PRESCRIBING MEDICATION THROUGH THE PRACTICE OF TELEMEDICINE: A COMPARATIVE ANALYSIS OF FEDERAL AND STATE ONLINE PRESCRIBING POLICIES, AND POLICY CONSIDERATIONS FOR THE FUTURE

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I. **INTRODUCTION**

Telemedicine is a process by which healthcare providers communicate with patients remotely using telecommunications technology.¹ This practice is growing rapidly in the United States,² and some scholars estimate that the global telemedicine market will reach \$130 billion by 2025.³ In response to this rapid growth, both the federal government and most state governments have adapted their policies to accommodate the practice of telemedicine. For example, reimbursement for telemedicine appointments is now required under Medicare in certain circumstances, and reimbursement for telemedicine appointments is required for private insurers by a majority of states.4

As telemedicine becomes more ubiquitous in the American healthcare system, governments must establish the circumstances under which it is appropriate for a telemedicine provider to prescribe medication to patients. The federal government attempted to do so under the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, which regulates the circumstances in which controlled substances can be prescribed over the Internet.⁵ The act was passed to curb the rate of overdose deaths caused by unscrupulous prescribing and was named in honor of Ryan Haight, who died

Prescribing Controlled Substances via Telemedicine, COMPLIANCE TODAY 28, 31-32 (Jul. 2018).

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See Telemedicine Defined, AMD GLOBAL TELEMEDICINE, https://amdtelemedicine.com/ telemedicine-defined (last visited Nov. 7, 2019).

Private insurance claims for telemedicine services grew 53% between 2016 and 2017, outpacing all other types of care. Jeff Lagasse, Growth in Telehealth Outpaces That of Other Avenues of Care - At Least from 2016 to 2017, HEALTHCARE FINANCE (Apr. 1, 2019), https://www.healthcarefinance news.com/news/growth-telehealth-outpaces-other-avenues-care-least-2016-2017

Dave Muoio, Report: Global Telemedicine Market Will Hit \$130B by 2025, MOBIHEALTHNEWS (Mar. 26, 2019), https://www.mobihealthnews.com/content/report-global-telemedicine-market-will-hit-130b-2025

⁴ See 42 C.F.R. § 410.78(b) (2018) (requiring reimbursement for "covered telehealth services" under Medicare Part B); *Telemedicine Reimbursement Guide*, EVISIT, https://evisit.com/resources/ telemedicine-reimbursement-guide (last visited May 19, 2021) (discussing the procedure for telemedicine reimbursement under Medicare and listing the states that require private insurers to reimburse telemedicine appointments). The fact that many states have recently adopted policies for both public and private insurers to reimburse certain telemedicine appointments equally to in-person appointments, often called "telemedicine (or telehealth) parity," is outside the scope of this analysis. ⁵ 21 U.S.C. § 829; see Nathaniel M. Lacktman & Jacqueline N. Acosta, *Compliance Issues When*

after overdosing on prescription Vicodin that he ordered over the Internet without ever speaking to a doctor.6

In its current form, the Ryan Haight Act establishes a narrow set of circumstances under which controlled substances can be prescribed via telemedicine.⁷ As of January 2020, however, the DEA has failed to promulgate guidance on when telemedicine providers can prescribe medication outside of this narrow set of circumstances.⁸ Consequently, the federal policy exists in direct conflict with the policies of many states that seek to allow telemedicine providers to prescribe controlled substances more liberally.⁹ Moreover, state legislatures and state medical boards currently possess the bulk of policymaking power when it comes to prescribing medication via telemedicine. As a result, due to a vacuum created by the federal policy, some states have adopted highly restrictive policies that regulate beyond the intent underlying the Ryan Haight Act.¹⁰

Given the federal government's ongoing failure to expand the Ryan Haight Act, and given that states' online prescribing policies range from highly restrictive to highly liberal when compared with the federal policy, telemedicine providers currently practice under a degree of uncertainty, especially those who practice across state lines.¹¹ Furthermore, a variety of policy interests are implicated in the patchwork, nationwide regime of online prescribing. More liberal policies may spur growth in a variety of healthcare-related industries¹² and improve access to medication-assisted treatment,¹³ while more restrictive policies arguably stem from the proliferation of prescription drug abuse. For these reasons, it is worthwhile to describe in detail how state policies interact with the federal policy and to consider how a more cohesive regime could be implemented in the future that is cognizant of the various policy interests at play.

In this Note, I will describe online prescribing policies at the federal and state level and consider the future of online prescribing regulations as telemedicine becomes more integral to businesses within the American healthcare industry. To limit the scope of my analysis, in analyzing the federal policy and every state's policy, I sought to answer the following question: When you seek to establish a *patient-provider relationship* through a telemedicine encounter, under what circumstances can the provider write a

⁶ Telehealth Opioids and Ryan Haight Act: Update, TELEHEALTH.ORG (May 21, 2021), https://telehealth.org/ryan-haight-act/.

²¹ U.S.C. § 802(54)(A)–(G); Lacktman & Acosta, *supra* note 5, at 31.

⁸ Jacqueline N. Acosta & Nathaniel M. Lacktman, President Signs New Law Allowing Telemedicine Prescribing of Controlled Substances: DEA Special Registration to Go Live, FOLEY & LARDNER LLP: HEALTH CARE L. TODAY BLOG (Oct. 25, 2018), https://www.foley.com/en/insights/publications/ 2018/10/president-signs-new-law-allowing-telemedicine-pres. ⁹ See, e.g., CAL, BUS. & PROF. CODE § 2242 (West 2019) (allowing "dangerous" drugs, including

controlled substances, to be prescribed at the provider's professional discretion).

¹⁰ See, e.g., GA. COMP. R. & REGS. 360-3-.07 (2013); Nathaniel M. Lacktman & Thomas B. Ferrante, 10 Tips for Complying with Georgia's Telemedicine Laws, FOLEY & LARDNER LLP: HEALTH CARE L. TODAY BLOG (Feb. 26, 2018), https://www.foley.com/en/insights/publications/2018/02/10-tips-forcomplying-with-georgias-telemedicine-I. ¹¹ See Lacktman & Acosta, supra note 5, at 31–32.

¹² Xtelligent Healthcare Media Staff, Decade-Defining Moments in Healthcare Innovation, Reform, EHR INTELLIGENCE (Dec. 20, 2019), https://ehrintelligence.com/news/decade-defining-moments-inhealthcare-innovation-reform.

¹³ Lewei Lin et al., Telemedicine-Delivered Treatment Interventions for Substance Use Disorders: A Systematic Review, 101 J. SUBSTANCE ABUSE TREATMENT 38, 47 (2019).

valid prescription? Through the course of this analysis, I use the term "online prescribing" to represent this discrete situation. ¹⁴

In Part I, I will provide an overview of prescription drug regulation and enforcement in the United States, including a discussion of the extent to which the Controlled Substances Act preempts state laws. In Part II, I will describe the three major elements within online prescribing policies: 1) defining a valid patient-provider relationship; 2) limiting the types of technologies that can be considered "telemedicine"; and 3) establishing the types of medications that can be prescribed via telemedicine. In Part III, I will describe the federal government's regulation of online prescribing under the Controlled Substances Act and describe some findings from the limited case law on this subject. In Part IV, I will describe the overarching differences in all fifty states' online prescribing policies and tabulate those differences into a "liberality scale" based on how they differ from the federal online prescribing policy. These findings indicate that many states take a stricter approach to online prescribing than the federal government, while other states openly defy the federal policy by permitting controlled substances to be prescribed under a broader range of circumstances than those permitted under the Controlled Substances Act. In Part V, I will weigh the policy interests at stake and consider how expanding the nationwide regime of online prescribing poses both benefits and risks to the American healthcare system. I will then conclude that both the federal government and state governments should strictly regulate online prescribing for controlled and/or dangerous substances, but states should adopt more liberal policies in the context of prescribing non-dangerous medications to facilitate the benefits associated with telemedicine.

II. OVERVIEW OF PRESCRIPTION DRUG REGULATION IN THE UNITED STATES

Providers seeking to prescribe medication must comply with a variety of laws and regulations. Below, I have briefly outlined the relevant laws and regulations at the state and federal level, as well as the controversy over the interaction between policies at the state and federal level.

¹⁴ Naturally, "online prescribing" is not limited to these encounters. Other circumstances where "online prescribing" can legitimately transpire (depending on the state) include referrals from a provider with whom a patient has established a patient-provider relationship and various types of medical emergencies, such as a patient's life being in imminent danger, infectious disease outbreaks, or a patient's named sexual partner(s) being at risk of having a sexually transmitted disease. *See, e.g.*, Press Release, Iowa Bd. of Med., New Rule Sets Standards of Practice for Physicians Who Use Telemedicine (June 3, 2015) (on file with author). I limited my analysis to the above question given the structure of both the federal policy and state policies, which regulate by describing valid circumstances in which patientprovider relationships can be established. This circumstance would most commonly be a first-time encounter with a telemedicine provider, and the bulk of this analysis discusses first-time encounters. This analysis also does not discuss "e-prescribing" laws, which allow for providers to digitally transmit prescriptions to pharmacies and are undoubtedly crucial to any workable online prescribing policy. Eprescribing necessitates a patient-provider relationship, so it was outside the scope of this analysis. For a study on the massive benefits of expanding e-prescribing laws, see Amber Porterfield et al., *Electronic Prescribing: Improving the Efficiency and Accuracy of Prescribing in the Ambulatory Care Setting*, 11 PERSPS. HEALTH INFO. MGMT. 1 (Apr. 1, 2014) (stating that "medication errors have been reduced to as little as a seventh of their previous level, and cost savings due to improved patient outcomes and decreased patient visits are estimated to be between \$140 billion and \$240 billion over 10 years for practices that implement e-prescribing").

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STATE LAWS AND REGULATIONS A.

At the state level, providers are subject to restrictions on their conduct by the civil and criminal arms of state government and the disciplinary authority of state medical boards.¹⁵ State governments impose civil and/or criminal liability for unlawful provider conduct, while state medical boards control providers' licenses to practice medicine and have the power to revoke licenses when providers fail to comply with their professional and ethical obligations to patients.¹⁶ In the context of prescribing medication, state medical boards and state law enforcement often work in conjunction with each other; for example, a felony conviction for misprescribing often results in automatic revocation of a provider's license.17

Along with regulating the conduct of providers, most state governments denote substances that are subject to a heightened degree of oversight. All states have counterparts to the federal Controlled Substances Act (CSA) (described below), denoting "schedules" of substances of increasingly dangerous character with increasingly more stringent criminal penalties for illegal distribution-Schedule I being the most dangerous of these substances with no currently accepted medical use (i.e. the substance cannot be prescribed).¹⁸ Most states have "regulatory mechanisms, terminology, and provisions similar to those contained" in the federal CSA and impose criminal liability for prescribing these substances outside of the states' respective standards for legitimate medical practice.¹⁹ However, many state policies differ fundamentally from the CSA, which will be explored in detail in Part IV.²⁰

B. FEDERAL LAWS AND REGULATIONS

Prescription drugs are regulated at the federal level primarily by the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA). In general, the FDA is responsible for drug safety and affixing "Rx only" labels to drugs, while the DEA enforces restrictions on the distribution and prescription of controlled substances.²¹ Below, I have described the broad roles that the FDA and the DEA possess in the context of prescription medication.

¹⁵ Kelly K. Dineen & James M. DuBois, Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?, 42 AM. J. L. & MED. 7, 16 Presc. (2016). ¹⁶ Id.

¹⁷*Id*.

¹⁸ NAT'L CRIM. JUST. ASSOC., A GUIDE TO STATE CONTROLLED SUBSTANCES ACTS 5 (1999); see,

e.g., New Jersey Controlled Dangerous Substances Act, N.J. REV. STAT. §§ 24:21-4 to -5 (2013). ¹⁹ THE DEVELOPMENT OF MEDICATIONS FOR THE TREATMENT OF OPIATE AND COCAINE ADDICTIONS: ISSUES FOR THE GOVERNMENT AND PRIVATE SECTOR 14, 174 (Carolyn E. Fulco et al. eds.,

^{1995).} ²⁰ Cong. Rsch. Serv., Legal Authorities Under the Controlled Substances Act to

²¹ What Does FDA Regulate?, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/fdabasics/what-does-fda-regulate (Last updated Aug. 3, 2020).

