

Symptoms of a Self-Medicated Society: Unresolved Ryan Haight Act Implications on the Use of Telemedicine to Prescribe Controlled Substances Post-Pandemic

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I. INTRODUCTION

On January 31, 2020, the Secretary of the U.S. Department of Health and Human Services (HHS) declared a public health emergency pursuant to the Public Health Service Act (PHSA) in response to the

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COVID-19 outbreak.¹ Under Section 319 of the PHS Act, the Secretary is authorized to declare a public health emergency if it is determined that the disease presents a significant public health risk.² Once a public health emergency is declared, the Secretary can modify the practice of telemedicine; enter into contracts; conduct and support investigations into the disease or disorder; grant an extension or waive requirements of certain Substance Abuse and Mental Health Services Administration (SAMHSA) grants on a state-by-state basis; and access funds appropriated to the Public Health Emergency Fund.³ On March 13, 2020, President Donald Trump echoed the declaration of a public health emergency pursuant to Sections 201 and 301 of the National Emergencies Act and Section 1135 of the Social Security Act.⁴

The declaration of a public health emergency allowed for numerous waivers of statutes that regulate the practice of medicine. Such waivers included the relaxation of telemedicine requirements.⁵ Telemedicine is the use of telecommunication technology, such as video or audio conferencing, to provide medical care and services remotely.⁶ This can include consultations, diagnoses, and even remote monitoring.⁷ Telemedicine became increasingly important during the COVID-19 crisis in helping to prevent the spread of the virus, provide access to care, and support social distancing. Nonetheless, it remains essential to regulate telemedicine to guarantee accessible healthcare and prevent fraudulent activities.

¹ Determination of Public Health Emergency, 85 Fed. Reg. 7,316, 7,317 (Feb. 4, 2020); Public Health Service Act, 42 U.S.C. § 201 et seq. (2018).

² 42 U.S.C. § 247d (authorizing the HHS Secretary to lead all federal public health and medical response to public health emergencies and incidents covered by the National Response Framework, to declare a public health emergency, and take such actions as may be appropriate to respond to the public health emergency consistent with existing authorities).

³ *Id.* § 247d(a)(2) (“the Secretary may take such action as may be appropriate to respond to the public health emergency, including making grants, providing awards for expenses, and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder as described in paragraphs (1) and (2). Any such determination of a public health emergency terminates upon the Secretary declaring that the emergency no longer exists, or upon the expiration of the 90-day period beginning on the date on which the determination is made by the Secretary, whichever occurs first.”).

⁴ Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak, 85 Fed. Reg. 15,337, 15,338 (Mar. 18, 2020).

⁵ 42 U.S.C. § 247d.

⁶ *The Basics of Telehealth*, HEALTH RES. & SERV. ADMIN., https://telehealth.hhs.gov/documents/Basics+of+Telehealth_15Feb22.pdf (last visited Mar. 29, 2024).

⁷ *Id.*

Fourteen years ago, the Ryan Haight Act (RHA) was enacted to regulate the distribution of controlled substances through online platforms.⁸ The RHA prohibits providers from prescribing controlled substances by means of the internet without a valid prescription.⁹ Throughout the pandemic, the Secretary suspended or waived many key requirements set forth in the RHA in response to the public health emergency. Temporary relaxation of the RHA's requirements led to unregulated prescription of controlled substances, a disparity between the medical professional community and governmental oversight, and a lack of guidance for the future of telemedicine in a post-pandemic world. Part II of this Comment discusses the legislative history of the RHA and regulations pertaining to controlled substances through online platforms. Part III examines the possibility of a special registration pursuant to the RHA as well as the roadmap for proposed post-pandemic changes set forth by HHS on February 9, 2023. Part IV concludes with the proposition that permanent legislative action is required to reduce the risk of unregulated telemedicine as it pertains to the prescription of controlled substances through online channels.

II. THE HISTORY OF INTERNET PHARMACIES AND TELEMEDICINE REGULATIONS

A. *History of the Ryan Haight Act*

In 1999, Clayton Fuchs developed a business plan that would permit him to use his pharmacy license to establish an online pharmacy.¹⁰ Fuchs set up a company that allowed customers to visit a website, complete a registration form, and order prescription medications of their choice.¹¹ After customers submitted an order request for prescription medication, Fuchs forwarded the orders to a physician for review.¹² The physician, located in Texas, would issue the prescription without ever having seen or spoken to the patient.¹³ The prescriptions would be filled and shipped to customers nationwide

⁸ Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Pub. L. No. 110-425, 122 Stat. 4820 (codified as amended in scattered sections of 21 U.S.C.).

⁹ *Id.* (defining a valid prescription for a controlled substance as one issued for a legitimate medical purpose in the usual course of professional practice by a practitioner who conducted at least one in-person medical evaluation of the patient or a covering practitioner who conducts a medical evaluation at the request of a temporarily unavailable practitioner who had conducted an in-person medical evaluation of the patient within the past twenty four months).

¹⁰ *United States v. Fuchs*, 467 F.3d 889, 896 (5th Cir. 2006).

¹¹ *Id.*

¹² *Id.* at 897.

¹³ *Id.*

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upon physician approval.¹⁴ Fuchs's online pharmacy had various customers, including Ryan Haight, a seventeen-year-old high school student who utilized the online pharmacy to purchase Vicodin¹⁵ from Fuchs' online pharmacy.¹⁶ Ryan Haight tragically passed away from an overdose of prescription medication that Fuchs' business had delivered directly to his doorstep.¹⁷ Ryan Haight's death is an example of the tragedy that results when practitioners abuse technology in the practice of medicine and profit off the unregulated distribution of prescription medication. This story inspired the Ryan Haight Act,¹⁸ an amendment to the Controlled Substances Act (CSA).¹⁹

1. Ryan Haight Act Requirements

With the RHA in place, practices like Fuchs's are not only dangerous to the public, they are also unethical and illegal.²⁰ The RHA was passed to prevent rogue pharmacies from illegally distributing controlled substances through online platforms.²¹ The Food and Drug Administration (FDA) warns that a rogue pharmacy is one that engages in offering the sale of "unapproved prescription drugs of unknown

¹⁴ *Id.*

¹⁵ DEA, *Hydrocodone Trade Names: Vicodin, Lortab, Lorcet-HD, Hycodan, Vicoprofen* (October 2019), <https://www.dea.gov/divisions/office-of-diversion-control/drug-chemical-information/hydrocodone.pdf> (last visited Mar. 29, 2024).

¹⁶ Bethany Lipman, *Prescribing Medicine for Online Pharmacies: An Assessment of the Law and a Proposal to Combat Illegal Drug Outlets*, 50 AM. CRIM. L. REV. 545, 545–46 (2013).

¹⁷ *Id.* at 546.

¹⁸ Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Pub. L. No. 110-425, 122 Stat. 4820 (codified as amended in scattered sections of 21 U.S.C.).

¹⁹ Controlled Substances Act, 21 U.S.C. §§ 801 et seq. (2018); *see also* 21 U.S.C. § 841(a)(1) (stating that even prior to the enactment of the RHA, the distribution of controlled substances over the internet was criminalized by the CSA); *Texas State Board of Pharmacy v. Clayton Howard Fuchs*, No. 515-01-3688, 2002 WL 33853208, at *1 (Tex. State Off. Admin. Hearings, Jan. 22, 2002) (revoking Clayton Fuch's license to practice pharmacy).

²⁰ Ryan Haight Online Pharmacy Consumer Protection Act of 2008, *supra* note 8; *see generally Congress Approves Bill Sponsored by Senators Feinstein and Sessions to Stop Controlled Substances from Being Sold Online Without Valid Prescription*, U.S. SENATOR FOR CAL. DIANNE FEINSTEIN (Sept. 30, 2008), <https://web.archive.org/web/20230325234421/https://www.feinstein.senate.gov/public/index.cfm/press-releases?ID=b89fb3af-9349-fbb2-d756-26a5ad6cd990> (Senator Feinstein stating "We know of at least 18 people that have died due to overdoses from drugs purchased on the Internet through these pharmacies and even more who have entered rehabilitation or suffered injuries due to these drugs. No more. I look forward to this important legislation becoming law.").

