled substances in the state where the patient is located.[21] Third, the practitioners must maintain compliance with federal and state laws when delivering, distributing, dispensing, and prescribing a controlled substance.[22]

The Ryan Haight Act expressly exempts certain manufacturers, distributors, and dispensers of controlled substances and certain Department of Veterans Affairs (VA) practitioners and VA-contracted practitioners from needing to obtain a special registration for telemedicine in each state where the entities and practitioners choose to practice.[23] To be exempted, a manufacturer, distributor, or dispenser of a controlled substance must have a DEA waiver that exempts the entity from needing to obtain an annual registration to manufacture, distribute, and dispense the controlled substance.[24] A VA practitioner or VA-contracted practitioner must meet two conditions to be exempted.[25] First, the practitioner must prescribe the controlled substance within the scope of his or her employment at the VA. Second, the practitioner must either (1) hold at least one state registration to prescribe a controlled substance or (2) prescribe in a VA health care facility while using the registration of that facility.

The Practice of Telemedicine

The special registration for telemedicine is one of seven categories under the *practice of telemedicine* authority recognized by the CSA.[26] **Table 1** describes the seven categories. The practice of telemedicine is the federal authority that allows a health care practitioner to prescribe a controlled substance via telemedicine even in the absence of performing an in-person medical examination of the patient.[27] Section 802(54) of Title 21, U.S.C., defines the practice of telemedicine as "the practice of medicine in accordance with applicable [f]ederal and [s]tate 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 telecommunication system referred to in section 1395m(m) of title 42, [U.S.C.]."[28]

A practitioner who prescribes a controlled substance via telemedicine in noncompliance with the requirements described in **Table 1** would be considered to be in violation of the CSA.[29]

---

[20] 21 U.S.C. §831(h)(1)(A).

[21] 21 U.S.C. §831(h)(1)(B); and CRS Report R45164, *Legal Authorities Under the Controlled Substances Act to Combat the Opioid Crisis*.

[22] 21 U.S.C. §802(54).

[23] 21 U.S.C. §831(h)(1)(B).

[24] 21 U.S.C. §822(d).

[25] 21 U.S.C. §831(h)(1).

[26] 21 U.S.C. §802(54).

[27] The Ryan Haight Act requires that a practitioner conduct an in-person medical evaluation of a patient prior to the delivery, distribution, or dispensing of controlled substances by means of the internet, 21 U.S.C. §829(e)(1), (e)(2), although 21 U.S.C. §829(e)(3)(A) is an exception to this requirement for any provider "engaged in the practice of telemedicine."

[28] A practitioner may use at least one of three telecommunication systems (referred to as *telehealth modalities*) under the practice of telemedicine: (1) live-video (synchronous), (2) remote patient monitoring (RPM), and (3) mobile health (mHealth); see 42 C.F.R. §410.78(a)(3) and CRS Report R45021, *Telehealth Services Proposed for Medicare Part B Reimbursements, 2018: Fact Sheet*.

[29] 21 U.S.C. §829(e); and DEA, "Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008," 74 *Federal Register* 15599-15603, April 6, 2009. ("[T]he Ryan Haight Act makes it unambiguous that it is a *per*

Table 1. Descriptions of the Seven Categories Under the Practice of Telemedicine

Seven Categories	Health Care Practitioner Requirements	Other Requirements	Exemptions
Category 1. The practice of telemedicine is delivered to a patient that is located in a hospital or clinic.	**(1)** The practitioner must practice in accordance with federal and state laws. **(2)** The practitioner must be registered to prescribe via telemedicine a controlled substance in the state where the patient is located. **(3)** The practitioner must hold a Drug Enforcement Administration (DEA) registration to prescribe or conduct research on controlled substances.[a]	**(1)** The hospital and clinic must hold a DEA registration to dispense or conduct research on controlled substances.	**(1)** A manufacturer, distributor, or dispenser of controlled substances is exempted if the entity holds a DEA waiver that exempts the entity from needing to obtain an annual registration to manufacture, distribute, and dispense controlled substances.[b] **(2)** VA practitioners and VA-contracted practitioners are exempted, if they meet two conditions. First, the practitioners must practice within the scope of their employment or under their contracts at the VA. Second, the practitioners must either (1) hold at least one state registration to prescribe or conduct research on controlled substances or (2) prescribe or conduct research on controlled substances in a VA health care facility while using the registration of that facility.
Category 2. The practice of telemedicine is conducted during an in-person examination with another practitioner.	**(1)** The practitioner must practice in accordance with federal and state laws. **(2)** The practitioner must be registered to prescribe via telemedicine a controlled substance in the state where the patient is located. **(3)** The practitioner must hold a DEA registration to prescribe or conduct research on controlled substances.[a]	**(1)** The health care practitioner at the *distant site* must provide the telemedicine service to a patient that is physically in the presence of a health care practitioner at the *originating site*.[c]	**(1)** A manufacturer, distributor, or dispenser of controlled substances is exempted if the entity holds a DEA waiver that exempts the entity from needing to obtain an annual registration to manufacture, distribute, and dispense controlled substances.[b] **(2)** VA practitioners and VA-contracted practitioners are exempted if they meet two conditions. First, the practitioners must practice within the scope of their employment or under their contracts at the VA. Second, the practitioners must either (1) hold at least one state registration to prescribe or conduct research on controlled substances or (2) prescribe or conduct research on controlled substances in a VA health care facility while using the registration of that facility.
Category 3. The practice of telemedicine is conducted through the Indian Health Service (IHS).	**(1)** The practitioner must meet two conditions to practice under this category. First, the practitioner must either (1) be an IHS employee or contractor or (2) be an Indian tribe or tribal worker as part of a contract or compact under the Indian Self-Determination and Education Assistance Act (P.L. 93-638). Second, the practitioner must be designated as an Internet Eligible Controlled Substances Provider.[d]	None.	None.