1. The Food and Drug Administration

The FDA is a federal agency within the U.S. Department of Health and Human Services (HHS) that controls and supervises the commercial sale of various items, including prescription drugs.²² The FDA's authority in the context of prescription drugs stems from the Food, Drug, and Cosmetic Act (FDCA) of 1938.²³ Under the FDCA, the FDA is tasked with determining which medications (drugs/devices) can only be distributed through prescriptions by authorized providers for legitimate medical purposes.²⁴ The FDCA requires that drugs be administered by licensed practitioners when, "because of [the drug's] toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, [the drug] is not safe for use except under the supervision of a [licensed practitioner]."25 At a minimum, these drugs must bear the label "Rx only" or otherwise be designated that they can only be distributed by an authorized provider. ²⁶ Since 1962, the FDCA has deemed "new" drugs to be "Rx only" through a premarket approval process, in which the FDA evaluates evidence of the drug's safety and efficacy submitted by the drug's sponsor (e.g. the manufacturer).²⁷ Approval will only be granted when there is "substantial evidence" of the drug's effectiveness for the conditions for which it is offered, which, in general, may be satisfied after preclinical trials (e.g. animal studies) and at least three "phases" of clinical trials on humans.²⁸ The FDA also recommends the appropriate schedule for drugs in the CSA, although the DEA is "ultimately responsible for scheduling drugs and enforcing" the CSA.²⁹ Lastly, it should be noted that some "Rx only" drugs are not controlled substances under federal law but are regulated in tandem with controlled substances by states (often called "dangerous" drugs in state policies).30

2. The Drug Enforcement Administration

The DEA is a federal agency within the U.S. Department of Justice. In the context of prescribing medication, the DEA enforces the restrictions on provider conduct within the CSA. Specifically, the DEA is responsible for 1) classification of substances into "schedules" based on "the substance's medical use, potential for abuse, and safety or dependence liability;" 2)

²² Introduction: About HSS: Mission Statement, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/about/strategic-plan/introduction/index.html (last visited Dec. 20, 2019). In addition to housing the FDA, HHS also houses the Centers for Medicare and Medicaid Services, which have the power to implement and/or expand payment models for medication-assisted treatment through telemedicine. See generally U.S. DEP'T HEALTH & HUM. SERVS., USING TELEHEALTH TO IDENTIFY AND MANAGE HEALTH AND SUBSTANCE USE DISORDER CONDITIONS IN RURAL AREAS (2017). HHS also promulgated the current definition of "telemedicine" that the DEA applies to enforce the Ryan Haight Act. 42 C.F.R. § 410.78 (effective Jan. 1, 2019). ²³ 21 U.S.C. § 301. ²⁴ 21 U.S.C. § 321(g)–(h). ²⁵ 21 U.S.C. § 353(b)(1)(A). ²⁶ See 21 C.F.R. 801.109(b)(1). ²⁷ Seconsored W 21 U.S.C. § 355

 ²⁷ See generally 21 U.S.C. § 355.
²⁸ See 21 U.S.C. § 355(d).

²⁹ Dineen & DuBois, *supra* note 15, at 18.

³⁰ See, e.g., CAL BUS, & PROF. CODE § 2242 (West 2019) (describing online prescribing policy for "dangerous" drugs); CAL BUS, & PROF. CODE § 4022 (West 2019) (defining "dangerous" drugs as any drug affixed with the "Rx only" label by the FDA).

registration to distribute or handle controlled substances; 3) responsibilities for maintaining valid registrations; and 4) enforcing regulatory compliance with the CSA.³¹ The substances within the DEA's purview are sorted into five "schedules," supposedly arranged in descending degree of potential for abuse, lack of "accepted medical use in treatment," and "lack of accepted safety."³² Below is a brief description of each of the schedules within the CSA³³.

Schedule I: Drugs that have "no accepted medical use in the United States" (i.e. cannot be prescribed) and have a high abuse potential. Examples: heroin, LSD, peyote, mescaline, and some fentanyl analogs.

Schedule II: Drugs with a "high abuse potential with severe psychological or physical dependence" but have "accepted medical use in the U.S." Examples: opium, morphine, methadone, cocaine, oxycodone, amphetamine, and fentanyl.

Schedule III: Drugs with less abuse potential and dependence liability than those in Schedule I and II and have an accepted medical use in the United States. Examples: Derivatives of barbituric acid (sleep/seizure aids); buprenorphine (opioid addiction aid).

Schedule IV: Drugs with less abuse potential and dependence liability than those in Schedule III and have an accepted medical use in the United States. Examples: diazepam (Valium), alprazolam (Xanax).

Schedule V: Drugs with less abuse potential and dependence liability than those in Schedule IV and have an accepted medical use in the United States. Includes "preparations containing limited quantities of certain narcotic drugs generally for antitussive and antidiarrheal purposes." Examples: Robitussin AC (cough medication with small amounts of codeine); Lomotil (antidiarrheal medication).³⁴

Under the CSA, it is lawful for registered physicians to issue prescriptions for controlled substances for a "legitimate medical purpose," so long as they operate in the "usual course of professional practice."³⁵ Thus, physicians violate the CSA and can be subject to criminal liability if they knowingly prescribe substances for an illegitimate medical purpose outside the scope of professional practice, although there is no universally-accepted standard for when a physician's conduct rises to that level.³⁶ This lack of a nationwide standard in the context of online prescribing will be explored in greater detail in Parts II-IV.

³¹ CONG. RSCH. SERV., supra note 20, at intro.

See generally 21 U.S.C. § 812(b).
See 21 C.F.R. §§ 1308.11 –1308.15 for a full list of controlled substances.

³⁴ ROBERT C. BONNER & GENE R. HAISLIP, U.S. DEP'T OF JUST. DRUG ENF'T ADMIN., CONTROLLED SUBSTANCES SECURITY MANUAL: AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT OF 1970, at 8–9 (1991). ³⁵ 21 U.S.C. § 829(e)(2)(A).

³⁶ Dineen & DuBois, *supra* note 15, at 18–19.

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C. PREEMPTION AND FEDERALISM

Perhaps the most notable discussion of the interplay between federalism and the Controlled Substances Act can be found in Gonzales v. Raich, in which the Supreme Court held that the CSA extends to personal production and use of cannabis under the Commerce Clause given the effect of such behavior on the supply and demand of the national market.³⁷ Arguably, this indicates that the CSA "generally preempts, or overrides, state laws regarding controlled substances" when "the two cannot consistently stand together.""³⁸ Scholars, however, have argued that the "preemptive reach" of the CSA is "relatively modest."³⁹ Specifically, they have argued that any claim that the CSA is the "supreme law of the land" under the Constitution's Supremacy Clause is qualified by the anti-commandeering principle developed by Supreme Court precedent, meaning "[w]hile states cannot stop the federal government from enforcing federal law within their territory, the federal government cannot command the state to create a law criminalizing the conduct."40 In other words, states arguably do not run afoul of the Constitution by decriminalizing the conduct proscribed by the CSA. However, statutory language and case law indicate that the CSA does preempt state laws when there is a "positive conflict" rendering "compliance with both federal and state regulations . . . a physical impossibility."41 Consequently, a state law that actively requires providers to defy the CSA (e.g. requiring providers to prescribe heroin for chronic pain) would very likely be preempted by the CSA. The nuances of preemption doctrine in the context of online prescribing will be explored in greater detail in Part III.

In sum, prescription drugs are regulated primarily by the following entities: state legislatures and regulators, state medical boards, Congress, the FDA, and the DEA. The extent to which the CSA preempts state laws is an unsettled question. Thus, given the uncertainty surrounding preemption of states' online prescribing policies, it is important to understand the differences between the federal policy and many state policies. Before doing so, however, I will provide a brief overview of the core elements underlying online prescribing policies.

III. THE ELEMENTS OF AN ONLINE PRESCRIBING POLICY

Before describing the policies of the federal government and each state, it is worthwhile to consider the core elements of online prescribing policies and the overarching justifications for each. Below are explanations and justifications of the core elements of online prescribing policies: 1) Establishing a valid patient-provider relationship; 2) Defining appropriate

 ³⁷ See generally Gonzales v. Raich, 545 U.S. 1 (2005).
³⁸ CONG. RSCH. SERV., *supra* note 20, at 18 (quoting Implementation of the Methamphetamine Production Prevention Act of 2008, 76 Fed. Reg. 74,696 § 903 (Dec. 1, 2011).

Erwin Chemerinsky et al., Cooperative Federalism and Marijuana Regulation, 62 UCLA L. REV. 74, 79 (2015). See generally Robert A. Mikos, Preemption Under the Controlled Substances Act, 16 J. HEALTH CARE L. & POL'Y 5 (2013).

Chemerinsky et al., supra note 39, at 102-03.

⁴¹ See S. Blasting Servs., Inc. v. Wilkes Cnty., 288 F.3d 584, 591 (4th Cir. 2002) (interpreting 18 U.S.C. § 848).

telemedicine technology; and 3) Limiting medications that can be prescribed via telemedicine.

A. ESTABLISHING A VALID PATIENT-PROVIDER RELATIONSHIP

As telemedicine has become more ubiquitous in the American healthcare system, governments and professional organizations have sought to ensure that telemedicine appointments yield the same degree of information-sharing that would occur during an in-person appointment. In general, when a patient and provider share a sufficient degree of information, a patient-provider relationship (PPR)⁴² has been established.

There is no nationwide definition of a valid PPR. However, there is a near-universal consensus at the state level that PPRs can be established via telemedicine for the purpose of prescribing medication.⁴³ Furthermore, the American Medical Association (AMA), a leading professional organization for physicians, opines that PPRs established via telemedicine are permissible under its code of ethics.44

Despite a consensus over the validity of telemedicine PPRs for online prescribing, however, the requirements for establishing PPRs are not uniform among the states.⁴⁵ The baseline for ethical telemedicine PPRs, according to the AMA, only requires that physicians "uphold the standards of professionalism expected in in-person interactions" and comply with applicable federal and state laws.⁴⁶ With regard to establishing PPRs for the purpose of prescribing medication, the AMA posits four requirements for the prescribing physician:

1) Establishing the patient's identity[;]

2) Confirming that telehealth/telemedicine services are appropriate for that patient's individual situation and medical needs[;]

3) Evaluating the indication, appropriateness and safety of any prescription in keeping with best practice guidelines and any formulary limitations that apply to the electronic interaction[; and]

4) Documenting the clinical evaluation and prescription.⁴⁷

Most states align in spirit with the AMA's opinion (hereafter, the "AMA guidelines"), requiring a similar degree of information-sharing for valid

⁴² I prefer the term "provider" in this context, and I use the term throughout this analysis when accurate, though other terms (e.g., "practitioner" or "physician") will arise when I describe the language used by various governments and institutions. It should be noted that the requirements to obtain a license to prescribe medication differ among states and differ based on the medication in question, and most of these nuances fall outside the scope of this analysis. The reader should keep in mind, however, that the ⁴³ I say near-universal because three states do not have telemedicine policies; every state that does

have a telemedicine policy explicitly allows PPRs to be established via telemedicine. *See generally* AM. MED. ASS'N, 50-STATE SURVEY: ESTABLISHMENT OF A PATIENT-PHYSICIAN RELATIONSHIP VIA TELEMEDICINE (2018) (describing the PPR requirements via telemedicine for each state). For a more upto-date list of citations for each state, see Part IV.

⁴⁴Ethical Practice in Telemedicine, AM. MED. ASS'N, https://www.ama-assn.org/delivering-care/ethics/ethical-practice-telemedicine (last visited Oct. 25, 2019).

 ⁴⁵ AM. MED. ASS'N, *supra* note 43, at 1.
⁴⁶ See Ethical Practice in Telemedicine, supra note 44.

⁴⁷ Id.

telemedicine PPRs and broadly defining situations in which prescribing via telemedicine is appropriate.⁴⁸ There are some nuances, however, between state policies.⁴⁹ These nuances will be demonstrated in Part IV.