²¹ Ryan Haight Online Pharmacy Consumer Protection Act of 2008, *supra* note 8.

origin, safety, and effectiveness, offering prescription drugs without a prescription, offering prescription drugs without adequate directions for safe use; and offering prescription drugs without FDA-required warnings to consumers about the serious health risks associated with the prescription drug.”²² Prescribing controlled substances via telemedicine differs from prescribing other non-controlled substances in several ways, including the legal requirements, regulations, and guidelines that govern their use.²³ Controlled substances are drugs that are regulated by the Drug Enforcement Administration (DEA) because of their potential for abuse, addiction, and harm.²⁴ These substances are classified into different schedules based on their level of risk and potential for abuse.²⁵ Overall, prescribing controlled substances via telemedicine requires additional steps and precautions to ensure the safety and appropriate use of these medications.

The RHA prohibits controlled substances dispensed by means of the internet such that “[n]o 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.”²⁶ A valid prescription is one that is “issued for a legitimate medical purpose in the usual course of professional practice by a practitioner that has conducted at least one *in-person* medical evaluation of the patient, or a covering practitioner.”²⁷ Therefore, to comply with federal law, a practitioner prescribing a controlled substance through telemedicine must have already evaluated the patient in person or have a covering practitioner evaluate the patient.²⁸ A covering practitioner is a practitioner who conducts a medical evaluation at the request of a practitioner who “has conducted at least one *in-person* evaluation of the patient or an evaluation of the patient through the practice of telemedicine within the previous twenty-four months, and is currently unavailable to conduct the evaluation.”²⁹

²² *Internet Pharmacy Warning Letters*, U.S. FDA, <https://www.fda.gov/drugs/drug-supply-chain-integrity/internet-pharmacy-warning-letters> (collecting letters) (last updated Feb. 20, 2024).

²³ See generally American Academy of Family Physicians, *Legal Requirements for Telehealth*, American Academy of Family Physicians, <https://www.aafp.org/family-physician/practice-and-career/managing-your-practice/telehealth-and-telemedicine/legal-requirements-for-telehealth.html> (last visited Apr. 5, 2024).

²⁴ *Id.*

²⁵ *Id.*

²⁶ 21 U.S.C. § 829(e)(1).

²⁷ *Id.* § 829(e)(2)(A)(i)–(ii).

²⁸ *Id.*

²⁹ *Id.* § 829(e)(2)(C)(i)–(ii) (emphasis added).

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2. Issues with the Ryan Haight Act

Although the RHA has successfully reduced the number of rogue online pharmacies, it has also created roadblocks for legitimate telehealth providers.³⁰ The most popular contention with the RHA regards the DEA's failure to create exceptions carved out for legitimate telehealth providers.³¹ The exceptions are intended to provide legal support for legitimate patient-provider encounters utilizing telemedicine.³² 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."³³ Pursuant to the exceptions, the Attorney General is authorized to issue special registration to telemedicine providers.³⁴ Special registration can be provided upon a showing that the practitioner has a legitimate need for the special registration and the practitioner registers in the state in which the patient is located when receiving telemedicine services.³⁵ To date, no practitioner has received access to the special registration process.³⁶ Organizations, professional associations, and politicians have made public statements expressing their discontent with the DEA's failure to enact the special registration program.³⁷ Without the special

³⁰ Dillon Vaughn, Comment, *Amending the Ryan Haight Act: Elevating Telemedicine Law to New Heights*, 7 TEX. A&M L. REV. 475, 495 (2020) ("Additionally, the Ryan Haight Act has prevented individuals from getting treatment they need—a consequence unintended by Congress when it passed the Act.") [<https://doi.org/10.37419/LR.V7.I2.6>].

³¹ 21 U.S.C. § 831(h) ("Special registration for telemedicine"); Heather Landi, *Will the DEA, Finally, Set Special Registration Process for Telehealth Prescribing? Doctors and Lawmakers Urge Yes Doctors and Lawmakers Say it's Long Overdue*, FIERCE HEALTHCARE (Sept. 13, 2023, 2:00 PM), <https://www.fiercehealthcare.com/health-tech/will-dea-finally-set-special-registration-process-telehealth-prescribing-doctors-and>.

³² VICTORIA L. ELLIOT, CONG. RSCH. SERV., R45240, THE SPECIAL REGISTRATION FOR TELEMEDICINE: IN BRIEF, (updated Dec. 7, 2018), <https://sgp.fas.org/crs/misc/R45240.pdf>.

³³ *Id.* at 2; see also *Naloxone DrugFacts*, NAT'L INST. ON DRUG ABUSE (Jan. 11, 2022), <https://nida.nih.gov/publications/drugfacts/naloxone>.

³⁴ 21 U.S.C. § 831(h) ("The Attorney General may issue to a practitioner a special registration to engage in the practice of telemedicine for purposes . . . of this title if the practitioner, upon application for such special registration—(A) demonstrates a legitimate need for the special registration; and (B) is registered under section 823(g) in which the patient will be located when receiving the telemedicine treatment.").

³⁵ 21 U.S.C. § 831(h)(1)(A)–(B).

³⁶ ELLIOT, *supra* note 32, at 2.

³⁷ Letter from Senator Claire McCaskill, Senator Lisa Murkowski & Senator Dan Sullivan to Robert W. Patterson, Acting Adm'r, DEA, (Jan. 30, 2018), <https://www.hsgac.senate.gov/wp-content/uploads/imo/media/doc/2018-01->

registration process, almost all telemedicine providers that prescribed controlled substances over the internet without an in-person exam have become obsolete. An absence of such registration has erased rogue online pharmacies and legitimized online providers in its wake. Legitimate providers include healthcare professionals who are licensed, certified, and authorized to provide medical care in their respective jurisdictions. However, DEA waivers during the public health emergency have materially changed how the RHA is applied, possibly making the Act a remnant of abandoned legislation.

B. COVID-19 and the Relaxation of the Ryan Haight Act

In December 2019, COVID-19 spread globally and forever changed the healthcare landscape in the United States.³⁸ Preventative and proactive measures intended to slow the spread of the virus were implemented, including instituting quarantine periods for those evacuated from foreign nations.³⁹ The World Health Organization characterized the novel outbreak as a pandemic due to increased infection rates across the United States and around the world.⁴⁰ The President published an executive order that granted the Secretary of Health and Human Services (“The Secretary”) the authority to modify or waive certain healthcare-related requirements to mitigate the impact of the disease throughout the country.⁴¹

Generally, a prescription for a controlled substance by means of the internet must be predicated on an in-person examination by a provider as required by the RHA.⁴² However, an exception to this rule was allowed when the Secretary declared a public health emergency pursuant to the PHSA.⁴³ On March 16, 2020, the Secretary, with the concurrence of the DEA administrator, designated that the telemedicine

30%20CMC%20Murkowski%20Sullivan%20ltr%20to%20DEA%20re%20telemedicine.pdf.

³⁸ Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak, *supra* note 4.

³⁹ Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak, *supra* note 4.

⁴⁰ Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak, *supra* note 4.

⁴¹ Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak, *supra* note 4.

⁴² 21 U.S.C. § 829(e)(2)(A)(i) (“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.”).

⁴³ 21 U.S.C. § 831(h); Public Health Service Act, 42 U.S.C. §§ 201 et seq. (2018).

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allowance under Section 802(54)(D) “applies to all schedule II-V controlled substances in the United States.”⁴⁴ In practice, this allows prescribers in all areas of the United States to issue prescriptions for controlled substances to patients for whom they have *not* examined in person, provided that certain conditions are met:

- (1) The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of their professional practice;⁴⁵
- (2) The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system;⁴⁶ and
- (3) The practitioner is acting in accordance with applicable Federal and State laws.⁴⁷

These new provisions were intended to continue for as long as the Secretary’s designation of a public health emergency remained in effect.⁴⁸ If a practitioner is able to satisfy the required conditions, they may issue prescriptions using any qualifying method set forth in the DEA regulations.⁴⁹ It is important to note that if the prescriber has previously performed an in-person examination of the patient, the prescriber may issue a prescription for a controlled substance upon communicating with the patient via telemedicine or any other means, regardless of whether a public health emergency has been declared.⁵⁰

On March 31, 2020, the DEA released a statement exercising its authority “to provide flexibility in the prescribing controlled substances to ensure necessary patient therapies remain accessible.”⁵¹ The DEA

⁴⁴ Telemedicine Flexibilities, 42 C.F.R. § 12.1(b)(2)(i) (2023).