Seven Categories	Health Care Practitioner Requirements	Other Requirements	Exemptions
Category 4. The practice of telemedicine is conducted during a public health emergency.	**(1)** The practitioner must provide the telemedicine services during a public health emergency.[e] **(2)** The practitioner must provide the telemedicine services to patients that live in the area that is declared a public health emergency.	**(1)** The Secretary of the Department of Health and Human Services (HHS) must declare the public health emergency.	None.
Category 5. The practice of telemedicine is conducted by a health care practitioner that has obtained a *special registration for telemedicine*.[f]	**(1)** The practitioner must demonstrate that there is a legitimate need for the special registration. **(2)** The practitioner must be registered to deliver, distribute, dispense, or prescribe via telemedicine a controlled substance in the state where the patient is located. **(3)** The practitioner must maintain compliance with federal and state laws when delivering, distributing, dispensing, and prescribing a controlled substance.	None.	**(1)** A manufacturer, distributor, or dispenser of controlled substances is exempted if the entity holds a DEA waiver that exempts the entity from needing to obtain an annual registration to manufacture, distribute, and dispense controlled substances.[b] **(2)** A VA practitioner or VA-contracted practitioner must meet two conditions to be exempted. First, the practitioner must prescribe the controlled substance within the scope of their employment or under their contracts at the VA. Second, the practitioner must either (1) hold at least one state registration to prescribe a controlled substance or (2) prescribe in a VA health care facility while using the registration of that facility.
Category 6. The practice of telemedicine is conducted during a medical emergency situation.	**(1)** The practitioner must meet three conditions to practice under this category. First, the practitioner must be a VA practitioner or VA-contracted practitioner who is practicing within the scope of his or her employment or contract within the VA. Second the practitioner must either (1) hold at least one state registration to prescribe or conduct research on controlled substances or (2) prescribe or conduct research on controlled substances in a VA health care facility while using the registration of that facility. Third, the practitioner is prohibited from writing more than a five-day prescription for a controlled substance that is refillable and extendable, for a single patient.	**(1)** There are four conditions that make a situation a medical emergency situation under this category. First, the situation must prevent the patient from receiving an in-person examination from a VA practitioner or VA-contracted practitioner. Second, the situation must prevent the patient from being seen in a VA health care facility. Third, the situation must prevent the patient's primary care practitioner and other VA telehealth practitioners from examining the patient. Fourth, the situation must require that the patient receives an immediate prescription for a controlled substance.	None.

Seven Categories	Health Care Practitioner Requirements	Other Requirements	Exemptions
Category 7. The practice of telemedicine is conducted at the discretion of the DEA.	**(1)** The practitioner must provide the telehealth service at the discretion of the DEA.	None.	None.

Source: Table prepared by CRS using 21 U.S.C. §802(54) and 21 U.S.C. §831(h).

Notes: This table provides only the requirements that are found in 21 U.S.C. §802(54) and 21 U.S.C. §831(h). The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act; P.L. 110-425) contains other important requirements that practitioners must meet to adhere to the practice of medicine, but those requirements are beyond the scope of this table. For example and according to 21 U.S.C. §829(e)(2)(A)(i), a practitioner must have performed at least one in-person medical examination on his or her patient prior to prescribing a controlled substance via the internet.

a. 21 U.S.C. §823(f).

b. 21 U.S.C. §822(d).

c. During the delivery of telemedicine, the *distant site* is where the provider is located and the *originating site* is where the patient is located; see 42 C.F.R. §410.78(a).

d. The DEA designates a health care provider as an Internet Eligible Controlled Substances Provider when there is a legitimate need for the provider to prescribe controlled substances via telemedicine to patients that are experiencing access barriers to health care in remote areas; see 21 U.S.C. §831(g)(2).

e. 42 U.S.C. §247d.

f. Under a special registration for telemedicine, a practitioner may deliver, distribute, dispense, or prescribe via telemedicine a controlled substance to a patient who has not been medically examined in-person by the prescribing practitioner.

Author Information

Victoria L. Elliott
Analyst in Health Policy

Disclaimer