В. DEFINING APPROPRIATE TELEMEDICINE TECHNOLOGY

In-person communication with providers is an integral component of the modern medical profession, particularly in prescribing dangerous or addictive medication. Through in-person appointments, providers can make thoughtful value judgments-not only on the medical necessity of a particular treatment but also on a patient's risk of substance abuse and addiction.⁵⁰ Some telemedicine technologies allow for audio-visual conferences which, at least, closely resemble in-person appointments and provide doctors with the opportunity to make these value judgments.⁵¹ Other technologies, however, allow providers to conduct more expedient appointments through direct messaging or surveys, which may provide insufficient information to accurately prescribe medication.⁵² Most states, consequently, forbid prescribing medication solely on the basis of telemedicine encounters that do not involve real-time interpersonal communication (e.g. online questionnaires),⁵³ and the CSA has been interpreted by both the executive and judicial branches to forbid such prescribing when "scheduled" drugs are involved.54

C. LIMITING MEDICATIONS THAT CAN BE PRESCRIBED VIA **TELEMEDICINE**

Particularly in states with liberal telemedicine policies, providers may be encouraged to engage in unscrupulous prescribing and opportunistic uses of telemedicine to distribute addictive and/or dangerous medication.⁵⁵ In

31 HEALTH LAWYER 1, 4 (2019). ⁵² See id.

⁴⁸ AM. MED. ASS'N, *supra* note 43, at 1. It should be noted that, as a leading professional organization for physicians, the AMA and its code of ethics have great weight on some state policies. See Chalmers C Clark, In Harm's Way: AMA Physicians and the Duty to Treat, 30 J. MED. & PHIL. 65, 67 (Jan. 1, 2005). However, only 25% of American physicians are members of the AMA, which may undermine the importance of its code of ethics. Judith Graham, 'Like a Slap in the Face': Doctors No Longer Feel the Nation's Largest Doctors Group Represents Their Interests, BUS. INSIDER (Dec. 22, 2016, 10:00 PM), https://www.businessinsider.com/doctors-american-medical-association-2016-12. It should also be noted that violating the AMA's Code of Medical Ethics does not necessarily impose legal liability on the violating physician; however, the AMA states that the profession's "ethical values and legal principles are usually closely related" and that "ethical responsibilities usually exceed legal duties." Tanya Albert Henry, Medical Laws and Ethics: What to Do When Conflicts Occur, AM. MED. ASS'N (Sept. 14, 2018), https://www.ama-assn.org/councils/council-ethical-judicial-affairs/medical-laws-and-ethics-what-dowhen-conflicts-occur.

Compare FLA. STAT. § 456.47(1)-(2) (2019), and FLA. ADMIN. CODE ANN. r. 54B8-9.0141 (2019), with MINN. STAT. § 151.37(a) (2019).

 ⁵⁰ Michael F. Weaver et al., Role of the Primary Care Physician in Problems of Substance Abuse, 159
ARCHIVES INTERNAL MED. 913 (May 10, 1999); see also 10 Pros and Cons of Telemedicine, EVISIT, https://evisit.com/resources/10-pros-and-cons-of-telemedicine (last visited May 20, 2021).
⁵¹ See Libby L. Baney & Niamh M. Lewis, Internet Pharmacies: Trends, Opportunities, and Risks, 21 Uro 11 Uro 12 (2010).

⁵³ See id.

⁵⁴ See, e.g., United States v. Kanner, 603 F.3d 530 (8th Cir. 2010); United States v. Maye, 649 Fed. Appx. 15 (2d Cir. 2016); see also 42 C.F.R. § 410.78 (2019).

Federal controlled substances (which are often dangerous and/or addictive) comprise roughly 10% of the illegal online marketplace. LEGITSCRIPT, THE INTERNET PHARMACY MARKET IN 2016: TRENDS, CHALLENGES, AND OPPORTUNITIES 6-7 (2016), https://safemedsonline.org/wp-content/uploads/2016/01/

addition, more than 50 percent of Americans using prescription medication take medication prescribed by more than one provider, which may cause unfortunate or unnecessary drug reactions.⁵⁶ Liberal online prescribing policies could contribute to this information problem, where a patient's primary care provider may be unaware of medication prescribed online by another provider, or where an online provider may not adequately review a patient's medical record to consider interactions with drugs prescribed by a primary care provider.

However, not all prescriptions are alike; where it may be reasonable for a provider to prescribe contact lenses through direct messaging (provided that sufficient information is shared),⁵⁷ it may be unreasonable to prescribe oxycodone or clonazepam through the same procedure. Some states reflect this logic in their policies by imposing strict restrictions on establishing PPRs via telemedicine only for controlled or "dangerous" substances,58 and the federal government may implicitly support this logic by tightly regulating online prescribing only in the context of controlled substances.⁵

In sum, there are three primary elements of an online prescribing policy: 1) establishing a valid PPR; 2) defining appropriate telemedicine technologies; and 3) limiting the types of medication that can be prescribed via telemedicine. Policies embodying these elements have emerged in recent years as the unscrupulous distribution of pharmaceuticals over the Internet has remained exceedingly common. In fact, a 2016 study found that 92 percent of online pharmacies were engaged in unlawful, "rogue" behavior by "doing one or more of three things: selling prescription drugs without a *[valid] prescription*, selling unapproved and unregulated drugs, and [failing] to obtain legally required pharmacy licenses" (emphasis added).⁶⁰ Although the Internet provides profound opportunities to expand access to healthcare treatment, with such a high rate of unscrupulous prescribing behavior on the Internet, strong online prescribing policies are needed to limit prescription drug abuse and protect patients.

In Part III, I will describe the current federal regime of online prescribing, which was enacted in reaction to high rates of unscrupulous online prescribing and embodies all three of the above online prescribing elements by: 1) requiring that online prescriptions fall within the scope of a

The-Internet-Pharmacy-Market-in-2016.pdf. Prosecutions involving online pharmacies that prescribe controlled substances are discussed in greater detail below.

Teresa Carr, Too Many Meds? America's Love Affair with Prescription Medication, CONSUMER REPS. (Aug. 3, 2017), https://www.consumerreports.org/prescription-drugs/too-many-meds-americaslove-affair-with-prescription-medication.

See, e.g. Getting Started, HIMS.COM (last visited Nov. 29, 2019), https://support.forhims.com/hc/ en-us/sections/360006103992-getting-started (describing how interactions with doctors are conducted through secure messaging). ⁵⁸ N.J. REV. STAT. § 45:1-62(c) to (e) (2017).

⁵⁹ As discussed in Part I, prescribing medication is limited generally by the FDA's requirement that "Rx only" drugs be prescribed for legitimate medical purposes. In addition, online prescribing is implicated in other contexts through the federal government's Medicare and Medicaid services. Medicare Part B pays for "covered telehealth services" so long as the physician is licensed to practice telemedicine under state law. See 42 C.F.R. § 410.78(b). Medicaid will also pay for telemedicine services if providers act within the scope of practice *defined by the state(s) in which they are practicing. See Telemedicine*, MEDICAD.GOV, https://www.medicaid.gov/medicaid/benefits/telemed/index.html (last visited Dec. 20, 2019). In general, while the federal government undoubtedly plays a role in online prescribing outside of the context of controlled substances, the bulk of policymaking for non-controlled substances occurs at the state level.

⁶⁰ LEGITSCRIPT, supra note 55, at 6–7.

provider's "professional practice"; 2) requiring that telemedicine appointments occur through real-time, two-way, audio-visual communication; and 3) imposing these restrictions exclusively on federal controlled substances.

IV. THE FEDERAL GOVERNMENT'S ONLINE PRESCRIBING POLICY

THE RYAN HAIGHT ACT A.

In recent years, the federal government has heavily restricted online prescribing of controlled substances. These restrictions stem from the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (the "Ryan Haight Act"), which amended the federal Controlled Substances Act (CSA) and provides that "[n]o controlled substance that is a prescription drug . . . may be delivered, distributed, or dispensed by means of the Internet without a valid prescription."⁶¹ "Valid prescription[s]" of controlled substances are defined as prescriptions issued for a legitimate medical purpose in the usual course of professional practice.⁶² The statute requires at least one "in-person" evaluation by a practitioner to obtain a valid prescription.⁶³ However, controlled substances may be prescribed under certain circumstances through the "practice of telemedicine."⁶⁴

This portion of the statute does not explicitly define the word "telemedicine."65 However, it does establish that "telemedicine" is the use of a "telecommunications system" by practitioners, not including pharmacists, to communicate remotely with patients.⁶⁶ It also points to another section of the United States Code for an illustration of the term "telecommunications system."67 However, the section referenced does not provide an explicit definition of a "telecommunications system," only establishing that storeand-forward technologies are included in the definition of telemedicine.⁶⁸

Fortunately, the DEA's guidance regarding online prescribing of controlled substances does point to an explicit definition of telemedicine,

⁶¹ 21 U.S.C. § 829(e); Francine Haight, Illegal Sales of Pharmaceuticals on the Internet, 16 ALB. L.J. SCI. & TECH. 565, 566 (2006) (firsthand account from Ryan Haight's mother).

²¹ U.S.C. § 829(e)(2)(A); see also id. § 353(b)(1) (providing that valid prescriptions are required for drugs that are unsafe due to their toxicity or other possibly deleterious effects); 21 C.F.R. § 1306.04(a) (providing that practitioners must only issue controlled substances "for a legitimate medical purpose ... acting in the usual course of his professional practice."

 ⁶³ 21 U.S.C. § 829(e)(2).
⁶⁴ Id. § 802(54); see also U.S. DEP'T OF JUST. DRUG ENF'T ADMIN. DIVERSION CONTROL DIV., USE OF TELEMEDICINE WHILE PROVIDING MEDICATION ASSISTED TREATMENT (MAT) 1 (2018), https://www.hhs.gov/opioids/sites/default/files/2018-09/hhs-telemedicine-dea-final-508compliant.pdf.

⁶⁵ See generally 21 U.S.C. § 802(54).

⁶⁶ Id. ⁶⁷ Id.

⁶⁸ See 42 U.S.C. § 1395m(m). Store-and-forward technologies allow for secure, digital transmissions of patients' health information from one provider to another, and, generally, these transmissions stem from a provider with whom a patient has already established a PPR. See What is Telehealth?, CTR. FOR CONNECTED HEALTH POL'Y, https://www.cchpca.org/about/about-telehealth (last visited Nov. 29, 2019). Consequently, given that this analysis deals with patients and providers seeking to establish PPRs via telemedicine, the inclusion of store-and-forward technologies in the federal policy (and many state policies) is mostly outside the scope of this analysis. For a circumstance in which store-and-forward technology is relevant to this analysis, see, e.g., N.J. REV. STAT. § 45:1-62(c) to (e) (discussed in greater detail in Part IV).

stating that telemedicine is an "interactive telecommunications system" as defined in a recently amended rule issued by the Department of Health and Human Services.⁶⁹ This rule states that an "interactive telecommunications system" is "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner."70

Given this definition, if providers are communicating with patients using real-time, two-way, audio-visual technology, it is safe to conclude they will be engaged in the "practice of telemedicine" and are permitted under the Ryan Haight Act to prescribe controlled substances under the following seven circumstances:71

1) the patient is being treated within a DEA-registered hospital by a practitioner who is registered to dispense Schedule II-V substances by the Attorney General. The Attorney General must only issue registrations to dispense controlled substances over the Internet if doing so is permissible under the laws of the state in which the practitioner is licensed, and if doing so aligns with the "public interest";⁷²

2) the patient is in "the physical presence" of a practitioner who is registered through the same procedure listed above;⁷³

3) the practitioner is an employee or contractor of the Indian Health Service and is designated as eligible to prescribe controlled substances over the Internet:74

4) the telemedicine appointment occurs during a "public health emergency" (e.g. bioterrorist attack or infectious disease outbreak);⁷

5) the practitioner has a "special registration" to prescribe via telemedicine, which is issued by the Attorney General after the practitioner demonstrates a legitimate need for such registration.⁷⁶ Aligning with the registration requirements of the first and second exceptions, the Attorney General can only issue special registrations if doing so is permissible under state law and aligns with the "public interest";77

6) there is a "medical emergency situation" inhibiting patients from being in the physical presence of a practitioner within the Veterans Health Administration;⁷⁸

7) the appointment occurs in "any other circumstances" that the Attorney General and the DEA have jointly deemed to be "consistent with effective controls against diversion and otherwise consistent with the public health and safety."79

^{69 42} C.F.R. § 410.78 (2019).

⁷⁰ Id.

⁷¹ 21 U.S.C. § 802(54).

⁷² Id. § 802(54)(A); see also id. § 823(f) (registration procedure for practitioners to dispense Schedule II-V controlled substances over the Internet).
⁷³ Id. § 802(54)(B).
⁷⁴ Id. § 802(54)(C).
⁷⁵ Id. § 802(54)(C).
⁷⁵ Id. § 802(54)(D); see also 42 U.S.C. § 247d(a)(2).
⁷⁶ 21 U.S.C. § 802(54)(E); see also id. § 831(h). This section is not in effect as of January 2020

⁽discussed in greater detail below).