⁴⁵ See 21 C.F.R. § 1306.04(a) (“A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.”).

⁴⁶ Press Release, U.S. DEA, DEA’s Response to COVID-19 (Mar. 20, 2020), <https://www.dea.gov/press-releases/2020/03/20/deas-response-covid-19>.

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ U.S. Drug Enforcement Administration, Telemedicine, COVID-19 Information Page, <https://www.deadiversion.usdoj.gov/faq/coronavirus-faq.html#telemedicine> (last visited Apr. 5, 2024).

⁵¹ Letter from Thomas W. Prevoznik, Deputy Assistant Adm’r Diversion Control Division, U.S. Dep’t of Just: DEA, to DEA Qualifying Practitioners (March 31, 2020) [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-022\)\(DEA068\)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20\(Final\)%20+Esign.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf).

partnered with SAMHSA to clarify the regulations and waivers surrounding treatment of patients with opioid use disorder (OUD) throughout the duration of the public health emergency.⁵² This statement also addressed a new flexibility regarding the prescribing of buprenorphine for detoxification treatment.⁵³ The DEA granted practitioners further authority to prescribe “to new and existing patients with OUD via telephone ... without requiring such practitioners to first conduct an examination of the patient *in person* or via telemedicine.”⁵⁴ This new additional flexibility was intended to remain in effect until the public health emergency ends or unless the DEA specifies an earlier date.⁵⁵

The CSA allows providers to prescribe certain medications, including buprenorphine, to patients with OUD for treatment if the provider registers with the DEA as an opioid treatment program.⁵⁶ There is also a waiver for this registration under the CSA for practitioners dispensing schedule III, IV, or V narcotic controlled substances approved by the FDA specifically for the use in maintenance or detoxification treatment.⁵⁷ Buprenorphine is the only controlled substance to meet these criteria. Despite the CSA’s restriction on prescribing controlled substances through online means, a practitioner may prescribe buprenorphine to a new patient via telemedicine without performing an *in-person* examination during the public health emergency.⁵⁸ Independently, SAMHSA exempted opioid treatment providers from the *in-person* visit requirement and allowed for the prescription of buprenorphine to patients by providers after an evaluation via telephone.⁵⁹

When addressing the various public health emergency waivers, the DEA expressed its reservation to allow treatment for OUD with a

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ 21 U.S.C. § 823(h) (“Practitioners who dispense narcotic drugs ... to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment.”).

⁵⁷ *Id.*; see also 21 C.F.R. § 1301.28.

⁵⁸ 21 U.S.C. § 802(54)(D).

⁵⁹ *FAQs: Provision of Methadone and Buprenorphine for the Treatment of Opioid Use Disorder in the COVID-19 Emergency*, SAMHSA (updated Apr. 21, 2020), <https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf>.

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controlled substance based on a “mere phone call” and acknowledged that doing so creates a high risk of diversion from the intended goal.⁶⁰ The DEA goes on to state that these new guidelines and rules for the prescription of controlled substances are subject to change after the cessation of the public health emergency.⁶¹ Through its own guidance, the DEA showed hesitation to allow this loosened version of prescription guidelines to continue in a post-pandemic world.⁶²

C. Cross-State Reciprocity for Telemedicine

After the Secretary declared a public health emergency in response to COVID-19, many states followed suit.⁶³ In addition to state-specific public health emergency declarations, many states granted reciprocity to neighboring states with regard to medical licensing requirements.⁶⁴ This means that practitioners in participating states are now permitted by state law to prescribe in states with which their home state has reciprocity.⁶⁵ The DEA’s registration requirement in each state in which a practitioner intends to prescribe is a core requirement to diversion control and would not typically be subject to an exemption.⁶⁶ However, the DEA attributes this rare waiver to the “extraordinary circumstances that have arisen during this public health emergency, and in order to ensure adequate medical care for the duration of this public health emergency.”⁶⁷ In doing so, the DEA granted an exception for practitioners in participating states to the provision that would normally require the practitioner to register in each state where they prescribe controlled substances.⁶⁸ This waiver was only intended to last so long as the public health emergency declaration is active.⁶⁹

⁶⁰ Letter from Thomas W. Prevoznik, *supra* note 51.

⁶¹ Letter from Thomas W. Prevoznik, *supra* note 51.

⁶² Letter from Thomas W. Prevoznik, *supra* note 51.

⁶³ Letter from William T. McDermott, Assistant Adm’r, Diversion Control Division, U.S. Dep’t of Just: DEA, to DEA Registrants (March 25, 2020), [https://www.deaiversion.usdoj.gov/GDP/\(DEA-DC-018\)\(DEA067\)%20DEA%20state%20reciprocity%20\(final\)\(Signed\).pdf](https://www.deaiversion.usdoj.gov/GDP/(DEA-DC-018)(DEA067)%20DEA%20state%20reciprocity%20(final)(Signed).pdf).

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.*; see generally 21 C.F.R. § 1307.03 (“Any person may apply for an exception to the application of any provision of this chapter by filing a written request with the Office of Diversion Control, Drug Enforcement Administration, stating the reasons for such exception.”).

⁶⁷ Letter from William T. McDermott, *supra* note 63.

⁶⁸ Letter from William T. McDermott, *supra* note 63.

⁶⁹ Letter from William T. McDermott, *supra* note 63.

In summary, practitioners are required to be registered with the DEA in at least one state and must be authorized under state law to prescribe controlled substances in the state where the medication is dispensed.⁷⁰ According to DEA guidance, “a practitioner must continue to comply with the laws and regulations of the state in which they are registered and to the laws and regulations of the state in which they are practicing, if different.”⁷¹ Accordingly, if one state’s laws are more restrictive than another, the practitioner is advised to follow the more restrictive laws in order to guarantee compliance and ensure the grant of reciprocity.⁷²

III. THE NEED FOR POST-PANDEMIC TELEMEDICINE REGULATION

The pandemic disrupted the course of traditional medical practices, which led to waived regulations, new technological advances, and a host of unanswered questions. Tension amongst government branches, agencies, and the general public has spurred discussion of a post-pandemic plan. During the pandemic, politicians urged for telemedicine regulation by way of RHA special registration.⁷³ However, HHS released its own proposal for the future of telemedicine upon the official end of the public health emergency.⁷⁴ Both plans offer opportunities to regulate telemedicine, each offering support for their conclusions. Part III examines both the possibility of a special registration pursuant to the RHA as well as the roadmap set forth by HHS on February 9, 2023.

A. *Special Registration Pursuant to the RHA*

The RHA has acted as a barrier to accessing medication-assisted treatment for those who suffer from both substance abuse issues and

⁷⁰ Letter from William T. McDermott, *supra* note 63.

⁷¹ Letter from William T. McDermott, *supra* note 63.

⁷² Letter from William T. McDermott, *supra* note 63.

⁷³ Letter from Senator Mark Warner, Virginia, to Merrick Garland, Att’y Gen., and Hon. Anne Milgram, Adm’r DEA, (Aug. 16, 2022), <https://www.warner.senate.gov/public/index.cfm/2022/8/warner-pushes-for-plan-to-ensure-patient-access-to-care-pending-expiration-of-covid-19-public-health-emergency> (asking the agencies to explain their plan to ensure continuity of care for patients being prescribed controlled substances via COVID-19 Public Health Emergency (PHE) telemedicine flexibilities).

⁷⁴ *Telehealth Policy Changes After the COVID-19 Public Health Emergency*, TELEHEALTH.HHS.GOV, <https://telehealth.hhs.gov/providers/policy-changes-during-the-covid-19-public-health-emergency/policy-changes-after-the-covid-19-public-health-emergency> (last updated Dec. 19, 2023).