 ⁷⁷ See id. § 823(f).
⁷⁸ Id. § 802(54)(F).
⁷⁹ Id. § 802(54)(G).

As evidenced by the statute's wording, states can impose even stricter requirements on providers registered within the state.⁸⁰ Indeed, some states flatly prohibit prescribing controlled substances via telemedicine.⁸¹

The DEA also suggests that narrower restrictions apply when a patient is being treated with Schedule III-V substances for opioid addiction.⁸² Under this circumstance, prescriptions are only valid during appointments described in the first and second exceptions of 21 U.S.C. 802(54); that is, the patient either must be in a DEA-registered hospital or in the presence of a DEA-registered provider.⁸³

In general, the first two exceptions are the most common.⁸⁴ This phenomenon is caused in part by the DEA's decade-long failure to issue guidance on the "special registration" exception (the fifth exception in the statute), which has rendered the exception moot since the passage of the Ryan Haight Act.⁸⁵ Recognizing the need for guidance on "special registrations," Congress passed the Special Registration for Telemedicine Clarification Act of 2018, ordering the DEA to issue a regulation by October 24, 2019 clarifying when providers can receive government-approved exemption from the narrow exceptions of the Ryan Haight Act.⁸⁶ Unfortunately, the DEA missed its deadline and has not issued a rule as of January 2020.⁸⁷ Many professional organizations favor relaxing the Ryan Haight Act so that controlled substances may be prescribed via telemedicine in contexts outside of DEA-registered hospitals, such as prescribing to individuals in their homes or in school.⁸⁸ Whether the DEA has such a viewpoint is uncertain,⁸⁹ and it is worth reiterating that under the "special registration" exception as written, states that seek to have a more restrictive online prescribing policy for controlled substances can effectively nullify the DEA's rule once it is promulgated.

In sum, the federal government's approach to online prescribing in recent years is as follows: Providers cannot prescribe controlled substances over the Internet, unless: 1) the provider has met the patient in-person on at least one occasion; or 2) the provider is engaged in a real-time, two-way, audio-visual telemedicine encounter that falls under one of the seven circumstances in 21 U.S.C. § 802(54)(A)-(G). To prescribe Schedule III-V substances for opioid

⁸⁷ Malka Berro, *DEA Misses Deadline for Teleprescribing Special Registration*, NAT'L COUNCIL FOR BEHAV. HEALTH (Oct. 31, 2019), https://www.thenationalcouncil.org/capitol-connector/2019/10/deamisses-deadline-for-teleprescribing-special-registration.

⁸⁸ See, e.g., Robert Caudill, *Update on Developments with Ryan Haight and Online Prescribing*, PSYCHIATRY.ORG (Mar. 22, 2018), https://www.psychiatry.org/psychiatrists/practice/telepsychiatry/blog/ update-on-developments-with-ryan-haight-and-online-prescribing.

⁸⁹ See Mohana Ravindranath, *Doubts Surround Pending DEA Telemedicine Rule*, AM. TELEMEDICINE ASS'N (Apr. 19, 2019) https://www.americantelemed.org/industry-news/doubts-surround-pending-dea-telemedicine-rule.

⁸⁰ See U.S. DEP'T OF JUST. DRUG ENF'T ADMIN. DIVERSION CONTROL DIV., supra note 64, at 1–2.

⁸¹ See GA. COMP. R. & REGS. 360-3-.07 (2013); Lacktman & Ferrante, *supra* note 10.

⁸² U.S. DEP'T OF JUST. DRUG ENF'T ADMIN. DIVERSION CONTROL DIV., *supra* note 64, at 2.

⁸³ *Id.* at 1–2.

⁸⁴ See Nathaniel M. Lacktman, *Prescribing Controlled Substances Without an In-Person Exam: The Practice of Telemedicine Under the Ryan Haight Act*, BECKER'S HEALTH IT & CIO REPORT (Apr. 19, 2017), https://www.beckershospitalreview.com/healthcare-information-technology/prescribing-contro lled-substances-without-an-in-person-exam-the-practice-of-telemedicine-under-the-ryan-haight-act.html.

⁸⁵ Acosta & Lacktman, *supra* note 8.

⁸⁶ See id.

addiction via telemedicine, the appointment must occur at a DEA-registered or in the physical presence of a DEA-registered practitioner. These two scenarios are also the most common for prescribing any controlled substance via telemedicine. Once the DEA issues guidance on the "special registration" requirement, providers will be able to prescribe controlled substances via telemedicine under a broader set of circumstances; state laws, however, can prohibit or limit such registrations.

B. RECENT CASE LAW INVOLVING ONLINE PRESCRIBING OF CONTROLLED SUBSTANCES

Given the strict requirements imposed by the Controlled Substances Act, several providers and online pharmacies have been prosecuted in recent years for illegally prescribing and distributing controlled substances over the Internet. Two possible insights can be gleaned from the selected federal criminal cases: 1) The vague "professional practice"/"legitimate medical purpose" requirement of the CSA likely forbids prescribing controlled substances without an audio-visual, real-time encounter in which a provider reviews a patient's medical history and evaluates the patient for diagnosis; and 2) The CSA likely preempts any state laws that permit prescribing controlled substances under broader circumstances than those stipulated by the Ryan Haight Act.

1. Interpretations of the "Professional Practice"/"Legitimate Medical Purpose" Requirement

In United States v. Birbragher, the 8th Circuit affirmed a lower court's sentencing against defendant for violating the CSA.⁹⁰ Defendant Birbragher and his alleged co-conspirators operated a company called "Pharmacom," which managed various websites where consumers could place orders for prescription drugs by completing a health history questionnaire and providing their credit card information.⁹¹ Pharmacom hired doctors to review the prescription drug orders who, in turn, approved consumers' prescription drug orders who, in turn, approved consumers' prescription drug orders who, in turn, approved consumers' prescription drug orders without conducting in-person examinations and, frequently, without reviewing patients' medical records.⁹² After the doctors reviewed the orders, Pharmacom would affix the doctors' signatures to prescription orders and transmit these orders to pharmacies across the United States; thereafter, the pharmacies would fill the prescriptions and ship them directly to consumers.⁹³ In total, between 2003 and 2004, Pharmacom issued almost 250,000 "prescriptions" for Schedule III and IV controlled substances, totaling more than 14 million dosage units.⁹⁴ Defendant Birbragher was indicted and prosecuted for conspiring to distribute controlled substances "outside the usual course of professional practice."⁹⁵

Defendant Birbragher asserted that, given that Pharmacom operated between 2003 and 2004 (prior to the passage of the Ryan Haight Act of

 $^{^{90}}$ See generally United States v. Birbragher, 603 F.3d 478 (8th Cir. 2010). 91 Id. at 481.

 $^{^{92}}$ *Id.* at 92 *Id.*

⁹³ *Id*.

⁹⁴ *Id.* at 481-82.

⁹⁵ *Id.* at 487.

2008), it was unclear whether the Controlled Substances Act (CSA) proscribed his conduct, rendering his conviction unconstitutionally vague.⁹⁶ The 8th Circuit, however, determined that the CSA's prohibition on distributing controlled substances outside the scope of professional practice can be constitutionally interpreted to proscribe "the distribution of controlled substances over the Internet without a face-to-face meeting between patient and doctor."97 That is, the Ryan Haight Act's per se prohibition on Birbragher's conduct reaffirms the virtues of a valid PPR implicit in the "professional practice" requirement of the Controlled Substances Act-that prescribers should interact with patients face-to-face, review their medical records, and only issue prescriptions for legitimate medical reasons.⁹⁸

For a similar fact pattern, see United States v. Darii. In this case, the Sixth Circuit held that the Controlled Substances Act was not unconstitutionally vague as applied to defendants who prescribed medication over the Internet without face-to-face consultations prior to the passage of the Ryan Haight Act. Given that doctors involved in the drug conspiracy "willingly participated in the dispensation of controlled substances based on cursory consultations and review of medical records on an internet platform," it was constitutional to prosecute defendants for violating the CSA's prohibition on dispensing controlled substances without valid prescriptions.99

Lastly, in United States v. Maye, the Second Circuit provided a more explicit set of factors for evaluating conduct under the "professional practice" requirement under the CSA in the context of online prescribing. Specifically, the Second Circuit opined that an online pharmacy owner (Maye) was not acting in accordance with the Controlled Substances Act given evidence that Maye was not acting in the usual course of medical practice, evidence that Maye never conducted in-person examinations of patients, evidence that Maye authorized prescriptions without obtaining or reviewing medical records, evidence that Maye authorized prescriptions after extremely brief conversations with patients, or no conversations with patients, evidence that Maye did not make diagnoses prior to prescribing medication, and evidence regarding the quantities and types of medications he dispensed.100

Consequently, the Second Circuit affirmed the defendant's conviction for violating the Controlled Substances Act.¹⁰

In sum, the CSA's "professional practice" requirement has been interpreted in close alignment with the AMA guidelines: that providers cannot prescribe controlled substances unless providers have face-to-face

⁹⁶ Id. at 489.

⁹⁷ *Id.* (quoting United States v. Lovin, No. 07cr2016-IEG, 2008 U.S. Dist. LEXIS 80258, at *5 (S.D. Cal. Sept. 29, 2008)). ⁹⁸ See id.

 ⁹⁹ United States v. Darji, 609 Fed. Appx. 320, 333 (6th Cir. 2015).
¹⁰⁰ United States v. Maye, 649 Fed. Appx. 15, 16 (2d Cir. 2016).

¹⁰¹ *Id.* It should be noted that the lower court in this case excluded reference to the Ryan Haight Act under Federal Rule of Evidence 403 due to "limited probative value which was outweighed by the potential for jury confusion"; the Second Circuit determined that the lower court did not abuse its discretion in doing so. Id.

interactions with patients, review their medical records, and make a legitimate diagnosis.

2. Preemption of Liberal State Online Prescribing Policies

Although scholars have argued that the preemption effect of the CSA is "relatively modest,"¹⁰² there are several problems with applying this logic to the federal online prescribing policy. Most of the discussions surrounding CSA preemption, including the landmark Gonzales v. Raich case, involve marijuana and its Schedule I status. Consequently, existing doctrine, state marijuana laws, and academic discussions may not indicate the CSA's lack of supremacy over the states but merely a narrow exception in the law manifested through powerful political processes.¹⁰³ Here, online prescribing is not nearly as popular of a political issue. Furthermore, online prescribing is a broad category of *conduct* restricted by the CSA in which parties cannot engage unless they obtain a DEA registration to prescribe controlled substances.¹⁰⁴ Therefore, any preemption argument in support of broad state online prescribing policies is severely limited by the practical control that the DEA currently exerts over providers and hospitals—an opinion which has been expressed in at least two federal district court cases. Of note, in *Vogel v. United States*, the Eastern District of Texas stated:

[Defendants'] prescription of opioid drugs, purportedly for medical use, is analogous to the growth and use of medical marijuana at issue in Gonzales. Following the Supreme Court's rationale in that case . . . [Defendants' behavior] is subject to federal regulation under Congress' commerce power. Moreover, even if [Defendants] complied with Texas law governing the prescription of opioid drugs . . . the state's regulatory action does not circumscribe Congress' authority to legislate on such matters.¹⁰⁵

With this reasoning, the district court upheld a Magistrate Judge's conclusion that defendant was not entitled to habeas relief on the basis that his conviction under the CSA violated the 10th Amendment.

Evidently, both the Gonzales holding and preemption doctrine provide a strong basis to conclude that liberal state online prescribing policies as they pertain to controlled substances are preempted by the CSA. However, the preemption question for online prescribing has not been settled by a higher court, and there has been little action even by the DEA to enforce the Ryan Haight Act. In fact, the DEA has not punished a provider for violating the Ryan Haight Act since 2011, when it revoked a practitioner's DEAregistration for prescribing in a manner that defied the public interest.¹⁰⁶ In

¹⁰⁶ See Bradley S. Davidsen, New State Laws Allow Telehealth Prescriptions for Controlled Substances; Yet, Regulatory Obstacles Still Remain, EPSTEIN BECKER GREEN: HEALTH L. ADVISOR (Jan.