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mental health disorders.⁷⁵ These unfavorable unintended consequences were unknown to Congress fourteen years ago when the RHA was passed.⁷⁶ During the pandemic, the RHA initially prohibited providers from using telemedicine to supplement interrupted health care. The government provided various waivers that allowed for exceptions to regulations in order to allow health care to continue during the public health emergency. Waivers only temporarily solve a greater issue: the absence of a permanent telemedicine regulatory scheme. Medical professionals and policymakers have viewed the RHA special registration provision as the answer to their concerns.⁷⁷ The RHA indicated that the DEA is to create a special registration to be provided upon a showing that the practitioner has a legitimate need for the special registration and is registered in the state where the patient is located when receiving telemedicine services.⁷⁸ However, such registration has not been created.

In 2018, during an effort to force open the DEA's special registration process, President Trump signed into law the SUPPORT for Patients and Communities Act ("the SUPPORT Act").⁷⁹ The SUPPORT Act contained a chapter labeled "Special Registration for Telemedicine Clarification Act of 2018."⁸⁰ Specifically, it stated that:

Not later than [one] 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 ... the limited circumstances in which a special registration under this subsection may be issued; and ... the procedure for obtaining a special registration under this subsection.⁸¹

⁷⁵ Kayla R. Bryant, *STRATEGIC PERSPECTIVES: States Fail to Fully Use Telemedicine to Fight Public Health Crises*, WOLTERS KLUWER: HEALTH LAW DAILY WRAP UP (Sept. 28, 2018), <https://perma.cc/WX6A-J3MJ>.

⁷⁶ See generally Shilpa N. Gajarawala & Jessica N. Pelkowski, *Telehealth Benefits and Barriers*, 17 J. FOR NURSE PRAC. 218 (Feb. 17, 2021) ("The original concept of telehealth was providing basic care to rural and underserved patients. Wider acceptance and incorporation of telehealth can be attributed to several factors. . . . With increasing emphasis and pressure for hospitals and providers to provide quality patient care and cut costs, telehealth has found acceptance and success in multiple medical specialties and settings.") [<https://doi.org/10.1016/j.nurpra.2020.09.013>].

⁷⁷ 21 U.S.C. § 831(h).

⁷⁸ *Id.*

⁷⁹ Support for Patients and Communities Act, Pub. L. No. 115-271, 132 Stat. 3892 (2018).

⁸⁰ *Id.* at 3949–50.

⁸¹ *Id.*

The SUPPORT Act required the DEA to establish the special registration process within ninety days of enactment; however, the DEA indicated that this expedited timeline would be burdensome and requested an extension.⁸² In response, the government extended the deadline to within one year of enactment.⁸³ This deadline and an opportunity to remedy the uncertainty surrounding the future of telemedicine was yet again missed.

On October 26, 2020, more than eighty organizations continued to call upon the DEA to finalize the special registration.⁸⁴ In a letter to the DEA, the organizations stated their experience during the public health emergency “has demonstrated the value of increased access to telemedicine to enable all qualified providers, including Community Mental Health Centers and addiction treatment facilities, to prescribe Medication Assisted Treatment to patients with Opioid Use Disorder.”⁸⁵ The delay by the DEA continued to frustrate health care providers, given the growing demand for prescription medication via telehealth throughout the country.⁸⁶ At the time the letter was written, six months into the COVID-19 pandemic, more than forty states reported increases in opioid-related deaths.⁸⁷ The organizations took the position that “[t]elemedicine is one of the key means of addressing this worsening crisis by expanding access to addiction treatment in underserved communities, rural areas, and communities of color.”⁸⁸ Although the DEA had loosened the telemedicine restrictions during the public health emergency, these organizations were acutely aware of the need for permanent statutory change. The letter concluded with a final plea for change:

The DEA also recognized the immediate need for expanded access to remote care during the pandemic and, in partnership with the Substance Abuse and Mental Health Services Administration (SAMHSA), exercised its regulatory authority to permit remote prescribing of controlled substances using

⁸² Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, 88 Fed. Reg. 12875 (proposed Mar. 1, 2023) (to be codified at 21 C.F.R. pts. 1300, 1304 & 1306).

⁸³ Support for Patients and Communities Act, Pub. L. No. 115-271, 132 Stat. 3892, 3949–50 (2018).

⁸⁴ Letter from Abbott House, et al., to the Honorable Timothy Shea, Acting Adm’r, DEA (Oct. 26, 2020), <https://www.pursuecare.com/wp-content/uploads/Group-Letter-on-Special-Telemedicine-Registration-10-26-20-1.pdf>.

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ *Id.*

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telemedicine without a prior in-person exam, regardless of the patient's location (if the prescribing is medically appropriate and the prescriber is DEA registered). In particular, this has allowed buprenorphine/Suboxone initiation over telemedicine. While we appreciate these PHE-related changes, statute requires the implementation of a permanent regulation. The time for that regulation is long overdue.⁸⁹

The organizations encouraged the DEA to open the special registration process to enable SAMHSA waived clinicians, mental health centers, and addiction treatment facilities to prescribe medically assisted treatment to patients with OUD and other mental health disorders via telemedicine.⁹⁰ This proposition garnered support from political figures as well. In August of 2022, Senator Mark Warner wrote to the Attorney General and DEA Administrator expressing his frustrations regarding the special registration for telemedicine providers.⁹¹ In his letter, Senator Warner stated his concern for patients at risk of having their health care interrupted when the DEA public health emergency flexibilities ceased.⁹² No progress was made in effectuating permanent legislature regulating telemedicine. The stalemate continued between healthcare providers and the DEA.

1. Fraud and Abuse Potential

The need for a special registration process became more evident as practitioners began engaging in modernized telemedicine fraud and abuse.⁹³ As just one example, in April of 2022, the Department of Justice (DOJ) released information regarding an indictment charging an orthopedic surgeon with a litany of offenses involving abuse of telemedicine.⁹⁴ Breon Peace, United States Attorney for the Eastern

⁸⁹ *Id.*

⁹⁰ Letter from More than Eighty Organizations, *supra* note 84.

⁹¹ Letter from Mark R. Warner, Senator for Virginia, to Merrick B. Garland, Attorney General, and Anne Milgram, DEA Adm'r, (Aug. 16, 2022) https://www.warner.senate.gov/public/_cache/files/1/c/1cec8036-b470-4ebd-9d9e-123dff876c48/AAB5069A5C4A588DE453DC645A7334D1.2022.08.16-dea-phe.pdf.

⁹² *Id.*

⁹³ *Telehealth-Related Fraud Has Spiked, Government Watchdog Warns*, KFF HEALTH NEWS (Feb. 22, 2021), <https://khn.org/morning-breakout/telehealth-related-fraud-has-spiked-government-watchdog-warns/> ("A federal government watchdog is sounding the alarm that Americans' growing enthusiasm for telehealth services during the coronavirus pandemic has led to a worrying parallel: a 'dramatic increase' in telehealth-related fraud.").

⁹⁴ Press Release, U.S. Att'y Off. E.D.N.Y., Physician Indicted in \$10 Million Telemedicine Health Care Fraud Scheme (Apr. 21, 2022),

District of New York, stated that “[i]n exchange for kickbacks from telemedicine companies, Dr. Raffai allegedly submitted millions of dollars in false and fraudulent claims to Medicare on behalf of beneficiaries without even examining them or based on conversations on the phone that lasted less than three minutes.”⁹⁵ According to the indictment, Dr. Raffai engaged in the purported practice of telemedicine with numerous telemedicine providers that would then compensate him for consultations with patients.⁹⁶ This type of arrangement between doctors and telemedicine companies opens the door for abuse of telemedicine, injury to patients, as well as the unnecessary cost on federally funded health care programs.⁹⁷

On July 20, 2022, HHS released a special alert with information pertaining to arrangements with telemedicine companies and indicated characteristics which could be viewed as suspect for fraud or abuse.⁹⁸ The OIG conducted dozens of investigations into fraud schemes through the use of telehealth, telemedicine, and other online medical platforms.⁹⁹ For example,

in some of these fraud schemes Telemedicine Companies intentionally paid physicians and nonphysician practitioners kickbacks to generate orders or prescriptions for medically unnecessary durable medical equipment, genetic testing, wound care items, or prescription medications, resulting in submissions of fraudulent claims to Medicare, Medicaid, and other Federal health care programs.¹⁰⁰

This special fraud alert, in addition to all past OIG alerts, was intended to put medical professionals and other providers on notice of

<https://www.justice.gov/usao-edny/pr/physician-indicted-10-million-telemedicine-health-care-fraud-scheme>.

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.* (FBI Special Agent-in-Charge stating “[h]ealthcare fraud is a serious crime that impacts every American. Dr. Raffai cheated the system for his own personal gain in the amount of \$10 million. Like many others who commit healthcare fraud, Dr. Raffai’s crimes contribute to the rising cost of health care for everyone. The FBI, along with our partners, will continue to investigate healthcare fraud to ensure these individuals who willingly defraud the American people are brought to justice.”).

⁹⁸ U.S. Dep’t of Health and Hum. Serv., *Special Fraud Alert: OIG Alerts Practitioners to Exercise Caution When Entering into Arrangements with Purported Telemedicine Companies* (July 20, 2022), <https://oig.hhs.gov/documents/root/1045/sfa-telefraud.pdf>. [hereinafter *Special Fraud Alert*]

⁹⁹ *Id.*

¹⁰⁰ *Id.*

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potentially illegal behaviors.¹⁰¹ This alert, in particular, draws focus to the potential for harm through the abuse of telemedicine.¹⁰² The increase in telemedicine fraud schemes during the public health emergency carries with it the possibility for federal law implications.¹⁰³ Practitioner arrangements with telemedicine companies may also lead to criminal, civil, or administrative liability under other Federal laws including, for example, OIG's exclusion authority related to kickbacks,¹⁰⁴ the Civil Monetary Penalties Law provision for kickbacks,¹⁰⁵ the criminal health care fraud statute,¹⁰⁶ and the False Claims Act.¹⁰⁷ Practitioners and telemedicine companies have been held civilly, criminally, and administratively liable for federal crimes.¹⁰⁸ Fraud and abuse of telemedicine during a time of relaxed regulations due to a public health emergency further strengthen the conclusion that serious consideration into permanent regulations should be a priority in post-pandemic legislature. Implementing the DEA special registration provision would provide a pathway for legitimate telemedicine providers to engage with telemedicine companies in a legal and ethical relationship to provide medical services to qualifying patients.

¹⁰¹ See, e.g., U.S. Dep't of Health and Hum. Serv., *Special Fraud Alert: Laboratory Payments to Referring Physicians* (June 25, 2014), https://oig.hhs.gov/documents/special-fraud-alerts/866/OIG_SFA_Laboratory_Payments_06252014.pdf; see also U.S. Dep't of Health and Hum. Serv., *Special Fraud Alert: Physician Liability for Certifications in the Provision of Medical Equipment and Supplies and Home Health Services* (Jan. 1999), <https://oig.hhs.gov/documents/special-fraud-alerts/872/dme.htm.html>; U.S. Dep't of Health and Hum. Serv., *Special Fraud Alert: Arrangements for the Provision of Clinical Laboratory Services* (Dec. 19, 1994), <https://oig.hhs.gov/documents/physicians-resources/980/121994.pdf>.

¹⁰² *Special Fraud Alert*, *supra* note 98.

¹⁰³ 42 U.S.C. § 1128B(b) (The Social Security Act) (The Federal anti-kickback statute applies broadly to remuneration to induce or reward referrals of patients as well as the payment of remuneration intended to induce or reward the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any item or service reimbursable by any Federal health care program.)

¹⁰⁴ 42 U.S.C. § 1320a-7(b).

¹⁰⁵ 42 U.S.C. § 1128A(a)(7); 42 U.S.C. § 1128B(b).

¹⁰⁶ 18 U.S.C. § 1347.

¹⁰⁷ 31 U.S.C. § 3729.

¹⁰⁸ See, e.g., Press Release, U.S. Att'y Off. for S.D. of Ga., Georgia Nurse Practitioner Convicted of Health Care Fraud in Complex Telemedicine Fraud Scheme (Feb. 2, 2022); Press Release, U.S. Att'y Off. for the W.D. of Mich., U.S. Attorney Announces Criminal and Civil Enforcement Actions Against Medical Practitioners For Roles In Telemedicine Fraud Schemes (Aug. 24, 2021); Press Release, U.S. Att'y Off. for the District of Mont., Two Montana Nurse Practitioners Admit Telemedicine Scheme to Defraud Medicare of More Than \$18 Million (Apr. 21, 2021).

2. The Return of Pre-RHA Rogue Online Pharmacies

The lack of regulatory guidance on telemedicine has essentially made way for the return of distribution of controlled substances through rogue online pharmacies. The FDA and DEA issued warning letters in April of 2022 pertaining to two websites illegally selling Schedule II stimulants, including amphetamine drug products marketed as Adderall.¹⁰⁹ These rogue online pharmacies sold Adderall, a controlled substance, without a prescription putting consumers at risk.¹¹⁰ The sale of controlled substances through unregulated online pharmacies in 2022 was the exact situation the RHA set out to prevent in 2008.¹¹¹ As stated by the FDA Commissioner,

The illegal sale of prescription drug stimulants online puts Americans at risk and contributes to potential abuse, misuse and overdose. These particular types of online pharmacies also undermine our efforts to help consumers safely purchase legitimate prescription medicines over the internet. FDA will continue partnering with DEA in an effort to safeguard public health and protect consumers who need access to these important medicines.¹¹²

The illegal marketing of prescription medication by online pharmacies puts consumer health at risk because the products may be “counterfeit, contaminated, expired or otherwise harmful.”¹¹³ In a warning letter, the Center for Drug Evaluation and Research (CDER) requested that the online pharmacies take any necessary corrective action and notify the DEA and the FDA of any remedial steps that they have taken to address violations of federal law.¹¹⁴ The letter goes on to explain to the recipients why the violations fall under the RHA and how

¹⁰⁹ U.S. FDA, *FDA and DEA Warn Online Pharmacies Illegally Selling Adderall to Consumers*, PR NEWswire (Apr. 12, 2022), <https://www.prnewswire.com/news-releases/fda-and-dea-warn-online-pharmacies-illegally-selling-adderall-to-consumers-301524032.html> (“Adderall is an FDA-approved prescription drug that has a high potential for abuse and addiction and should only be used under the supervision of a licensed health care professional.”).

¹¹⁰ *Id.*; see also NAT’L ASS’N OF BDS. OF PHARMACY, *Rogue Online Pharmacies in the Time of Pandemic: Capitalizing on Misinformation and Fear* (May 2020), <https://nabp.pharmacy/wp-content/uploads/2020/05/Rogue-Rx-Activity-Report-May-2020.pdf> (“Rogue internet pharmacy networks are run by criminal opportunists.”).

¹¹¹ U.S. FDA, *supra* note 109.

¹¹² U.S. FDA, *supra* note 109.

¹¹³ U.S. FDA, *supra* note 109.

¹¹⁴ Letter from The U. S. FDA and The U.S. DEA, to www.kubapharm.com (March 30, 2022) (on file with U.S. FDA), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/kubapharmcom-622051-03302022> [hereinafter Letter to www.kubapharm.com]

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their actions have led to violations of federal law.¹¹⁵ The perpetuation of rogue online pharmacies through the exploitation of telemedicine has led to implications unperceivable at the time of the RHA's enactment.

The CDER warning letter notes that the companies are not entitled to a modified or waived DEA registration that would otherwise allow for the distribution of scheduled medications within interstate commerce by means of the internet.¹¹⁶ Unfortunately, the increase in acceptance of telemedicine has allowed companies such as KubaPharm to bend the rules of regulations pertaining to the prescription of scheduled drugs through online telemedicine platforms.¹¹⁷ KubaPharm specifically markets a service described as "Buy Adderall Online Now" which promotes the prescription of the amphetamine drug product.¹¹⁸ Adderall, an FDA-approved medication for the treatment of attention deficit hyperactivity and narcolepsy, requires a prescription; however, KubaPharm distributed the medication to consumers without proper prescriptions.¹¹⁹ PremiumLightSupplier, another online pharmacy, received a similar warning from the CDER pertaining to its illegal activity distributing similar scheduled medications online.¹²⁰ Rogue online pharmacies such as KubaPharm and PremiumLightSupplier violate the RHA by failing to register with the DEA despite knowingly or intentionally advertising the sale of and distributing controlled substances.¹²¹ CDER provided these companies with fifteen days to respond to the appropriate agencies with specific steps to address the violations or steps they plan on taking to prevent to reoccurrence of similar violations.¹²²

This is the exact situation that would be avoided by a special registration procedure promulgated by the DEA. Special registration would ensure that legitimate healthcare providers are the only ones able to prescribe controlled substances via telemedicine. By restricting

¹¹⁵ *Id.*

¹¹⁶ *Id.* (stating that the company does not possess a valid modified DEA registration authorizing such activity, and your actions do not fall into the exceptions of 21 U.S.C. § 843(c)(2)(C)).