 ¹⁰² Chemerinsky et al., supra note 39, at 79.
¹⁰³ See Legal Medical Marijuana States and DC, PROCON.ORG (May 18, 2021), https://medicalmarijuana.procon.org/legal-medical-marijuana-states-and-dc. But see Lenny Bernstein, U.S. Affirms Its Prohibition on Medical Marijuana, WASH. POST (Aug. 11, 2016, 11:00 AM), https://www.washingtonpost.com/news/to-your-health/wp/2016/08/10/u-s-affirms-its-prohibition-onmedical-marijuana (describing the DEA's refusal to remove marijuana from Schedule I)

¹⁰⁴ See generally 21 U.S.C. § 822.

¹⁰⁵ Vogel v. United States, No. 4:13 CV323, 2016 U.S. Dist. LEXIS 104438, at *22-23 (E.D. Tex. Aug. 8, 2016); see also Sodipo v. United States, No. ELH-06-0444, 2016 U.S. Dist. LEXIS 159190, at *38 (D. Md. Nov. 17, 2016) (finding that Florida's online prescribing policy was rightfully excluded from trial as inadmissible because those regulations were irrelevant to the "legitimate medical purpose" requirement of the CSA).

addition, most state online prescribing policies have been passed or amended in the past few years, so it is unclear how administrative and judicial entities will react in light of new policies, particularly policies that openly defy the Ryan Haight Act.

It is worthwhile, therefore, to consider how state policies differ from the federal policy. For example, if the above reasoning is widely adopted, even when providers act in accordance with broader state policies, they may still violate the CSA and be criminally prosecuted by the federal government. Conversely, since the CSA permits states to impose additional limits on providers' ability to prescribe controlled substances, various players (e.g. providers, hospital systems, retail pharmacies) may face economic disadvantages in states with more restrictive policies, even if these players have every intention to comply with the ethical underpinnings and statutory requirements of the CSA. Lastly, federal-controlled substances only comprise a portion of the dangerous and/or addictive medications that are regularly prescribed in this country,¹⁰⁷ and some states openly defy the policy justifications behind a limited online prescribing regime for such medications.¹⁰⁸ For these reasons, in the section below, I will describe the current regime of online prescribing at the state level.

V. STATE ONLINE PRESCRIBING POLICIES

Given that online prescribing policy under the CSA only applies to controlled substances (and even this policy bends to restrictions imposed by individual states' policies), the vast majority of policymaking for online prescribing occurs at the state level, and state policies vary widely in terms of the requirements they impose on physicians. It is important, therefore, to consider the differences in liberality among state policies and to consider how these policies balance the interests between patient safety and stimulating the benefits associated with telemedicine-interests that gave rise to the passage of the Ryan Haight Act.¹⁰⁹

This research was conducted between September and December 2019, so it should only serve as a snapshot of state policies during a particularly dynamic moment in the brief history of telemedicine regulation.¹¹⁰ The findings from this snapshot of state policies help guide the policy analysis in Part V.

s-for-controlled-substances-yet-regulatory-obstacles-still-remain (citing Carlos Gonzalez, M.D., 76 Fed. Reg. 63,118 (Dep't of Just. Oct. 11, 2011) (decision and order).

¹⁰⁷ See generally Terri D'Arrigo, Misuse and Abuse of Noncontrolled Drugs: It's Not Just Prescription Opioids Anymore, 23 PHARMACY TODAY 30 (June 1, 2017).

Prescription Opioids Anymore, 23 PHARMACY 10DAY 30 (June 1, 2017).
¹⁰⁸ See, e.g. CAL. BUS. & PROF. CODE § 2242 (West 2019).
¹⁰⁹ Lacktman & Acosta, supra note 5, at 31–32. For a general discussion of how states adhere to or defy the intent behind the Ryan Haight Act, see Davidsen, supra note 106.
¹¹⁰ Notably, this Note does not address the emergency changes in state and federal telemedicine policies elicited by the COVID-19 outbreak in the United States in March 2020. For a dynamic list on changes in state policies, see Telehealth in the Time of COVID-19, CTR. FOR CONNECTED HEALTH POL'Y, https://www.ochoca.org/resources/covid-19-related-state-actions (last visited May 21 - 2021). For the https://www.cchpca.org/resources/covid-19-related-state-actions, (last visited May 21, 2021). For the various waivers and guidance from the Department of Health and Human Services on using telemedicine during the COVID-19 pandemic, see Telehealth: Delivering Care Safely During COVID-19, HHS.GOV, https://www.hhs.gov/coronavirus/telehealth/index.html (last visited Aug. 22, 2020).

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A. METHODOLOGY

To assess the liberality of states' online prescribing policies, I weighed the policies against the benchmark established by the Ryan Haight Act, considering the three major elements of online prescribing policies described in Part II. First, under what circumstances can a PPR be established via telemedicine (*PPR Restrictions*) for the purpose of prescribing medication? Second, if PPRs can be established via telemedicine, how does the state policy define "telemedicine" (*Telemedicine Definition*)? Lastly, which drugs, if any, are prohibited from being prescribed via telemedicine (*Medication Restrictions*)?

By answering these questions for each state, I was able to sort state online prescribing policies into three primary tiers, in ascending order of liberality:

1) *Restrictive*. The state policy is more restrictive than the requirements ostensibly imposed by the federal policy. Factors to consider include:

a) Does the state policy impose specific *PPR Restrictions* beyond general standards of professionalism (e.g. something more stringent than the AMA guidelines)?

b) Does the state policy's *Telemedicine Definition* only allow for real-time, two-way, audio-visual communication or some modality that is even narrower?

c) Most importantly, does the state policy impose *Medication Restrictions* beyond those required by the Ryan Haight Act (e.g. flatly prohibiting online prescribing of opioids)?

2) *Moderate*. Equivalent or comparable to the requirements imposed by the Ryan Haight Act. Factors to consider:

a) Does the state policy only impose vague *PPR Restrictions* such as comporting with "the standards of the medical profession" or allowing for telemedicine PPRs "at the discretion of the provider"? Or, does the state adopt the AMA guidelines as they pertain to online prescribing?

b) Does the state policy's *Telemedicine Definition* only exclude communication via email, fax, audio-only telephone consults, and online questionnaire?

c) Does the state policy only impose *Medication Restrictions* such as "in accordance with federal law" or "in accordance with The Ryan Haight Act"? Does the policy only allow for online prescribing of controlled substances in circumstances similar to those described in the Ryan Haight Act (e.g. only when the patient is in a state-registered hospital or in the presence of a state-registered physician)?

3) *Liberal.* The state policy has similarly discretionary *PPR Restrictions* to states in the Moderate category, but either a) its *Telemedicine Definition* is broader than the HHS definition (e.g. defining telemedicine to include audio-only consults or direct messaging); or b) its *Medication Restrictions* do not restrict prescribing controlled substances in the same manner as the Ryan Haight Act (e.g. broadly allowing online prescribing so long as the provider acts in accordance with the standards of the profession, or explicitly allowing

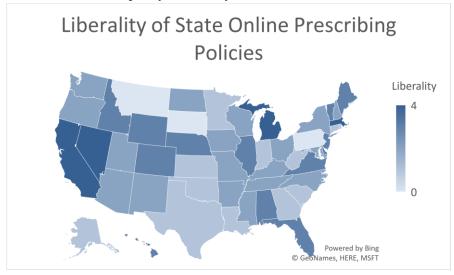
for online prescribing of controlled substances in circumstances broader than the exceptions within the Ryan Haight Act). The state policy, therefore, is arguably in conflict with, or preempted by, the Ryan Haight Act with respect to controlled substances.

In addition, a fourth designation of *Very Liberal* was given to California, Massachusetts, Michigan, and Nevada due to highly deferential language for all three factors that places the policies in direct conflict with the more nuanced and restrictive federal policy.

B. LIBERALITY OF STATES' ONLINE PRESCRIBING POLICIES

Based on the methodology described above, I analyzed each of the 50 states' *PPR Restrictions*, *Telemedicine Definition*, and *Medication Restrictions* and assigned each element a score of "0" through "4" based on congruence with the federal policy (a score of "0" indicates that the state does not have a telemedicine policy as of January 2020, although these states are likely Moderate in practice). Each element of the federal policy was deemed a "2" or "Moderate" policy for the sake of this analysis. Aside from the four "Very Liberal" policies, when any single element of a state policy deviated substantially from the federal policy, the state policy was deemed "Liberal" or "Restrictive." When all elements of a state policy was deemed "Moderate."

Those findings are tabulated in the map below this paragraph, and the same information is presented in a chart immediately below the map. In the chart, the numbers beneath each column to the right of the "Liberality" column indicate the weight that was given for each of the three primary elements of an online prescribing policy. For each state in the chart, I have also provided citations to the statutory language, regulatory language, practitioner analysis, and/or medical board opinions upon which I based my determination of the policy's liberality.



State	Liberality	PPR Restrict- ions	Telemed- icine Definition	Medication Restrict- ions
AL ¹¹¹	2	2	2	2
AK ¹¹²	1	1	2	1
AZ ¹¹³	2	2	2	2
AR ¹¹⁴	2	2	2	2
CA115	4	2	3	4
CO ¹¹⁶	3	2	3	2
CT ¹¹⁷	1	2	2	1
DE118	3	2	2	3
FL ¹¹⁹	3	3	2	2
GA ¹²⁰	1	2	2	1
HI ¹²¹	3	2	3	2
ID ¹²²	3	2	2	3
IL ¹²³	3	2	3	2
IN ¹²⁴	1	2	2	1
IA ¹²⁵	2	2	2	2

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CARE L. TODAY BLOG (July 13, 2016), https://www.foley.com/en/insights/publications/2016/07/alaskaenacts-new-telemedicine-law-what-providers.

¹¹³ ARIZ. REV. STAT. § 32-1401 (LexisNexis 2018).
¹¹⁴ ARK. CODE ANN. § 17-80-117 (2017).
¹¹⁵ CAL. BUS. & PROF. CODE § 2242 (West 2019).

¹¹⁶ 7 COLO. CODE REGS. § 1101-3 Rule 18-5(J) (LexisNexis 2015); see also Nathaniel M. Lacktman & Richard C. Werblow, Colorado Proposes New Telehealth Rules, 5 NAT'L L. REV. (July 16, 2015).

⁷ 2015 Conn. Pub. Acts 15–88; Nathaniel M. Lacktman, New Connecticut Law Allows Telemedicine Prescribing of Controlled Substances, FOLEY & LARDNER LLP: HEALTH CARE L. TODAY BLOG (June 27, 2018), https://www.foley.com/en/insights/publications/2018/06/new-connecticut-law-allows-telemedic

²⁰¹⁸/ https://www.toley.com/en/insights/publications/2018/06/new-connecticut-law-allows-telemedic ine-prescribin.
¹¹⁸ DEL. CODE ANN. tit. 24, § 1769D(c) (2016); *see also* Stephanie T. Eckerle, *Delaware Issues New Regulation to Clarify Telemedicine Statute*, LEXOLOGY (July 17, 2018), https://www.lexology.com/library/detail.aspx?g=ceca4cb8-2529-451e-af9a-951e00dd6812.
¹¹⁹ FLA. STAT. § 456.47(1)–(2) (2019); Fla. Admin. Code Ann. r. 54B8-9.0141 (2019).
¹²⁰ GA. COMP. R. & REGS. 360-3-07 (2013); Lacktman & Ferrante, *supra* note 10.

¹²¹ HAW. REV. STAT. § 453-1.3 (2019).

¹²² IDAHO BD. OF MED., GUIDELINES FOR APPROPRIATE REGULATION OF TELEMEDICINE 7 (2014),

 https://isb.idaho.gov/wp-content/uploads/150402_hea_materials4.pdf.
¹²³ 225 ILL. COMP. STAT. 60/49.5 (2018); see also Illinois Telemedicine Rules: Licensing, Practice, Payment, FOLEY & LARDNER LLP: HEALTH CARE L. TODAY BLOG (Feb. 25, 2016), https://www.foley.com/en/insights/publications/2016/02/illinois-telemedicine-rules-licensing-practicepay.

¹²⁴ IND. CODE § 25-1-9.5-8 (2019); see generally IND. FAM. & SOC. SERVS. ADMIN., TELEMEDICINE AND TELEHEALTH SERVICES (Jan. 1, 2019), https://www.in.gov/medicaid/files/telemedicine%20and% 20telehealth%20services.pdf.

¹²⁵ Press Release, Iowa Bd. Of Med., *supra* note 14; IOWA CODE § 124.308(2)(b) (2021).

¹¹¹ ALA. ADMIN. CODE r. 540-x-9-.11(2) to (3) (2018); ALA. ADMIN. CODE r. 540-X-15-.10 (2018). ¹¹² ALASKA STAT. § 08.64.364 (2016); see also Nathaniel M. Lacktman & Thomas B. Ferrante, *Alaska Enacts New Telemedicine Law: What Providers Should Know*, FOLEY & LARDNER LLP: HEALTH

KS ¹²⁶	1	2	2	1
KY ¹²⁷	2	2	2	2
LA ¹²⁸	1	2	3	1
ME ¹²⁹	3	2	3	2
MD ¹³⁰	2	2	2	1
MA ¹³¹	4	2	3	4
MI ¹³²	4	2	3	4
MN ¹³³	1	2	2	1
MS ¹³⁴	2	2	2	2
MO ¹³⁵	2	2	2	2
MT ¹³⁶	0	0	0	0
NE ¹³⁷	3	2	3	2
NV ¹³⁸	4	2	2	4
NH ¹³⁹	2	2	2	2
NJ ¹⁴⁰	3	2	3	3
NM ¹⁴¹	2	2	2	2

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¹²⁶ See generally KAN. MED. ASSISTANCE PROGRAM, GENERAL BULLETIN 18224, KANSAS TELEMEDICINE ACT (2018), https://www.kmap-state-ks.us/Documents/Content/Bulletins/18224%20-%20General%20-%20Telemedicine 2.pdf.
¹²⁷ KY. REV. STAT. ANN. § 311.597 (West 2019); 907 KY. ADMIN. REGS. 3:170 (2020).
¹²⁸ LA. STAT. ANN. § 37:1271(2)(a)–(b) (2019); *id.* § 37:1271(4)(b); *Application & Instructions for Learning Compared Processing Processing Processing*

Initial Licensure - Telemedicine, LA. STATE BD. OF MED. EXAMINERS, http://www.lsbme.la.gov/content/ application-instructions-initial-licensure-telemedicine (last visited Nov. 29, 2019). ¹²⁹ ME. REV. STAT. ANN. tit. 24-A, § 4316 (2019). ¹³⁰ MD. CODE REGS. 10.32.05.05 (2020); *id.* at 10.32.05.06.

¹³¹ MASS. BD. of REGISTRATION IN MED., PRESCRIBING PRACTICES POLICY AND GUIDELINES 2, 6–7

 MASS. BD. OF REGISTRATION IN MED., PRESCRIBING PRACTICES POLICY AND GUIDELINES 2, 6–7
(adopted Oct. 8, 2015), https://www.mass.gov/files/documents/2016/10/wz/policy-15-05.pdf.
¹³² S. 213, 99th Leg., Reg. Sess. (Mich. 2017); MICH. ADMIN. CODE r. 333.16285 (2017); John Fisher II & Ruder Ware, Complying with Michigan's New Controlled Substance Laws – The Bona-Fide Prescriber-Patient Relationship Requirement, JD SUPRA (May 30, 2018), https://www.jdsupra.com/legalnews/complying-with-michigan-s-new-85302; see generally MICH. DEP'T OF HEALTH & HUM. SERVS., MICHIGAN OPIOID LAWS: FREQUENTLY ASKED QUESTIONS (FAQS) (Mar. 6, 2019), https://www.faust.com/legalnews/complying-with-michigan-s-new-85302; see generally MICH. DEP'T OF HEALTH & HUM. https://www.michigan.gov/documents/lara/LARA DHHS Opioid Laws FAQ 05-02-

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SUBSTANCE GUIDELINES FOR MISSOURI PRACTITIONERS 14 (Oct. 31, 2019), https://health.mo.gov/safety/bndd/doc/ practitionersguidelines.doc.
¹³⁶ No online prescribing policy.
¹³⁷ NEB. REV. STAT. § 71-8503 (2018); *id.* § 71-8504; *id.* § 71-8505.
¹³⁸ NEV. REV. STAT. § 630.020 (2016); *id.* § 639.235; *see generally* Megan Comlossy, *Fact Sheet: Telehealth in Nevada*, NEV. LEGIS. COUNS. BUREAU: RSCH. DIV. (Feb. 2016), https://www.leg.state.nv.us/Division/Research/Publications/Factsheets/Telehealth.pdf.
¹³⁹ N H PEV. STAT. & ANN & 2001 (2015)

 ¹³⁹ N.H. REV. STAT. ANN. § 329:1-c to -d (2015).
¹⁴⁰ N.J. REV. STAT. ANN. § 329:1-c to -d (2015).
¹⁴¹ N.M. CODE R. § 16.10.8.7 to .8 (LexisNexis 2013); N.M. STAT. ANN. § 59A-22-49.3(H) (2013);
see generally N.M. BD. OF PHARMACY, NEW MEXICO PRACTITIONER'S MANUAL (Aug. 2015),
http://www.rld.state.nm.us/uploads/FileLinks/bde0e0d28ef545cba3d8cd277c39749d/NM_Practitioners_ Manual_081315.pdf.

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NY ¹⁴²	2	2	2	2
NC ¹⁴³	2	2	2	2
ND ¹⁴⁴	2	2	2	2
OH ¹⁴⁵	2	2	3	2
OK ¹⁴⁶	1	2	2	1
OR ¹⁴⁷	2	2	2	2
PA^{148}	0	0	0	0
RI ¹⁴⁹	1	2	3	1
SC ¹⁵⁰	1	2	3	1
SD ¹⁵¹	0	0	0	0
TN ¹⁵²	2	2	2	2
TX ¹⁵³	1	2	2	1
UT ¹⁵⁴	2	2	2	2
VT ¹⁵⁵	3	2	2	3
VA ¹⁵⁶	3	2	2	3

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142 MEGAN PROKORYM, N.Y. DEP'T OF HEALTH, NEW YORK STATE TELEHEALTH PARITY LAW 12, 26 (Nov. 8, 2018), https://ahihealth.org/wp-content/uploads/2018/11/New-York-State-Telehealth-Parity-Law-M.-Prokorym.pdf; N.Y. PUB. HEALTH LAW § 2999-CC (McKinney 2021). ¹⁴³ Resources & Information: Contact with Patients Before Prescribing, N.C. MED. BD. (Jul. 2015),

https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/contact_with_patients_before_prescribing; N.C. MED. BD., POSITION STATEMENTS 54 (Aug. 2019), https://www.ncmedboard.org/images/uploads/other_pdfs/PS_

STATEMENTS 54 (Aug. 2019), https://www.ncmedboard.org/images/uploads/other_pdfs/PS_ August2019.pdf. ¹⁴⁴ N.D. ADMIN. CODE 50-02-05-03; N.D. CENT. CODE § 43-17-44 (2019). ¹⁴⁵ OHIO ADMIN. CODE 4731-11-09(C) to (D) (2017). ¹⁴⁶ Oklahoma Telemedicine Act, S. 726, 56th Leg., 1st Sess. (Okla. 2017); see also Nathaniel M. Lacktman & Thomas B. Ferrante, *Key Takeaways from Oklahoma's New Telemedicine Law*, FOLEY & LARDNER LLP: HEALTH CARE L. TODAY BLOG (July 5, 2017), https://www.foley.com/en/ insights/publications/2017/07/key-takeaways-from-oklahomas-new-telemedicine-law.

Telemedicine, OREGON.GOV (Oct. 2, 2020), https://www.oregon.gov/omb/board/philosophy/ Pages/Telemedicine.aspx; see also Prescribing, TELEHEALTH ALL. OF OR., https://www.ortelehealth.org/ content/prescribing (last visited Nov. 3, 2019)

No online prescribing policy.

¹⁴⁹ R.I. BD. OF MED. LICENSURE & DISCIPLINE, GUIDELINES FOR THE APPROPRIATE USE OF TELEMEDICINE AND THE INTERNET IN MEDICAL PRACTICE, http://www.health.ri.gov/publications/ guidelines/provider/AppropriateUseOfTelemedicineAndTheInternetInMedicalPractice.pdf (last visited

Oct. 13, 2019). ¹⁵⁰ S.C. CODE ANN. REGS. 40-47-37 (2016); see also Nathaniel M. Lacktman & Thomas B. Ferrante, South Carolina Enacts New Telemedicine Law: What You Should Know, FOLEY & LARDNER LLP: HEALTH CARE L. TODAY BLOG (Aug. 10, 2016), https://www.foley.com/en/insights/publications/ 2016/08/south-carolina-enacts-new-telemedicine-law-what-yo.

¹⁵¹ No online prescribing policy.

¹⁵² TENN. COMP. R. & REGS. 0880-02.14(7)(a) to (g) (2017). ¹⁵³ 22 TEX. ADMIN. CODE § 174.6(a)(1) (2017); *id.* § 174.5(c); Telemedicine FAQs, TEX. MED. BD., http://tmb.state.tx.us/page/laws-gc-fage-telemedicine (last visited Nov. 3, 2019). ¹⁵⁴ UTAH ADMIN. CODE r. 58-1-501(1)(f) (2019); *id.* at 26-60-102; *id.* at 58-82-201(2).

¹³⁴ UTAH ADMIN. CODE r. 58-1-501(1)(1) (2019); *id.* at 26-00-102; *id.* at 58-62-201(2).
¹⁵⁵ VT. BD. OF MED. PRACTICE, POLICY ON THE APPROPRIATE USE OF TELEMEDICINE TECHNOLOGIES
IN THE PRACTICE OF MEDICINE 3-5 (May 6, 2015), https://www.healthvermont.gov/sites/default/
files/documents/2016/12/BMP_Policies_Vermont%20Telemedicine%20Policy_05062015%20.pdf.
¹⁵⁶ See generally VA. BD. OF MED., TELEMEDICINE (Oct. 28, 2018), https://www.dhp.virginia.gov/
media/dhpweb/docs/med/guidance/85-12.pdf; VA. CODE ANN. § 38.2-3418.16 (2020).

WA ¹⁵⁷	2	2	2	2
WV ¹⁵⁸	1	2	2	1
WI ¹⁵⁹	2	2	2	2
WY ¹⁶⁰	3	2	3	3

C. DIFFERENCES BETWEEN STATE POLICIES

PPR Restrictions 1.

Among the three elements, PPR Restrictions varied the least among the states. Most state policies describe the proper circumstances under which a PPR can be established. Generally, these policies track the AMA guidelines and the overarching insights from the federal case law – that providers act outside the scope of their profession if they do not facilitate sufficient interpersonal information sharing.¹⁶¹ There is a general consensus among states that during a telemedicine appointment providers and patients should disclose their respective identities and locations, the provider should take a medical history of the patient, and the provider should maintain a medical record after the appointment.¹⁶² Florida, however, does not require providers to research patients' medical histories or conduct physical examinations to establish a valid telemedicine PPR.¹⁶³

It should also be noted that some states carve out "emergency" exceptions, permitting online prescribing without valid PPRs in narrow circumstances where, ostensibly, the necessity for dispensing medication outweighs any policy interest in sufficient information-sharing (such as infectious disease outbreaks).¹⁶⁴ The fact that a state has an "emergency" policy does not affect its PPR Restrictions score since emergency exceptions involve situations in which PPRs are unnecessary. Likewise, because there is a relatively unambiguous federal policy on renewals and refills for

¹⁵⁷ WASH. REV. CODE § 48.43.735 (2017); WASH. MED. QUALITY ASSURANCE COMM'N, APPROPRIATE USE OF TELEMEDICINE 4 (Oct. 3, 2014), https://wmc.wa.gov/sites/default/files/public/documents/MD2014-03TelemedicineGuideline approved10-3-14.pdf
¹⁵⁸ W. VA. CODE § 30-5-4(67)(C) (2017); *id.* § 30-3-13(a) to (c).
¹⁵⁹ WIS. ADMIN. CODE MED. § 24.02-24.07 (2017); EMILY H. WEIN, FOLEY & LARDNER LLP, TELEMEDICINE LAW AND REGULATION IN WISCONSIN 20 (Dec. 11, 2018). https://www.wha.org/

WisconsinHospitalAssociation/media/WHACommon/Health%20Care/PDFs/2018TelehealthWebinarSli des-FoleyLardner12-11.pdf.

WYO. HEALTHCARE LICENSING BDS., UNIFORM POLICY FOR THE APPROPRIATE USE OF TELEHEALTH TECHNOLOGIES IN THE DELIVERY OF HEALTHCARE 3-4, 6-7, https://www.uwyo.edu/wind/

files/docs/wytn-doc/resources/wyoning-telehealth-policy-final.pdf (last visited Oct. 7, 2019). ¹⁶¹ Ethical Practice in Telemedicine, AM. MED. ASs'N, https://www.ama-assn.org/delivering-care/ethics/ethical-practice-telemedicine (last visited Oct. 25, 2019).