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ Letter from The U.S. FDA and The U.S. DEA, to premiumlightsupplier.com (March 30, 2022) (on file with U.S. FDA), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/premiumlightsuppliercom-622056-03302022> [hereinafter Letter to premiumlightsupplier.com].

¹²¹ *Id.*

¹²² Letter to www.kubapharm.com, *supra* note 114; Letter to premiumlightsupplier.com, *supra* note 120.

the prescription of controlled substances to legitimate healthcare providers, the special registration requirement helps prevent rogue online pharmacies from dispensing these substances illegally. Additionally, the law imposes penalties and fines on those who violate its provisions, further deterring illegal online pharmacies from operating. While the special registration requirement may not prevent all forms of illegal online pharmacies, it does help to regulate the prescription of controlled substances via telemedicine and reduce the risks associated with such activities.

3. Identifying a Modern Rogue Online Pharmacy

As government agencies and elected officials continue to fail to make any progress on an official telemedicine special registration procedure, the average person is left vulnerable to multibillion-dollar telemedicine companies. The FDA has published consumer guidance to assist in identifying a rogue online pharmacy before engaging as a patient.¹²³ The FDA warns of online pharmacies that purport to sell medications at a drastically reduced rate, often without requiring a valid prescription.¹²⁴ Rogue online pharmacies often allow the purchase of prescription medicine without a valid prescription from a health care provider; do not have a U.S. state-licensed pharmacist available to answer your questions; offer very low prices that seem too good to be true; send spam or unsolicited email offering cheap medicine; and are located outside of the United States or ship worldwide.¹²⁵

The medications sold at unregulated pharmacies can be dangerous because they have an improper amount of the active ingredient, do not contain the right active ingredient, or even contain incorrect or harmful ingredients.¹²⁶ Additionally, the FDA encourages consumers to know the signs of a safe online pharmacy.¹²⁷ Safe online pharmacies require a valid prescription from a licensed prescriber, are licensed by the appropriate state board of pharmacy, and have a U.S. state-licensed pharmacist available to answer questions.¹²⁸ Consumers may also check

¹²³ *How to Buy Medicines Safely from an Online Pharmacy*, U.S. FDA (Nov. 16, 2022), <https://www.fda.gov/consumers/consumer-updates/how-buy-medicines-safely-online-pharmacy>.

¹²⁴ *Id.* (“These Internet-based pharmacies often sell unapproved, counterfeit or otherwise unsafe medicines outside the safeguards followed by licensed pharmacies.”) [hereinafter *How to Buy Medicines Safely*].

¹²⁵ *See id.*

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ *Id.*

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for the National Association of Boards of Pharmacy's (NABP) Verified Internet Pharmacy Practice Sites Seal, also known as the VIPPS Seal.¹²⁹ This seal indicates that the Internet pharmacy is safe to use because it has met state licensure requirements, as well as other NABP criteria.¹³⁰

"Rogue Internet pharmacies often sell unapproved prescription drugs—including those that are substandard, counterfeit, and have no therapeutic value or are harmful to consumers."¹³¹ Consumers who have purchased medications from rogue pharmacies have experienced a variety of health concerns that have led to emergency treatment and, in some cases, death.¹³² Allowing online drug manufacturers and distributors the ability to sell medications to consumers without a valid prescription will lead to unregulated self-medication at the cost of the public's health. The RHA intended to combat this undesirable outcome of online pharmacies; however, the loosened restrictions and waivers in response to the COVID-19 public health emergency declaration reverse much of the progress made in combatting online pill mills.¹³³ Loosening the restrictions to allow prescribers to write and fill prescriptions without ever having to see the patient seemed like the only solution to the world that COVID-19 created.¹³⁴ However, this is not a permanent solution. The special registration protocol must be opened to take the burden off of the public and, in turn, hold telemedicine providers accountable.

As society continues to strive for some sense of normalcy again, the legal and medical professions will once again have to decide at what level prescription medication should be regulated.¹³⁵ This will

¹²⁹ See *How to Buy Medicines Safely*, *supra* note 123.

¹³⁰ See *How to Buy Medicines Safely*, *supra* note 123.

¹³¹ See U.S. GOV'T ACCOUNTABILITY OFF., GAO-13-560, *INTERNET PHARMACIES: FEDERAL AGENCIES AND STATES FACE CHALLENGES COMBATING ROGUE SITES, PARTICULARLY THOSE ABROAD* (2013).

¹³² *Id.*

¹³³ See Libby Baney, Jillian Brady & Sarah-Lloyd Stevenson, *The Future of Telehealth and the Ryan Haight Act Post-Pandemic*, NABP Blog (Apr. 22, 2021), <https://nabp.pharmacy/news/blog/the-future-of-telehealth-and-the-ryan-haight-act-post-pandemic/>; see *Determination of Public Health Emergency*, *supra* note 1.

¹³⁴ See *generally Reduced Access to Care*, CTRS. FOR DISEASE CONTROL AND PREVENTION (last reviewed Aug. 6, 2021), <https://www.cdc.gov/nchs/covid19/rands/reduced-access-to-care.htm> ("The Household Pulse Survey, an online survey conducted in response to the COVID-19 pandemic by the Census Bureau in partnership with other federal agencies . . . also reports estimates of reduced access to care during the pandemic.").

¹³⁵ *Federal Public Health Emergency Updates for 2022*, AM. SPEECH-LANGUAGE-HEARING ASS'N (Oct. 13, 2022), <https://www.asha.org/news/2022/federal-public-health-emergency-updates-for-2022/> ("The U.S. Department of Health and Human Services

ultimately require a balancing act in considering both the positive and negative consequences of continuing to allow patients to be treated without ever having seen the prescriber.¹³⁶ Although patients and providers have reported high rates of satisfaction with telemedicine platforms, there is an underlying urge to return to in-person visits on both sides of the aisle.¹³⁷ Even prior to COVID-19 and the declaration of a public health emergency, there were concerns of the unintended consequences of telemedicine.¹³⁸ The DEA must consider the proper means of establishing the special registration protocol.

B. HHS Proposed Roadmap to Post-Pandemic Telemedicine

On February 9, 2023, HHS announced its intention for the public health emergency declared under Section 319 of the PHSA to expire at the end of day on May 11, 2023.¹³⁹ The proposed roadmap for post-pandemic healthcare provides insight on some telemedicine changes but is not exhaustive.¹⁴⁰ Access to buprenorphine for opioid use disorder treatment in Opioid Treatment Programs (OTPs) will not be affected.¹⁴¹ Early in the COVID-19 pandemic, SAMHSA released guidance allowing patients to start buprenorphine in an OTP by telehealth without the required in-person physical examination first.¹⁴²

must renew the federal public health emergency related to COVID-19 every 90 days to maintain certain health care flexibilities and waivers.”).

¹³⁶ See generally Stacy Weiner, *What Happens to Telemedicine After COVID-19?*, AAMC (Oct. 21, 2021), <https://www.aamc.org/news-insights/what-happens-telemedicine-after-covid-19> (“As COVID-19 blazed across the country, nearly every state relaxed their licensing rules so outside physicians could provide telemedicine. Previously, doctors had to complete lengthy forms and pay steep fees to get a license in every state where a patient received remote care. Now, states are beginning to retighten their licensing rules. At least half have already done so, and others are soon to follow.”).

¹³⁷ Yuki Noguchi, *Patients Say Telehealth Is OK, But Most Prefer to See Their Doctor in Person*, NPR NEWS (Oct. 18, 2021) (citing a poll from the Robert Wood Johnson Foundation and the T.H. Chan School of Public Health at Harvard, “[a]round 42% of respondents said someone in their household had used telehealth. Of those, 82% reported satisfaction, yet nearly two-thirds — 64% — would have preferred to see their nurse or doctor in person.”).

¹³⁸ See S. B. Gogia, et al., *Unintended Consequences of Tele Health and Their Possible Solution*, 1 YEARB MED INFORM. 41–46 (Nov. 10, 2016) [<https://doi.org/10.15265/IY-2016-012>].

¹³⁹ Press Release, Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap, HHS (Feb. 9, 2023) <https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html>.

¹⁴⁰ *Id.* (indicating that Major Medicare telehealth flexibilities would not be affected as the majority of Medicare flexibilities will remain in place until December 2024 due to the Consolidated Appropriations Act passed in 2022).

¹⁴¹ *Id.*

¹⁴² *Id.*

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This flexibility has proven to be safe and effective in patient care such that SAMHSA proposed to make this flexibility permanent as part of changes to OTP regulations in a Notice of Proposed Rulemaking that it released in December 2022.¹⁴³ SAMHSA has committed to providing an interim solution if the proposed OTP regulations are not finalized prior to May 11, 2023.¹⁴⁴

Dividing drugs into those used for opioid use disorder treatment and those that are not would not be a simple or feasible solution for several reasons. Classifying drugs based on a single use, such as treatment for opioid use disorder, would not be an accurate reflection of their potential for abuse, addiction, or harm.¹⁴⁵ Many drugs used to treat other conditions, such as benzodiazepines or stimulants, have the potential for abuse and harm.¹⁴⁶ Additionally, there is a need for individualized care. The appropriate use of controlled substances requires individualized care and monitoring based on the patient's medical history, condition, and response to treatment.¹⁴⁷

The ability of health care providers to safely dispense controlled substances via telemedicine without an in-person interaction is affected; however, agencies propose to extend these flexibilities.¹⁴⁸ During the PHE, the DEA and HHS adopted policies to allow DEA-registered practitioners to prescribe controlled substances to patients without an in-person interaction.¹⁴⁹ These policies permitted the use of

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ Juliet P. Lee & Tamar M.J. Antin, *How Do Researchers Categorize Drugs, and How Do Drug Users Categorize Them?*, 38 CONTEMP DRUG PROBS. 387, 395 (2012) ("Due to these complications, key scientific institutions have opted for typologizing drugs by their pharmacology rather than their effects.") [<https://doi.org/10.1177/009145091103800304>].

¹⁴⁶ See American Academy of Pediatrics, *Benzodiazepine and Stimulant Prescriptions Before Overdose in Youth*, Pediatrics (2020), <https://publications.aap.org/pediatrics/article/doi/10.1542/peds.2020-039179/181476/Benzodiazepine-and-Stimulant-Prescriptions-Before> (last visited Apr. 7, 2024) (A study published in Pediatrics by the American Academy of Pediatrics investigated the prescription patterns of medications like benzodiazepines and stimulants in youth who experienced medically treated overdoses).

¹⁴⁷ See generally Charles V. Preuss, Arun Kalava & Kevin C. King, *Prescription of Controlled Substances: Benefits and Risks*, STATPEARLS [INTERNET] (last updated April 29, 2023), <https://www.ncbi.nlm.nih.gov/books/NBK537318/>.

¹⁴⁸ Press Release, Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap, *supra* note 139.

¹⁴⁹ Press Release, Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap, *supra* note 139.

audio-only methods to begin prescribing buprenorphine.¹⁵⁰ The DEA plans to introduce regulatory changes that would continue these flexible measures under specific conditions without interrupting care, and it will offer further advice to healthcare providers.¹⁵¹ The proposed roadmap from HHS provides insight on what is to come; however, the roadmap does not sufficiently address many of the unanswered questions surrounding the future of telemedicine.

1. The Move to Make DEA Waivers Permanent

During the public health emergency lockdowns and quarantines, telemedicine services received a trial by fire. As telemedicine surged, however, public policy and legislation failed to move at the same speed, therefore, creating pending uncertainties. The most prominent material impact on the growth of telemedicine during the public health emergency stemmed from the DEA's waiver concerning certain provisions of the RHA.¹⁵² In waiving the in-person examination requirement, the DEA set forth new guidelines for controlled substances.¹⁵³ The prescription must be issued for a legitimate medical purpose; the prescription must be issued by a practitioner acting in the usual course of their professional practice; practitioners must act in accordance with applicable federal and state laws; and new patients may now get a controlled substance prescription via telemedicine (meaning, without an in-person examination) *if* the telemedicine communication was conducted using an audio-visual, real-time, and two-way interactive communication system.¹⁵⁴

¹⁵⁰ Press Release, Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap, *supra* note 139.

¹⁵¹ Press Release, Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap, *supra* note 139.

¹⁵² COVID-19 FAQ, TELEMEDICINE, DEA DIVERSION CONTROL DIV., <https://www.deadiversion.usdoj.gov/faq/coronavirus-faq.html> (last visited Mar. 24, 2024) ("On March 16, 2020, the Secretary, with the concurrence of the Acting DEA Administrator, designated that the telemedicine allowance under section 802(54)(D) applies to all schedule II-V controlled substances in all areas of the United States. Accordingly, as of March 16, 2020, and continuing for as long as the Secretary's designation of a public health emergency remains in effect, DEA-registered practitioners in all areas of the United States may issue prescriptions for all schedule II-V controlled substances to patients for whom they have not conducted an in-person medical evaluation, provided all . . . conditions are met.").

¹⁵³ Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, *supra* note 82.

¹⁵⁴ Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, *supra* note 82.

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Since the early stages of the COVID-19 pandemic, there have been significant efforts to ensure the DEA waivers become permanent after the pandemic subsides. In March of 2022, the American Psychiatric Association, along with seventy-one other organizations, sent a letter to the DEA and HHS calling for the complete removal of the in-person examination requirement for prescribing controlled substances via telemedicine.¹⁵⁵ Shortly after, U.S. senators expressed the same concern. Senators Rob Portman and Sheldon Whitehouse also sent letters to the DEA and HHS “urging the agencies to use their authority under the [RHA] to ensure Americans can continue to access important medication ... via telehealth once the COVID-19 public health emergency ends.”¹⁵⁶ The senators’ move to make the waiver permanent began in June 2020 when they introduced the Telehealth Response for E-prescribing Addiction Therapy Services (TREATS) Act.¹⁵⁷ The TREATS Act would essentially make the DEA waiver permanent by allowing providers to prescribe controlled substances without needing a prior in-person visit.¹⁵⁸ If this introduced federal legislation does not pass, a conflict between federal and state laws is likely. During the pandemic and the public health emergency continuance, some states have made permanent regulations permitting the prescription of controlled substances via telemedicine.¹⁵⁹

¹⁵⁵ Letter from American Psychiatric Association et al., to Anne Milgram, Administrator, Drug Enforcement Administration DEA & Xavier Becerra, Secretary, Dep’t of Health and Hum. Servs. HHS (Mar. 3, 2022).

¹⁵⁶ Press Release, Sheldon Whitehouse, Whitehouse, Portman Urge DEA and HHS to Extend Americans’ Access to Telehealth Once the COVID-19 Public Health Emergency is Terminated (Apr. 1, 2022), <https://www.whitehouse.senate.gov/news/release/whitehouse-portman-urge-dea-and-hhs-to-extend-americans-access-to-telehealth-once-the-covid-19-public-health-emergency-is-terminated/#:~:text=We%20urge%20the%20Drug%20Enforcement,to%20access%20vital%20medication%20via.>

¹⁵⁷ *Id.*; see Telehealth Response for E-prescribing Addiction Therapy Services Act, S. 340, 117th Cong. (2021–2022) (modifying requirements relating to coverage of certain telehealth services under Medicare). Specifically, the bill permanently allows telehealth services for substance-use disorders and mental health disorders to be provided via audio-only technology if a physician or practitioner has already conducted an in-person or video telehealth evaluation. Schedule III or IV controlled substances may also be prescribed online if a practitioner has conducted a telehealth evaluation with video.