 ¹⁶² See, e.g., IND. CODE § 25-1-9.5-8 (2019).
¹⁶³ FLA. STAT. § 456.47(1)–(2) (2019); FLA. ADMIN. CODE ANN. r. 54B8-9.0141 (2019).
¹⁶⁴ See, e.g., Press Release, Iowa Bd. of Med., supra note 14.. In Iowa, medication can be prescribed via telemedicine without an "interactive" interview under the following notable circumstances: 1) prescriptions on a "short-term basis" while scheduling an in-person appointment; 2) "initial admission orders for a neuky hostialized nationt." 3) calls between licensed providers where one has "established orders for a newly hospitalized patient;" 3) calls between licensed providers where one has "established a [PPR] with the patient;" 4) "emergency situations" where a patient's life is in danger or the public faces the risk of infectious disease outbreak; and 5) dispensations of antibiotics to a patient's named sexual partners after the patient has been diagnosed with a sexually transmitted disease. Id.

controlled substances that many states have codified,¹⁶⁵ and because refills and renewals necessitate by definition the existence of a patient-provider relationship, states' renewal and referral policies were not pertinent to their PPR Restrictions score. Lastly, state licensing requirements (e.g. allowing an out-of-state provider to receive a license to prescribe via telemedicine within the state) were generally not pertinent to states' PPR Restrictions scores since the requirements for valid telemedicine PPRs do not vary based on the geographic location of the provider. That being said, some state telemedicine laws were enacted with the explicit purpose to permit out-of-state providers to engage in lawful remote appointments with patients.¹⁶⁶

2. **Telemedicine Definition**

Many state statutes include a definition section defining "telemedicine" or "telehealth,"167 and a significant number of states incorporate language similar to the HHS rule, defining telemedicine as a technological medium that allows for real-time, two-way, audio-visual communication not including communication via telephone, online questionnaire, text message, email, or facsimile.¹⁶⁸ However, some states deviate from this language by defining telemedicine to include some, or most, of these technologies.¹⁶⁹ New Jersey, for example, allows providers to use store-and-forward technology in combination with "interactive, real-time, two-way audio . . . without video capabilities" if the "provider determines that the provider is able to meet the same standard of care as if the health care services were being provided in person."¹⁷⁰ California has an even broader policy. To conduct "appropriate prior examination[s]" in California, providers need not use "synchronous interaction"; they can use "a self-screening tool or a questionnaire" so long as they meet the requisite standard of care.¹⁷¹

3. Medication Restrictions

Many states that allow for PPRs to be established through a variety of technological modalities still impose limits on the prescribing of controlled substances, ostensibly to align with or amplify the restrictions imposed by the Ryan Haight Act. Thus, a more restrictive state policy could often be identified where it heavily restricted or flatly prohibited prescribing controlled substances via telemedicine.¹⁷² One of the more common

¹⁶⁵ See, e.g., N.Y. COMP. CODES R. & REGS. tit. 10, § 80.67 (2013). See generally TIMOTHY J. SHEA ET AL., U.S. DEP'T OF JUST. DRUG ENF'T ADMIN., PHARMACIST'S MANUAL: AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT (2020).

See, e.g., 225 ILL. COMP. STAT. 60/49.5(a) (2018) ("The General Assembly finds and declares that because of technological advances and changing practice patterns the practice of medicine is occurring with increasing frequency across state lines and across increasing geographical distances within the State of Illinois and that certain technological advances in the practice of medicine are in the public interest"). ¹⁶⁷ The terms "telemedicine" and "telehealth" are not used consistently among state legislatures, state

medical boards, practitioners, and scholars. I understand the term "telemedicine" as remote encounters between licensed providers and patients, whereas I understand the term "telehealth" as any health-related between licensed providers and patients, whereas I understand the term "telehealth" as any health-related activity involving mobile technology, including activities that do not implicate PPRs or the issuance of prescriptions. Given that this Note deals exclusively with online prescribing, and to avoid confusion, I universally apply the term "telemedicine" when describing states' online prescribing policies. ¹⁶⁸ See, e.g., VA. CODE ANN. § 38.2-3418.16 (2020). ¹⁶⁹ See, e.g., CAL. BUS. & PROF. CODE § 2242 (West 2019). ¹⁷⁰ N.J. REV. STAT. § 45:1-62(c)(2) (2017). ¹⁷¹ CAL. BUS. & PROF. CODE § 2242(a (West 2019). ¹⁷² See, e.g., MINN. STAT. § 151.37(d)–(e) (2020).

prohibitions involves heavily restricting online prescriptions for chronic pain medications.¹⁷³ Conversely, some states explicitly allow controlled substances to be prescribed via telemedicine under the provider's professional discretion, which, if followed (and depending on the circumstance), could subject the provider to criminal prosecution under the Ryan Haight Act.¹⁷⁴

VI. HOW SHOULD ONLINE PRESCRIBING BE REGULATED IN THE FUTURE?

WHY DO STATES DRAFT DIFFERENT ONLINE PRESCRIBING A. POLICIES?

As demonstrated above, it is clear that states vary widely in how they regulate online prescribing, particularly in terms of their Medication *Restrictions*. Surely, there are policy reasons for complying with the Ryan Haight Act's intent and restrictions or choosing to deviate from them, either through a more restrictive or more liberal approach. Below, I have described three possible reasons to account for the differences among states: 1) state culture; 2) supporting the institutional healthcare system; and 3) curbing the opioid epidemic.

1. State Culture

Often, regional differences on matters of policy can be accounted for by differences in regional cultures. A helpful proxy for culture is the partisanship of states within particular regions.¹⁷⁵ Glancing at a map of partisanship within each state,¹⁷⁶ however, there does not appear to be a strong relationship between state partisanship and the liberality of their online prescribing policies. For example, the Liberal and Very Liberal states include deeply "red" states like Wyoming and Idaho along with deeply "blue" states like California and Massachusetts. The Restrictive states are mostly "red" or "competitive" states, although Connecticut and Rhode Island are notable outliers. Partisanship is likely not a compelling reason for the differences among state policies.

Supporting the Institutional Healthcare System 2.

Given that more liberal online prescribing policies may increase both the demand for prescription medication and the number of prescriptions written,¹⁷⁷ state legislatures may draft more liberal policies to support various

MHEALTHINTELLIGENCE (Jan. 14, 2019), https://mhealthintelligence.com/news/ata-presses-dea-to-

¹⁷³ See, e.g., GA. COMP. R. & REGS. 360-3-.07 (2013); IND. CODE § 25-1-9.5-8 (2019); 22 TEX. ADMIN. CODE § 174.5(c) (2021). ¹⁷⁴ See, e.g., MICH. ADMIN. CODE r. 333.16285(1)–(2) (2017); CAL. BUS. & PROF. CODE § 2242 (West 2019); MASS. BD. OF REGISTRATION IN MED., *supra* note 131, at 2, 6–7; *see also* Davidsen, *supra* note

^{106.} ¹⁷⁵ See, e.g., Anna North, How Abortion Became a Partisan Issue in America, VOX (Apr. 10, 2019: 2010/1/10/19205512/abortion.2020.roe_ioe-hiden-democratshttps://www.vox.com/2019/4/10/18295513/abortion-2020-roe-joe-biden-democrats-AM),

republicans. ¹⁷⁶ Jeffrey M. Jones, GOP Maintains Edge in State Party Affiliation in 2016, GALLUP: NEWS (Jan. 30, 2017), https://news.gallup.com/poll/203117/gop-maintains-edge-state-party-affiliation-2016.aspx. ¹⁷⁷ See Erick Wicklund, ATA Presses DEA to Loosen Telemedicine Restrictions for Prescribing,

institutional healthcare interests (e.g. pharmaceutical companies, insurers, health systems)-particularly in states with "telehealth parity" that require equivalent reimbursements for in-person and telemedicine appointments. For example, the following ten regions are considered to be the top "pharmaceutical hubs" in the United States due to employment statistics, revenues, and evidence of growth: Chicago, IL; Los Angeles, CA; Raleigh-Durham, NC; Seattle, WA; Greater Philadelphia, PA; DC Metro, MA; San Diego, CA; New Jersey (statewide); San Francisco, CA; and Boston-Cambridge, MA.¹⁷⁸ Eight of these "pharmaceutical hubs" in the United States are in states with Liberal or Very Liberal online prescribing policies (Maryland is Moderate, and Pennsylvania does not have a telemedicine policy). Pharmaceutical companies also exert great influence on both state legislatures and the federal government through lobbying, collectively spending \$880 million on lobbying and campaign contributions between 2006 and 2015 to prevent legislation restricting the prescribing of opioids.¹⁷⁹ Thus, it is plausible that some state policies were drafted with consideration toward potential job growth and increased revenues in the pharmaceutical industry.

It may also be unsurprising that states with outsized influence on American commerce (i.e. states that house large, national businesses) tend to draft less restrictive online prescribing policies. For example, with the exception of Texas and Georgia, none of the states with GDPs higher than \$5 billion have Restrictive online prescribing policies.¹⁸⁰ States with low GDPs may also seek to increase healthcare revenues through liberalizing their online prescribing policies, which may explain the Liberal policies of the lowest-GDP states like Wyoming, Vermont, North Dakota, Idaho, Maine, and Delaware. Perhaps, a more liberal policy can be understood to prioritize various business interests over the potential for unscrupulous prescribing that the policy may elicit.

The Opioid Epidemic 3.

At odds with stimulating a region's business revenues is addressing the rising rate of opioid overdoses in the United States.¹⁸¹ However, a higher rate of opioid deaths does not appear to have a strong relationship with a more restrictive policy. For example, Massachusetts and Michigan have the most liberal policies but also have among the highest rates of opioid deaths per 100,000 persons; conversely, Texas and Oklahoma have Restrictive policies but have among the lowest rates of opioid deaths per 100,000 persons.¹⁸²

loosen-telemedicine-restrictions-for-prescribing (arguing that expanding the "special registration" requirement would allow "additional prescribers to use telemedicine to combat the opioid crisis [and] ¹⁷⁸ Darren Whyte, *Top 10 Pharmaceutical Hubs in the USA*, PROCLINICAL (Mar. 15, 2016),

https://www.proclinical.com/blogs/2016-3/top-10-pharmaceutical-hubs-in-the-usa. ¹⁷⁹ Bill H., *Big Pharma Influence in State, Federal Government, and Everyday Life*, ANGRY BEAR

⁽Feb. 19, 2018, 10:30 PM), https://angrybearblog.com/2018/02/big-pharma-influence-in-state-federalgovernment-and-everyday-life.html.

WORLD POPULATION REVIEW: GDP BY STATE 2019 (last visited Dec. 19, 2019), http://worldpopulationreview.com/states/gdp-by-state. ¹⁸¹ See Wicklund, supra note 177. ¹⁸² Opioid Summaries by State, NAT'L INST. ON DRUG ABUSE (May 2019),

https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state.

Aside from the data on opioid deaths, however, the fact that many Restrictive online prescribing policies impose restrictions specifically on chronic pain medication or opioids¹⁸³ may support the notion that some state legislatures drafted these policies with concerns about curbing the opioid epidemic. In addition, the Ryan Haight Act was drafted with the intent to curb prescription opioid overdoses,¹⁸⁴ so a Moderate policy can be understood to reaffirm that policy interest. Lastly, many states with Restrictive policies have among the highest rates of prescription drugs sales per capita; of note, other than Alabama, none of the top fifteen states have Liberal or Very Liberal policies.¹⁸⁵ States with high rates of prescription drug sales per capita (e.g. Kentucky, West Virginia, and Louisiana all have more than double the rate of California) may be especially concerned with unscrupulous practices by providers and drafted their telemedicine policies accordingly.

In sum, although state culture is likely not a strong factor supporting the differences among state policies, there are two key factors, perhaps at odds with each other, that may underly the differences between state policies: 1) stimulating revenues and job growth in the healthcare industry; and 2) curbing the opioid epidemic. The merits of these policy interests are explored in the next section.

B. WHY SHOULD THE CURRENT ONLINE PRESCRIBING REGIME CHANGE?

The Downside of Provider Confusion 1.