¹⁵⁸ Telehealth Response for E-prescribing Addiction Therapy Services Act, S. 340, 117th Cong. (2021–2022).

¹⁵⁹ See, e.g., Fla. Stat. § 456.47 (2022). During the 2019 legislative session, Florida passed section 456.47 Florida Statutes, which establishes standards of practice for telehealth services, including patient evaluations, and record-keeping. The law also authorizes out-of-state health care practitioners to perform telehealth services for

2. Consequences

There are compelling arguments against removing the in-person visit requirement for the prescription of certain medications, specifically controlled substances, and allowing telemedicine to continue pursuant to the public health emergency waivers. Telehealth platforms are limited in providing text, sight, and sound.¹⁶⁰ This forces providers to “treat an image” while being limited to listening to the patient’s concerns.¹⁶¹ Additionally, miscommunication affecting interpersonal relations between the care provider and the patient impacts quality of care.¹⁶² There is a myriad of requirements on top of compliance with new telehealth rules apart from just licensure, including “liability, jurisdiction, continuum of care, authentication, online prescription, data security, record keeping and in some instances the requirement of a prior doctor-patient relationship before a telemedicine consultation.”¹⁶³ Dependence on telehealth platforms added to the cost of care with less effect on positive outcomes. It is crucial that telehealth remains a system of support for existing care providers, but it should not be pushed as an engineering solution to the future of all health care.¹⁶⁴

The COVID-19-related DEA waivers allowing for increased flexibility for out-of-state providers have led and will continue to lead to unintended consequences such as fraud and limited patient access if made permanent.¹⁶⁵ Three major unintended consequences could prevail if permanent telehealth expansion is made post-public health emergency.¹⁶⁶

- (1) Limitations for vulnerable patients. People with limited internet access or tech literacy, including the elderly, poor and non-English speakers, may be left out of widespread expansions of telehealth.
- (2) Fraud increases. Many scammers are trying to steal patients’ identities and sell them on the black market.

patients in Florida. Signed by the Governor on June 25, 2019, this law became effective on July 1, 2019.

¹⁶⁰ S. B. Gogia, et al., *supra* note 138, § 1 Clinical Consequences.

¹⁶¹ S. B. Gogia, et al., *supra* note 138, § 1 Clinical Consequences.

¹⁶² S. B. Gogia, et al., *supra* note 138, § 2 Personnel.

¹⁶³ S. B. Gogia, et al., *supra* note 138, § 5 Legal and Ethical Considerations.

¹⁶⁴ S. B. Gogia, et al., *supra* note 138, § In Conclusion.

¹⁶⁵ See Jackie Drees, 3 *Unintended Consequences of Making Telehealth Rules Permanent*, KHN (March 22, 2021) <https://www.beckershospitalreview.com/telehealth/3-unintended-consequences-of-making-telehealth-rules-permanent-khn.html> (last visited Mar. 24, 2024).

¹⁶⁶ *Id.*

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- (3) Provider scams. Some providers have been overcharging for appointments, billing for services that weren't given or are not registered or licensed in the U.S.¹⁶⁷

C. *A New Regulatory Scheme*

As the future of online prescribing remains unknown, a new regulatory scheme for telehealth must be crafted. A moderate approach could be proposed; one that recognizes the need for telehealth, the interest in protecting patients with safety protocols, and the unique treatment of controlled substances. For example, the DEA could create a special registration process for legitimate telemedicine providers, which would enable the agency to implement oversight over the prescribers rather than restrict the prescribers' ability to practice medicine.¹⁶⁸

Interest in creating a carefully thought out legislative plan to regulate the practice of telemedicine continues to be a bi-partisan concern.¹⁶⁹ United States Representative Lloyd Doggett, a major voice on health care policy, stated that "he isn't against continuing a telehealth expansion that began with the pandemic, but is warning about the need to build protections against fraud into the law."¹⁷⁰ Doggett points out a flaw in the 2024 legislation extending Medicare reimbursements for medical visits that occur by video or phone call; "[w]henver billions of federal dollars are available anywhere, some will try to steal it and that's what's happening with telehealth."¹⁷¹ Concerns include that telehealth could become a modern avenue in enabling fraud, allowing providers to prescribe unneeded drugs at the cost of federal health care programs.¹⁷²

When reflecting on the changed landscape of how controlled substances are prescribed, it is evident that amidst the COVID-19 public health emergency, online rogue pharmacies have made their way

¹⁶⁷ *Id.*

¹⁶⁸ 21 U.S.C. § 831(h) (defining "practice of telemedicine" as including practice "conducted by a practitioner who has obtained from the Administrator a *special registration* under section 311(h) of the Act.").

¹⁶⁹ See Ben Leonard, *Fraud is the Killjoy at the Telehealth Party*, POLITICO (Aug. 7, 2022), <https://www.politico.com/news/2022/08/07/telehealth-pandemic-fraud-00049948> (last visited Mar. 24, 2024).

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

¹⁷² *Id.*

back.¹⁷³ In September of 2022, DEA agents began an investigation into Done Global Inc., a digital therapeutics company.¹⁷⁴

The inquiries in recent weeks suggest ongoing and potentially widening interest from federal authorities in online mental-health companies such as Done that during the Covid-19 pandemic have been prescribing stimulants like Adderall for treatment of attention-deficit hyperactivity disorder—drugs the U.S. government classifies as controlled substances in the same category as OxyContin.¹⁷⁵

Earlier in 2022, some of Done's clinicians felt that they were being pressured to prescribe controlled substances, as evidenced by an internal company report stating, "multiple Done providers have specifically expressed a perception of pressure to diagnose ADHD and prescribe stimulants."¹⁷⁶ Other telemedicine and telehealth providers have felt similar pressure from impending DEA investigations into the distribution of controlled substances via telemedicine.¹⁷⁷ The pandemic has acted as a trial run for telemedicine, and as the public health emergency approaches its final days, the DEA is in a position to act upon the future of telemedicine regulation, specifically as it pertains to controlled substances. It is evident that technology, medicine, and politics have evolved since 2008, further supporting the proposition that regulation of controlled substances through online pharmacies is a modern problem requiring a modern solution.

IV. CONCLUSION

The DEA waivers to the RHA and CSA during the COVID-19 public health emergency have had a detrimental effect on the policing of rogue online pharmacies.¹⁷⁸ There is a clear need for permanent regulations

¹⁷³ See generally 21 U.S.C. § 829; Nathaniel M. Lacktman, *Telemedicine Prescribing of Controlled Substances: What is the Ryan Haight Act?*, FOLEY & LARDNER LLP (April 3, 2017).

¹⁷⁴ Rolfe Winkler, *DEA Investigating ADHD Telehealth Provider Done*, WALL ST. J. (Sept. 16, 2022), <https://www.wsj.com/articles/dea-investigating-adhd-telehealth-provider-done-11663239601>.

¹⁷⁵ *Id.*

¹⁷⁶ *Id.*

¹⁷⁷ *Id.* (Truepill, another online medication providing platform, said in a statement that patient safety continues to be its top priority and that it currently isn't filling prescriptions for any controlled substances prescribed via telemedicine while it evaluates next steps).

¹⁷⁸ See, e.g., Press Release, Justice Department Charges Dozens for \$1.2 Billion in Health Care Fraud, Off. of Pub. Affs. (July 20, 2022) (announcing the criminal charges against telemedicine providing defendants for more than \$1.2 billion in alleged fraudulent telemedicine).

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to be proposed and adopted in order to address the future of telemedicine upon the conclusion of the public health emergency. Rogue online pharmacies dispensing controlled substances presented a grave concern in 2008 and they have resurfaced again as a concern aided primarily by DEA waivers. Both government officials and medical organizations have urged the DEA to finalize the special registration set forth in the RHA in hopes of addressing the problem before it is too late. The proposed roadmap released by the HHS on February 9, 2023, fails to consider special registration for legitimate telemedicine practitioners as an answer to the regulation of online healthcare practices. Rogue online pharmacies have taken advantage of waivers intended to ease the pains of the pandemic and have engaged in unregulated dispensing of controlled substances nationwide. The DEA must consider the doors it leaves open in a post-pandemic world when it fails to institute a uniform system for the policing of telemedicine, specifically the regulation of controlled and dangerous substances.