In all likelihood, the DEA will soon expand the "special registration" requirement, creating a more liberal federal policy. However, the language of the Ryan Haight Act will still allow for more restrictive state policies, including outright refusals to grant "special registrations" to providers.¹⁸⁶ As a result, regardless of the DEA's future actions, the nationwide regime of online prescribing will remain deeply fractured with little cohesion among the states. Providers practicing across state lines, therefore, face deep uncertainty in complying with controlled substance regulations, since they must consider the three relevant jurisdictions (their home state, the patient's state, and the nationwide, federal policy) and act in accordance with the most restrictive policy among the three to avoid civil or criminal liability, loss of DEA registration, and/or loss of state licensure. Regardless of whether a future regime is more restrictive or more liberal, a regime that is more *uniform* would make it easier for providers to practice across state lines, increasing the availability of specialists to patients.

¹⁸³ See, e.g., 22 TEX. ADMIN. CODE § 174.6(a)(1) (2017); *id.* § 174.5(c). ¹⁸⁴ See Guide to Telemedicine Prescribing for Providers, WHEEL (Feb. 27, 2019), https://www.wheel.com/blog/guide-to-telemedicine-prescribing-for-providers (stating that the Ryan Haight Act was "an effort to thwart the proliferation of rogue and fraudulent online pharmacies and the

illegal distribution of controlled substances"). ¹⁸⁵ Retail Prescription Drugs Filled at Pharmacies per Capita, KAISER FAM. FOUND., https://www.kff.org/health-costs/state-indicator/retail-rx-drugs-per-

capita/?activeTab=map¤tTimeframe=0&selectedDistributions=retail-rx-drugs-per-capita (last visited Dec. 19, 2019). ¹⁸⁶ See generally 21 U.S.C. § 802(54).

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2. The Benefits of Expanding Online Prescribing

Aside from the general uncertainty faced by out-of-state providers, restrictive online prescribing policies impose significant and perhaps arbitrary costs on patients, providers, health systems, and various business interests in the healthcare space. In the context of controlled substances, for example, a Moderate or Restrictive state inherently advantages able-bodied individuals who can visit state and DEA registered hospitals while disadvantaging physically impaired individuals who may struggle to leave their own homes.¹⁸⁷ Moreover, it is well-documented that travel is a significant barrier to patient self-management, especially for low-income individuals.¹⁸⁸ Patients not only face actual costs in getting to and from doctor's appointments, but they suffer from opportunity costs by needing to allot several hours to account for travel, wait times, and the appointment itself.¹⁸⁹ From a purely cost standpoint, expanding online prescribing so that patients need not be in the presence of a DEA-registered practitioner or within a DEA-registered hospital would likely have a positive impact on patients. It may also encourage patients to seek medication-assisted treatment from practitioners (as opposed to self-medicating or avoiding doctors generally), perhaps improving health outcomes among at-risk communities.

In the business context, commenters have noted that compliance issues and a lack of innovation in the contemporary regime have stifled the growth potential of telemedicine. There are two main reasons supporting that conclusion: 1) Health systems are unlikely to take significant compliance risks in changing the delivery of services; and 2) Integration of new technology into existing systems is extremely difficult due to concerns over data privacy and general wariness of providers and administrators, leading to low utilization rates of telemedicine technology.¹⁹⁰ Presumably, more liberal online prescribing policies would help remove some of the compliance barriers to innovation and implementation, stimulating growth for a variety of business interests.

Expanding online prescribing may also better serve the business interests of providers and health systems through increased demand.¹⁹¹ For example, through telemedicine appointments, providers could feasibly meet with more patients in a day given the inefficiency associated with wait times and

¹⁸⁷ See Wicklund, *supra* note 177 (arguing that telemedicine prescribing should expand to "reach more people in need of care and overcome barriers to access that may be geographical, cultural or economic").

economic"). ¹⁸⁸ See Ryan K. Gorman et al., Uncovering the Invisible Patient Work System Through a Case Study of Breast Cancer Self-Management, 12 ERGONOMICS 1575, 1580 (2018) (describing distance between "workspaces" as a potential barrier and/or facilitator to successful patient self-management). ¹⁸⁹ See Corinne Lewis et al., Listening to Low-Income Patients: Obstacles to the Care We Need, When

¹⁸⁹ See Corinne Lewis et al., *Listening to Low-Income Patients: Obstacles to the Care We Need, When We Need It*, COMMONWEALTH FUND (Dec. 1, 2017), https://www.commonwealthfund.org/blog/2017/ listening-low-income-patients-obstacles-care-we-need-when-we-need-it.

¹⁹⁰ Neal Khosla, *Why Digital Health Has Been Such a Disappointment, and How to Change That*, CNBC.COM (Dec. 15, 2019, 10:47 AM), https://www.nbc.com/2019/12/15/neal-khosla-on-why-digitalhealth-has-been-so-disappointing.html; *Telemedicine 'Not a Perfect Solution' to Health Care Access Issues*, HEALIO NEWS (Dec. 19, 2019), https://www.healio.com/news/primary-care/20191219/ telemedicine-not-a-perfect-solution-to-health-care-access-issues.

¹⁹¹ See Wicklund, supra note 177.

transporting patients to and from different rooms.¹⁹² If that is the case, then various business interests would almost certainly benefit from broader online prescribing policies; greater demand for health services may increase the quantity of fee-for-service payments, and it may also increase enrollment for insurance policies that reimburse favorably for telemedicine appointments.¹⁹³ Likewise, increased demand for telemedicine services would likely stimulate demand for telemedicine products and encourage telemedicine companies to continue innovating their products.¹⁹⁴ And, if more prescriptions are being written (which is, in fact, the trend in the United States¹⁹⁵), then retail drug sellers and pharmacy benefit managers would likely benefit from increased business.

Lastly, despite the Ryan Haight Act's laudable interest in curbing unscrupulous prescribing and prescription drug overdoses, expanding online prescribing may actually have a positive impact on those addicted to opioids and other dangerous substances. A systematic review of studies on substance abuse disorders (typically called "substance use disorders" or SUDs by practitioners) found that medication-assisted treatment through telemedicine could lead to improved treatment retention and higher client satisfaction.¹⁹⁶ Moreover, individuals with SUDs "experience one of largest gaps between treatment need and treatment utilization, with only a minority receiving treatment."¹⁹⁷ Thus, there may be a compelling and justifiable policy interest in expanding online prescribing of controlled substances, since it could encourage more addicts to choose treatment over self-medication or other destructive behaviors.

The Downside to Expanding Online Prescribing Regimes 3.

Despite the potential advantages of a more liberal regime, such a regime would naturally incentivize the unscrupulous practices that gave rise to the federal policy in the first place. Above all, it is important to reiterate the story of Ryan Haight and countless others. Not only will addicts strive at all costs to manipulate the healthcare system to feed their addictions, but there is a fundamental conflict of interest in the business of prescribing and distributing addictive drugs: more addicts lead to greater revenues. In other words, Ryan Haight's fate was not merely a consequence of his addiction; his case indicates the magnitude of suffering that can arise from a lack of government regulation in this context. The federal criminal cases discussed in Part III further indicate how egregiously unethical online prescribers can become if they are not tightly regulated by governments. Thus, in any future

¹⁹² Telemedicine 'Not a Perfect Solution' to Health Care Access Issues, supra note 190; Caroline Roberts, There's a Healthcare Crisis, and Telemedicine Wants to Cure It, CNET.COM (Dec. 6, 2019, 5:00 AM), https://www.cnet.com/news/can-telemedicine-solve-the-healthcare-crisis. ¹⁹³ See Xtelligent Healthcare Media Staff, *supra* note 12 ("[W]hile the healthcare industry has been

slow to embrace connected health, consumer-facing companies have jumped on the bandwagon with a wide variety of platforms, services, and devices.").

¹⁹⁵ AMERICAN ACADEMY OF ACTUARIES, PRESCRIPTION DRUG SPENDING IN THE U.S. HEALTH CARE SYSTEM 1 (2018), https://www.actuary.org/content/prescription-drug-spending-us-health-care-system (CMS projects that "spending for retail prescription drugs will be the fastest-growing health care category and will consistently outpace that of other health care spending").

Lin et al., supra note 13, at 47.

¹⁹⁷ *Id*.

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regime, it is essential to ensure that the virtues of legitimate online prescribing for dangerous drugs are preserved by government authorities, namely: 1) sufficient information-sharing; 2) using appropriate technologies; and 3) limiting the circumstances in which certain medications can be prescribed.

C. A SUGGESTION FOR THE FUTURE

In the context of controlled substances, the negatives associated with restrictive policies (privileging able-bodied people, unnecessary travel burdens, lower treatment retention, lower patient satisfaction), as well as the confusion arising from a lack of uniformity in online prescribing policies within an increasingly unified national economy, provide compelling reasons for Congress to preempt more restrictive policies under its Commerce and Supremacy Power. That is, it may be beneficial to remove the language within the Ryan Haight Act's telemedicine exceptions that currently allows states to effectively nullify these exceptions.

Even without the intervention of Congress, the DEA can still issue a rule that could sensibly balance interests between curbing the opioid crisis, stimulating various business interests, and limiting uncertainty across state lines. The American Telemedicine Association suggests four key recommendations for the DEA's impending rule:

1) Update the current DEA registration process to specify distinctions between traditional and telemedicine prescribing privileges;

2) Allow both sites (e.g. hospitals) and prescribers to register for telemedicine;

3) Ensure that telemedicine special registration is not restricted to any single discipline; and

4) Allow telemedicine prescribers to apply for DEA registration numbers in multiple states at once.¹⁹⁸

Along with these general suggestions, it may be sensible to explicitly allow "special registrations" for providers who wish to prescribe controlled substances via audio-visual encounter to patients outside of DEA-registered hospitals. Doing so would permit telemedicine providers to prescribe medication to physically impaired or low-income people within their homes, reducing the burdens associated with travel. It may also be sensible to allow online prescribing of certain medications to children (such as New Jersey's exception for Schedule II stimulants) provided that a parent or guardian is present to limit the possibility of any unscrupulous or unethical behavior. That being said, to avoid repeating a Ryan Haight or Pharmacom situation, the DEA's "special registration" rule should ensure that controlled substances cannot be prescribed via online questionnaire or without sufficient information-sharing (i.e. PPRs should align with the AMA guidelines).

¹⁹⁸ See Wicklund, supra note 177.

For non-controlled substances, more liberal policies likely allow for ease of access and stimulation of business that are generally not outweighed by concerns about addiction or death. Legislatures should carefully craft their policies so that dangerous drugs, even if not controlled substances, cannot be prescribed online through means that do not create valid PPRs—most notably, online questionnaires. Otherwise, it is reasonable to defer to the ethical and medical judgment of doctors, since they face the risk of losing their license in almost every state if they choose to deviate from the AMA guidelines on establishing PPRs via telemedicine.

VII. CONCLUSION

Through this analysis, I sought answer the following question: When you seek to establish a patient-provider relationship through a telemedicine encounter, under what circumstances can the provider write a valid prescription?

In short, it depends on the following: 1) what your state deems to be a valid PPR; 2) the types of technologies that are considered "telemedicine" in your state; and 3) the type of medication you are seeking. Most importantly, it depends on whether you are seeking a prescription for a federal controlled substance. Nonetheless, some near-universal requirements can be gleaned from these findings: 1) telemedicine providers should examine patients, take a medical history, and create and maintain a medical record before prescribing medication; 2) telemedicine appointments without real-time, two-way, audio-visual communication are usually insufficient to establish valid PPRs to prescribe dangerous medications; and 3) it would be unwise for a provider to prescribe controlled substances beneath the minimum threshold of the Ryan Haight Act, even if doing so complies with the provider's state policy.

That being said, state laws are continuously evolving, and the federal online prescribing policy will likely change soon once the DEA issues its rule on "special registrations." Consequently, this analysis serves as a guide to the state of online prescribing at a particularly dynamic moment in the brief history of telemedicine regulations and points to the various justifications for more liberal or more restrictive policies, including their effect on various business interests and their potential to curb or amplify the opioid epidemic. Above all, this analysis demonstrates the patchwork of policies across the country that may be untenable in a unified national economy, especially where telemedicine allows providers to readily, securely, and safely meet with patients across state lines.

Lastly, this analysis suggests an approach to escape from the compliance issues under the current regime: online prescribing of controlled substances should fall squarely in the domain of the federal government to allow for uniformity across state lines. Otherwise, state policies regarding noncontrolled substances should mirror the intent behind the Ryan Haight Act (preventing unscrupulous prescribing of dangerous and addictive drugs over the Internet) but should also stimulate patient access and business growth by shifting the ability to prescribe non-dangerous substances, when appropriate, onto the professional discretion of the provider.